Canadian Food Inspection Agency | Agence canadienne d'inspection des aliments

Ottawa, Ontario
K1A 0Y9

Date: June 1, 2010

MEAT HYGIENE DIRECTIVE:

2010 - 03

SUBJECT: Chapter 4

Review of Chapter 4 to clarify the requirements applicable to meat processing activities.

Changes made:

- removal of sections dealing with the slaughter and disposition of carcasses
- restructuring of sections on meat processing
- addition of cooking time tables (Annex D)

ENGLISH AND FRENCH VERSION

Please replace Chapter 4 with this new version in your Manual of Procedures.

Ottawa (Ontario)
K1A 0Y9

Date : 1er juin 2010

DIRECTIVE DE L'HYGIÈNE DES VIANDES :

2010 - 03

OBJET : Chapitre 4

Révision du chapitre 4 afin d'éclaircir les exigences applicables aux différents processus de transformation des viandes.

Changements apportés :

- retrait des sections portant sur l'abattage et la disposition des carcasses
- restructuration des sections traitant de la transformation des viandes
- ajout des tableaux de cuisson (Annexe D)

VERSION ANGLAISE ET FRANÇAISE

Veuillez remplacer le chapitre 4 par cette nouvelle version dans votre Manuel des méthodes.

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Canada

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Glossary

"Act" means the *Meat Inspection Act*
"Chief" means the Chief, Meat Processing
"CVS" means the Compliance Verification System
"Divisional" means by the Meat Programs Division (MPD)
"Director" means the Director of the MPD
"EDO" means the Area Executive Director, Operations designated by the President of the Agency
"FSEP" means the Food Safety Enhancement System
"FTM" means finely textured meat
"HACCP" means Hazard Analysis and Critical Control Point
"MIR" means the *Meat Inspection Regulations, 1990*
"MSM" means mechanically separated meat
"MOP" means the Meat Hygiene Manual of Procedures
"NRTE" means non ready-to-eat
"Registered" means registered under the authority of the *Meat Inspection Act* and *Regulations*
"RTE" means ready-to-eat
"SRM" means specified risk material

4.1 INTRODUCTION

The purpose of this chapter is to indicate the more important points of control in meat processing operations. Inspectors and operators must familiarize themselves with the control measures outlined in this chapter.

4.2 HANDLING OF MEAT PRODUCTS

Processing rooms (cutting and boning, formulation rooms, kitchens, packaging, etc.) shall be equipped to accommodate the particular process or processes conducted therein.

4.2.1 Refrigeration and related activities

4.2.1.1 Refrigeration

The primary purpose of refrigeration is to preserve meat products by slowing down the chemical and enzymatic changes which occur in tissues after slaughter and by slowing down or stopping multiplication of microorganisms which might give rise to spoilage or food poisoning. By definition in the regulations "refrigerate" means to lower the temperature of a meat product to, and to maintain the temperature at, 4ºC or lower, but does not include to freeze.

Rooms used for storage of refrigerated meat products shall be capable of maintaining a temperature of 4ºC or less. The temperature of the room shall not cause the product to become frozen.

Refrigeration of the environment in which meat products are handled is also important, not only in producing and maintaining lowered temperatures in the products themselves, but also in depressing the rate of multiplication of microorganisms in the environment. Refrigeration has, therefore, an important role to play in the field of sanitation. Since refrigeration is involved so extensively in many operations, common references will be found in sections of red meat and poultry chapters of this manual.

4.2.1.1.1 Room temperature exemptions

4.2.1.1.1.1 Exemption from refrigeration of processing areas

Where a low temperature is required for the preservation of a meat product, the temperature in a room or area of a registered establishment in which that meat product is processed, packaged, labeled or handled shall not exceed 10ºC.

The following areas are considered exempted from this requirement:

- cooking rooms (oven, kettles, fryers, etc.);
- fermentation and aging rooms;
- transfer areas into and out of cook rooms (e.g. hallways where no product is kept); and
- kill floors, evisceration floors, scalding rooms and slaughter associated processes such as tripe, feet, casings etc.

Exemptions from the requirement to maintain refrigeration (10ºC) in processing rooms can be granted by a Program Specialist, Meat Processing, if **ALL** of the four following conditions are met. Other proposals where the Operator provides a validated alternative as part of their HACCP program will be reviewed on a case by case basis.

