Department for Environment Food & Rural Affairs	**RMOP** **REQUIRED METHODS OF OPERATION PROCEDURES FOR ESTABLISHMENTS EXPORTING BEEF TO CANADA: COMPLIANCE WITH SPECIAL CONDITIONS**	Food Standards Agency Food Standards Scotland Department of Agriculture, Environment and Rural Affairs

Establishment Approval Number: ……..

Address: ……

……..

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Establishment type: Slaughterhouse/cutting-plant/processing plant …….

Species of meat intended for export to Canada: Bovine

Product type intended for export to Canada: Precursor Material (PM)/ Finished Raw Ground Beef Product (FRGBP)…….

Additional Product Description:	

Column 1 of the following table lists those requirements which go beyond EU legislation (referred to as 'special conditions') that Canadian Food Inspection Agency **(CFIA)** certified establishments have to comply with for the sampling and testing of beef intended for export to Canada (Article 12 of Regulation (EC) no 178/2002 refers). Column 2 must be completed to show all the facilities or procedures necessary to ensure that these requirements are met in the certified establishment. Column 3 must be completed with the names or job titles of establishment staff responsible for ensuring that the listed facilities and procedures listed are in place and operating correctly. All parties must keep abreast of the latest CFIA requirements by checking Annex O from the CFIA Manual of Procedures for more information on this requirement http://www.inspection.gc.ca/food/meat-and-poultry-products/manual-of-procedures/chapter-4/annex-o/eng/1370616273137/1370616333827

Column 1 **Requirement (Special Condition)**	Column 2 **Description of facility or control procedure by which the requirement will be met AND the corrective action envisaged, including to prevent a recurrence, in the case of process deviation / non-compliance**	Column 3 **Personnel responsible for supervision**
A. HACCP PLAN		
A.1. The HACCP* plan must include the following measures: a) Identification of the product and intended use with regards to *E.*		

coli O157 hazard and controls. b) *E. coli* O157 hazard is clearly identified and passed through a decision tree. c) The FBO must determine how the hazard will be controlled, for example, through 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.		
B. CONTROL MEASURES		
B.1. Dressing procedures. The FBO must 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.		
B.2. Airborne contamination. The FBO must develop, implement, and maintain a written control program within their HACCP system to prevent airborne contamination of the meat products, especially carcasses.		
B.3. GMP. The FBO must 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.		
B.4. Storage and transport. The FBOs must 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.		
C. MANDATED TESTING OF PRECURSOR MATERIAL (PM)* THAT IS INTENDED TO BE EXPORTED TO CANADA		

C.1. Testing protocol. FBOs must implement a robust testing protocol for each production lot of any type of PM according to appendix 2 of Annex O of the CFIA Manual of Procedures http://www.inspection.gc.ca/food/meat-and-poultry-products/manual-of-procedures/chapter-4/annex-o/eng/1370616273137/1370616333827#app1. In summary: - Sample pick up. - Lab the sample will be sent to. - Screening and/or confirmation methodology requirements. Also describe: • Sample storage and secure dispatch to lab.		
C.2. Sampling procedures. - A minimum of **60 sub-samples** must be examined per lot. - A lot cannot exceed **five combos** (or alternative unit such as a pallet of boxes) and cannot weigh more than 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. - The material collected for testing should represent the outside surface of the product. A USDA FSIS video, describing N60 sampling, can be found at https://www.youtube.com/watch?v=wlXizKqv70E The FBO must train named operatives to undertake the sampling and the CA (FSA/FSS/DAERA) must supervise FBO sampling of lots at a frequency of 10% reducing to 5% if the operative/s performance is satisfactory. A record of such supervision must be kept.		
C.3. Definition of lot. The FBO 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: a) 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 b) Determined by the operator when implementing a statistically based sampling program (robust testing or alternate sampling protocol accepted by the CFIA); or c) 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: (i) Perform full sanitation and cleaning at the end of each production day, (ii) The product lot does not exceed five consecutive calendar days of production and does not exceed approximately 4500 kg, (iii) 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. 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 FSA 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.		
D. TEST RESULTS		
D.1. Results of tests. All results must be transmitted directly to		

the OV for scrutiny and action as appropriate. A positive release policy must be established. Where receiving establishments are sampling PM it is recommended that all results, including results where E coli O157 is not detected, should be reported back to the supplying slaughter establishment on an ongoing basis.(to allow slaughter establishments to gather data in the case of a High Event Period occurring)		
D.2. Positive results. The FBO must describe what will happen in the event of obtaining positive results for *E. coli* O157; including what will the plant do with the product, how investigations will be carried out and how the plant will prevent a reoccurrence, describing all necessary follow up actions. This will apply to presumptive positive results where the FBO has decided not to carry out confirmatory testing. In all cases the principles outlined in the FSA draft guidance document on detection of STEC in food should be followed.https://www.food.gov.uk/sites/default/files/enf-w-16-016-draft_uk_working_policy.pdf In the case of positive results being obtained for a batch of meat originating in a slaughter establishment in another eligible Member State FSA will inform the competent authority of the supplying MS.		
E. PROCESS AWARENESS AND HIGH EVENT PERIOD (HEP)		
E.1. Process awareness. As a part of their HACCP system, FBOs must develop, implement and monitor process awareness programs and must analyse 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.		