1. The environment (equipment, contact surfaces, handlers) shall not pose a risk of product contamination at any time during operations. The operator has developed and implemented a **HACCP** program including microbiological assessment of the product and environment, which ensures that the process meets the minimum

criteria set out for the process in this document. Each HACCP program shall be reviewed and recommended by a team composed of the Inspector in Charge and a Program Specialist having the required specialized knowledge. After appropriate review, the program will be returned to the operator with the reviewers' conclusions. The operator must keep any letter of acceptance on file for future reference and review by the Inspector in Charge.

As each process will be inherently different, it is impossible to provide set microbiological guidelines suitable for all operations. Microbiological programs will therefore need to be developed by the operator on a case by case basis to the satisfaction of the Program Specialist and shall demonstrate the safety of the environment at all times during processing.

2. Any unclean equipment that was previously used and **left unused for a period of 2 hours or more** shall be completely taken apart, cleansed and sanitized before being reused;

3. Unless the operator is able to demonstrate the continual microbiological acceptability of the environment (by means of a valid microbiological sampling program), a complete mid-shift clean up (including equipment dismantling) of contact surfaces shall take place at least **once every 4 hours during operations**. Such a mid-shift cleanup procedure shall consist of removal of all meat products, other ingredients and packaging material from the room prior to conducting a thorough cleaning and sanitation of product contact surfaces. Should such cleaning create condensation on overhead structures, the condensate must be eliminated prior to the start-up of operations. At the end of a mid-shift clean-up, product contact surfaces shall meet the same criteria as for the pre-operational inspection stage.

4. The **type of operation** falls within one of the six categories listed below.

Category [1] Kitchen / formulation operations:

An exception for the refrigeration of formulation rooms under specific circumstances has been made. Most meat products entering these rooms come directly from the cooler and are at a relatively low temperature. All formulation, stuffing, handling, pre-blending, marination, etc. operations involved in the processing of meat products are eligible for exemption from refrigeration requirements provided **ALL** of the following additional conditions are met:

- the meat used in the product was either hot boned immediately prior to processing OR previously chilled to a temperature of 4ºC or less; **and**
- the meat surface temperature never exceeds 7ºC; **and**
- in the case of a non-cured product, cooking (product must be fully cooked), drying or fermenting of the product shall start within 2 hours of the time it first enters a non refrigerated area;
- in the case of a cured product, cooking (product must be fully cooked), drying or fermenting of the product shall start within 4 hours of the time it first enters a non refrigerated area.

Category [2] Comminuting operations:

Comminuting operations (**e.g., grinding, emulsifying, dicing, slicing, chopping, etc.** of raw meat products) are eligible for exemption from refrigeration requirements provided **ALL** of the following additional conditions are met:

- the meat to be comminuted was previously chilled to 4ºC or less; **and**

- the comminuted product cooking cycle is initiated within 2 hours from the time the product enters a non refrigerated area.

Note: Comminuting of raw meat product that is **intended to be sold as fresh ground meat** product or is intended to be further processed in a product that will be sold as raw or semi-cooked (i.e., not fully cooked) must be performed in a **fully refrigerated area**.

Category [3] Meat filled pasta/ meat filled pastries/ continuous line for breaded meat products:

The processing of **meat-filled** pastries and meat-filled pasta (e.g., ravioli, tortellini, etc.) that cannot technically be processed under refrigeration (because the dough will not stick together in a refrigerated area), as well as continuous lines for breaded meat products, could be allowed in a nonrefrigerated area provided **ALL** of the following conditions are met:

- the meat product has been chilled to a temperature of 4ºC or less before being transferred to the nonrefrigerated area **AND** the meat product surface temperature does not exceed **7ºC** at any time during the process; **and**
- the product is either:
  - placed in a freezer within 30 minutes after the preparation is completed; **OR**
  - fully cooked or pasteurized within 30 minutes after the preparation is completed and subsequently chilled or frozen.

Category [4] Handling of pork tongues, pork hocks and feet intended for immediate further acidification:

Such handling could be allowed in a nonrefrigerated area provided **ALL** of the following conditions are met:

- there is a continuous drop in product temperature as defined by the "Time/Temperature Guidelines for Cooling Heat Treated Processed Product" in Chapter 4, section 4.5 of the Manual of Procedures); **and**
- handling is done with all precautions being taken to avoid re-contamination of the cooked product (e.g. disposable gloves, use of hand sanitizers, restricted area, special ongoing sanitation of equipment as required, etc.).

Category [5] Assembling and packaging of meat products:

Different situations could occur with different levels of risk:

- Packaging of cooked refrigerated (4ºC or less) meat products **shall be done in a refrigerated room** (maximum temperature of 10ºC) in order to minimize reheating of product surfaces and possible growth of pathogens.

- Packaging of **frozen meat products** in a non refrigerated room could be allowed if:
  - the product **enters** the non refrigerated room in a **frozen condition**; **and**
  - the product's **surface temperature does not exceed 0ºC** while in the non refrigerated packaging room.

- **Assembly and packaging of entrées, such as pizzas and TV dinners** could be allowed in a non refrigerated room provided **ALL** of the following conditions are met:
  - the process is **continuous** in nature; and
  - the meat product has been **chilled to a temperature of 4ºC or les**s before being transferred to the non refrigerated area; and the product's surface temperature **does not exceed a temperature of 7ºC** at any time during the process;

    OR

- If trays of entrées such as TV dinners are hot filled, the chilling of the meat component (including the sauce) complies with the guidelines for cooling of heat processed meat products as given in section 4.4.1 of this chapter.
- Handling is done with all precautions being taken to avoid re-contamination of the cooked product (e.g. disposable gloves, use of hand sanitizers, restricted area, special ongoing sanitation of equipment as required, etc.); and
- The product freezing process is initiated within 30 minutes of the beginning of the assembly operation.

- Packaging/handling of meat products which have just been cooked but have not yet been refrigerated to the storage temperature of 4ºC or less, and the application of a surface coating or glazing to a cooked meat product (e.g. chicken wings, etc.) at the exit of the oven could be allowed in a non refrigerated area provided **ALL** of the following conditions are met:
  - packaging/handling operations are done while the product is still at 60ºC or above;
  - packaging/handling operations in a non refrigerated area **do not interfere with the product cooling process** (i.e. there is a continuous drop in product temperature: see requirements for cooling heat treated processed product in section 4.4 of this chapter; and
  - handling is done with all precautions being taken to avoid re-contamination of the cooked product (e.g. disposable gloves, use of and sanitizers, restricted area, special ongoing sanitation of equipment as required, etc.).

Category [6] Handling and packaging of dry soup mixes, bouillons, broths, concentrates, tallow, lard, suet, edible casing preparation, edible fat and shelf stable dry cured meats (if truly shelf stable i.e. the label does not have a "Keep refrigerated" statement):

Because these products are shelf stable and represent a very low health risk, an exemption could be granted.

Please note that the handling (e.g. boning, picking, dicing, etc.) of warm cooked meat product when those products could be used as ready-to-eat (RTE) products (e.g. diced chicken that could be used for salads) is not exempted and shall therefore be conducted in a fully refrigerated area.

It should be remembered that unless the operator is able to demonstrate the continual microbiological acceptability of the environment (by means of a valid microbiological sampling program), a thorough and complete mid-shift clean up (including equipment dismantling) and a preoperational check shall take place at least **once every 4 hours of operations**. Some discretion is permitted when dealing with enclosed equipment through which product is passing on an almost continuous basis, e.g. stuffers. In these instances, dismantling and cleaning may be permitted on a daily rather than a shift basis.

4.2.1.1.1.2 Mid-shift clean-up

The only other case where a mid-shift clean-up procedure is allowed in lieu of adequate refrigeration is when there has been a temporary mechanical failure of refrigeration equipment making it impossible to maintain the prescribed room temperature. In this case, measures must be taken to ensure that product temperatures do not exceed 10ºC. This may be accomplished by icing, or other satisfactory means. In those cases where the prescribed room temperature cannot be maintained, a thorough cleanup must be made after each four hours of operation.

Such a mid-shift clean-up procedure must consist of removal of all meat products, other ingredients and packaging materials from the room prior to a thorough cleaning of product contact surfaces and a rinse down of floor areas. Should such cleaning create

condensation on overhead structures, the condensate must be eliminated prior to the start-up of operations.

4.2.1.2 Freezing

Freezing reduces the temperature of a meat product below the freezing point, changing the state of water from liquid to solid form (ice). The formation of ice concentrates the dissolved solutes and reduces the water activity of the meat product. Freezing prevents the growth of, but does not destroy, microorganisms in food products.

The rate of freezing is important to prevent growth of microorganisms or production of their toxins prior to the product reaching freezing temperatures. Oxidative rancidity and other organoleptic quality issues can occur if freezing rates are slow. Operators should validate that their processes reduce the core temperature of products preserved by freezing, to a core temperature of -18ºC within a time frame allowing for the preservation of organoleptic and microbiological qualities.