As a part of process awareness, the FBOs must establish criteria/limits to define periods when the analysis indicates a potential loss of control.		
E.2. High Event Periods (HEP). Beef establishments producing PM and conducting robust N-60 sampling and testing programs must identify and document HEP criteria. 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 95%, 98.85% or 99.95 % confidence intervals. 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 slaughter and further processing establishments producing less than seven lots of PM per day are not required to develop HEP protocol but will have to investigate every positive test result.		
F. CONTROLS FOR SUPPLYING/RECEIVING PRECURSOR MATERIAL (PM)		

F.1. Establishments supplying raw material **Carcase meat** **When carcases (Whole, half or quarter) are supplied to a receiving establishment for the purpose of producing PM, the supplying slaughter plant does not have to test this meat for E coli O157.** **Primals, subprimals, Bench trim** **When an establishment supplies these PMs to a receiving establishment and they are destined for use in FRGBP, then the establishment producing these PMs is required to test for E. coli O157.** **(Annex O, 5.3 CFIA)**		
F2 Further processors receiving raw material Where receiving establishments process meat from more than one supplier, then the receiving establishment should either i) establish microbiological independence between lots from different suppliers to prevent cross contamination or ii) be aware that testing of processed lots which are not microbiologically independent may implicate more than one supplier for the purpose of traceback investigations when a positive result is obtained. Lotting, processing and testing protocols should be clearly defined and agreed between supplying and receiving establishments in a Letter of Guarantee. (see F3) When bench trims or PM for export are produced from sourced materials which have already been tested by the supplier it is not necessary to test		

the subsequent bench trims/ PM again. However this is on the basis that the lot has been clearly identified and segregated from other untested materials, with microbiological independence being maintained. When E Coli is detected , FBOs must verify the status of CCPs and test results, that have been taken at the supplying plant, to identify any deviation, unusual trends or HEP. This must take place as specified in the purchase specification agreement (please see point F.3) and the competent authority must be informed,		
F.3. Controls for suppliers of PM. FBOs supplying raw PM to other establishments, must review their HACCP system to ensure compliance with the purchase specifications. The purchase specifications agreement between the supplying and receiving plants must reflect the following controls: A. The letter of Guarantee (LOG), signed and dated by the FBOs of the supplying plant and receiving plant. It must include the CCPs and other measures used to reduce, prevent or eliminate *E. coli* O157-associated hazards. B. The supplier must have a written programme to monitor and verify that only products tested 'not detected' are supplied. The tests results must be sent with the production lot. C. If the sampling of the PM is carried out in the receiving plant: (i) there will be prior		

agreement as to whether a presumptive positive will be accepted as positive or confirmation will be pursued; (ii) the receiving plant must describe how they will maintain the microbiologicalintegrity of the lot during production and pending test results (iii) the receiving plant must inform the supplier and the competent authority of positive results. The supplier, if in another Member State, must inform the relevant Competent authority there. D. Plants supplying products pending results: (i) Must state whether a presumptive positive will be accepted as positive or confirmation will be pursued; (ii) In case of positive result the receiving plant and the competent authority must be informed; (iii) Must implement: - A written protocol. - Identify the product. - Keep records about product identification and quantity. - Control of product while in transit (company seal). - Get confirmation from the receiving plant that the product arrived. - Notify that the product cannot be used before notification of 'not detected' for O157.		

THE ABOVE DETAILS MUST NOT BE CHANGED WITHOUT FIRST HAVING GIVEN WRITTEN NOTICE TO YOUR OV AND HAVING OBTAINED HIS/HER AGREEMENT TO THE INTENDED CHANGE. ALL THE PROCEDURES WITHIN THIS DOCUMENT BECOME BINDING BETWEEN THE PARTIES AS FROM THE DATE OF OV SIGNATURE.

Establishment (FBO)
Signature

Print Name……
Position……
Date……...

FSA/FSS/DAERA Official Veterinarian
Signature

Print Name……
Position……
Date……...

FSA/FSS Veterinary Auditor
DAERA Official Veterinary Advisor

(1st verification check)
Signature
Print Name……

Date……...

FSA/FSS Field Veterinary Leader
DAERA Divisional / Supervisory Veterinary Officer
(2nd verification check)
Signature
Print Name…….
Date……
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