It is recommended that holding freezers be capable of maintaining temperatures of -18ºC or colder.
Refer to Annex P of this chapter for the CFIA procedures to evaluate bulk container freezing processes for meat products.

Freezing as an application for destruction of the parasites trichinae and *Cysticercus*, is described in Annex B of this chapter and Chapter 17 respectively.

4.2.2 Boning and cutting - red meats

Establishments receiving beef carcasses or partial carcasses from cattle 30 months or older containing SRM must follow control procedures as outlined in Chapter 17 of the MOP.

The cutting and boning rooms shall be equipped with refrigeration units capable of maintaining a temperature of 10ºC or less.

A carcass re-inspection station located prior to cutting and/or boning is required. This station must be equipped with a directly drained and remote controlled or timed hand wash facility, an 82ºC water sanitizer and adequate lighting. Facilities for the removal of bones and trimmings shall be provided.

Moving belts, conveyors and cutting boards should be monitored for wear and tear. Plant employees must be trained to store their equipment, i.e. knives, steels, gloves and aprons in designated areas. It is not permitted to store this equipment on top of the meat or boning table.

It is the responsibility of management to make sure that the inspection legend applied on cuts is legible. The use of two-inch needle point stamps has proven to be effective in reproducing the inspection legend. However, inspectors should monitor the procedure and advise management when it is not satisfactory. When cuts are identified, conformation to definition must be monitored.

4.2.2.1 Definitions

Boneless Meat:
Boneless meat from either cattle, calf, sheep, goat, horse or swine carcasses including boneless cuts and trimmings.

Trimmings:
Meat pieces obtained during deboning and which do not meet any meat cut labelling specification.

Lot:
For the purposes of this section a lot is whichever is the lesser of:

- a shipment or part of a shipment of boneless manufacturing meat derived from a single species destined to a single destination; or
- 4 hours production of boneless manufacturing meat derived from a single species from a single boning line

Boneless Meat Verification:
Evaluation technique for CFIA personnel in which samples are taken from the assembled "lot" of product to determine its wholesomeness

Lot Examination:
Evaluation technique for the operator in which samples are taken from the assembled "lot" of product to determine its wholesomeness.

On-Line Examination:
Operator's examination technique in which product is sampled from each production line or common source at a specified frequency to determine the ability of the process to produce wholesome product

4.2.2.2 Control program for boneless meat

Control procedures must be instituted by the operator at various points in the process to detect and eliminate any problems as early as possible. To that purpose, the operator shall design, implement and monitor a written control program for fresh boneless meat that includes monitoring, deviation and disposition procedures that are at least equivalent with the ones described in Annex F, Part 1 of this chapter, as well as verification procedures (e.g. direct observations of monitoring activities and corrective actions) and record keeping. Please note that this program applies to all boneless meat produced by the operator. The program must also be approved and verified by the CFIA.

Establishment employees are using lot and/or on-line examination procedures while implementing the control program procedures.

4.2.2.2.1 Lot examination

Sampling plans, methods and criteria for disposition of lots of boneless meat are found in Annex F, Part 1. Should the operator elect to use alternate sampling plans, methods and criteria, these must be evaluated by the CFIA to ensure that they reach the same objective or better. The operator is then monitored taking into consideration their accepted lot examination procedure, including the deviation procedures.

Each time a lot is evaluated, the following procedure should be followed by the operator:

- Once the lot is completely assembled, determine its size (in kg), and select the corresponding sampling plan (with reference to Annex F, Part 1).
- Randomly select the containers from the lot in proportion to different code marks, and remove the required number of 5.5 kg sample units from the containers.
- Examine the product, classify defects using the defect criteria table and determine acceptance or rejection according to sampling plan.
- Record results. **If the lot is rejected:** After reconditioning, re-inspect the rejected lot using the next higher sampling plan and double the frequency of monitoring for the rest of the production shift.

4.2.2.2.2 On-line examination

The operator of the establishment shall design, document and institute an on-line sampling and examination program for boneless meat at a point close to where the product is placed into containers. Examination results must be retained for a minimum of one year.

The minimum sampling size and schedule per boning line should be 15 kg for each 30 minutes of production (random time sampling twice hourly).

The examination program must be capable of achieving the following results:

- Assure that all boneless meat produced under the program is capable of passing the lot inspection/examination program previously described using the designated sampling plans and defect criteria.
- Reject, hold and recondition product when defects exceed limits. Product produced since the last satisfactory evaluation must be reconditioned.

Prior to approval by the Inspector in Charge, the effectiveness of the program must be evaluated using lot examination to assure that on-line examination achieves equivalent or better results than lot examination. The supporting documentation and evaluation must be kept in file by the CFIA.

4.2.2.3 CFIA verification of the operator's control program procedures for boneless meat

At the frequency stipulated by the Compliance Verification System (CVS), the following verifications must be carried out by the inspector:

- when appropriate, observe carcass cleanliness before boning;
- verify that plant personnel properly judges defects;
- monitor the on-line examination, and/or lot examination, done by the operator;
- if a rejection limit is reached, confirm that all targeted product is reconditioned and reexamined;
- if unacceptable product is passed by plant personnel, enforce lot examination of product under inspectional surveillance until it is demonstrated that on-line examination may resume. A minimum lot examination of the greater of 27,272 kg or 2 days production of boneless product must be carried out before resuming on-line examination;
- when appropriate, ensure the legibility of the meat inspection legend on meat cuts; and
- for identified meat cuts: ensure conformation to definition.

The inspector may also evaluate, as often as he deems necessary, the records of the operator's control program for timeliness, completeness and accuracy.

4.2.3 Handling of meat products which have fallen on the floor

Any contamination of meat products in a registered establishment must be controlled and **prevented**. The site of the fall, the reason for the fall should be noted. Corrective action to prevent future falls should be made as soon as possible. Congestion, overloading of tables and conveyors or insufficient staff to manage line speed must be corrected or production must be reduced to prevent meat products from falling on the floor.

4.2.3.1 Ready-to-eat (RTE) meat products

The handling of RTE meat products is very critical because these products will be eaten without further cooking or any other treatment to reduce the level of microorganisms. Exposure of the product to contamination must be minimal from the time it is cooked until

it is sold. Any known contamination of RTE meats in a registered establishment must be dealt drastically and without compromise within the establishment, as soon as possible and before it is shipped. The procedures for dealing with ready to eat meat products that have fallen on the floor are:

4.2.3.1.1 RTE meats covered by skin

- Wash skin covered surfaces thoroughly with potable water.
- Trim all other surfaces completely without re-contaminating the product.
- Fully re-cook product before sale or use as rework in fully cooked product.

4.2.3.1.2 RTE meats in casings

- If the casing is intact and the ends are sealed: wash and dry.
- If the casing is not intact, or the casing is edible:
  - Wash the casing covered surfaces thoroughly with potable water.
  - Remove the casing, trim exposed surfaces.
  - Fully re-cook the product before sale or use as rework in fully cooked product.

4.2.3.1.3 RTE meats not covered by skin or casing

- Trim all surfaces completely without re-contaminating the product.
- Fully re-cook product before sale or use as rework in fully cooked product.

4.2.3.2 Raw or non RTE meats

See Chapter 19 for poultry carcasses and Chapter 17 for red meat carcasses that have fallen on the floor.

Meat cuts, offal or portions must be washed thoroughly at a salvage station with potable water or hyper chlorinated water (if the establishment has a program for its use) and then used in a cooked product. Any surfaces that are contaminated should first be trimmed to eliminate visible contamination before the meat, offal or portion is washed.

Because trimming of ground products and meat trimmings is not practical, any meat trimmings or ground meat products that come in contact with the floor must be condemned. If trimming of contaminated surfaces of other non ready to eat meat is not practical, these products must also be condemned.

4.2.4 Comminuting

E. coli O157:H7 in raw ground beef is considered a biological hazard which is reasonably likely to occur and which must be addressed by the operator's HACCP system. See Annex O for policy specifications on the detection of *E. coli* O157:H7 in raw beef.

Should *E. coli* O157:H7 be detected in raw ground beef product, the CFIA must immediately be informed. If product has left the control of the establishment, the Food Recall and Emergency Response unit will coordinate a recall of all potentially affected products.

If the lot of ground product found positive for *E. coli* O157:H7 included raw ground beef material made during a previous production run (i.e. rework or carry-over), in order to address the possibility that the bacteria may have come from the original lot(s) of ground beef product and limit consumers' exposure to potentially contaminated lots with *E. coli* O157:H7, the recall will be extended in a similar manner to include all products made from the original lot(s).

For this reason, the practice of carrying over raw ground beef product made during prior production runs (i.e., before clean-up) as a rework ingredient in post-cleanup production runs is discouraged.

Where such carry-over of raw ground materials as rework does take place, the operator MUST:

- have controls built into their HACCP system (as per FSEP) which address the potential hazard for cross-contamination of lots with *E. coli* O157:H7*.*
- handle the product in such a way to limit the number of lots to be recalled in the event of a positive finding of *E. coli* O157:H7*,* for example, by limiting the types of fresh product which are made with rework ground beef and scheduling regular "breaks" which stop any carry-over of rework product from previous days; and
- include control measures to ensure the immediate traceback of rework ingredients and traceout of all affected product in the event of an *E. coli* O157:H7 result.

In addition, the operator's procedures must be provided to the CFIA for review. This package needs to include:

- a summary of the practices and controls at the establishment;
- a copy of Forms 5, 8 and 10 from the operator's HACCP plan(s) for ground products; and
- a copy of the establishment's recall procedure for ground product.

The material is first provided to the CFIA Responsible Inspector. The inspector will review the document and determine if it is complete and effective. If this is not the case, the operator must make the appropriate modifications to their procedures. If acceptable, the inspector will state this in writing and forward the package to the Area Program Specialist - Meat Processing for oversight review. The results of the oversight review by the program specialist will be provided in writing to the inspector and operator.

4.2.5 Mechanical separation of muscle tissue from bones - production of finely textured meat (FTM) and mechanically separated meat (MSM)

Manufacturers of MSM and FTM **(NOTE: The term "meat" is replaced with the name of the animal species, for example, beef, pork or chicken)** must operate Quality Control programs and testing programs in accord with requirements set out in sub-sections 4.2.5.8 and 4.2.5.9.

4.2.5.1 Definitions and compositional standards

Mechanical meat/bone separation equipment operates by using mechanical pressure to separate muscle tissue from the attached bones. The equipment operates on the differing resistance of bone and soft tissue to pass through small openings, such as sieves or screens. Depending on the composition of the final product, the resulting edible product is referred to as finely textured meat or mechanically separated meat (e.g. finely textured chicken or mechanically separated chicken).

MSM is an edible product obtained by removing muscle tissue attached to bones by the means of mechanical meat/bone separation equipment that contains:

- no more than 0.027% of calcium for every 1% of protein;
- no bone particles larger than 2 mm in size; and
- a minimum protein content of:
  - 10%; or
  - if destined for retail sale, 14%.

FTM is an edible product obtained by removing muscle tissue attached to bones by the means of mechanical meat/bone separation equipment that contains:

- no skin;
- no more than 0.15% of calcium;
- no bone particles larger than 1.5 mm in size and a maximum of 20% of the bone particles larger than 1 mm in size; and
- a minimum protein content of:
  - 10%; or
  - if destined for retail sale, 14%.

FTM can be used in the preparation of ground meat or identified as ground meat when:

- it has a minimum protein content of 14%; and
- it complies with the standards set out within Schedule 1 of the *Meat Inspection Regulations, 1990*. The term "regular", "medium", "lean" or "extra lean" must be used as appropriate in order to indicate the maximum fat content (i.e. 30%, 23%, 17% or 10% respectively).

4.2.5.2 Raw material used in the preparation of FTM and MSM

Only bones, dressed carcasses or parts of dressed carcasses from food animals which have been approved for human consumption may be used. With regards to FTM, hand or mechanically deboned trimmings that contain bone particles or cartilage may be used. For MSM, the regulatory definition prohibits the use of any previously deboned meat as input material. Please note that the raw material used can only make one passing through the mechanical separation equipment.

Important considerations:

- lungs must be removed from all poultry carcasses and portions prior to their use as material for mechanical separation;
- poultry carcasses dressed with kidneys may be used for **MSM** only, as long as the resulting product is properly labelled. The mention "Contains kidneys" or "With kidneys" must then appear by the product name. It is to be noted that this mention must also appear on the ingredients list of any product made with MSM containing kidneys;
- skulls shall not be used; and
- the spinal cord must be removed from ruminant, equine and porcine carcasses and portions prior to their use as material for mechanical separation.

4.2.5.3 Treatment of raw material prior to mechanical separation

Bones, carcasses or parts of a carcass shall be kept or transported at time/temperature combinations that will ensure their hygienic acceptability when used for mechanical separation.

Bones shall be:

- maintained at a temperature *not exceeding* 10ºC and mechanically separated within 5 hours of boning; or
- refrigerated to 4ºC and mechanically separated within 72 hours of boning; or
- refrigerated to -2ºC and mechanically separated within 120 hours of boning; or
- immediately placed in a freezer and frozen within 48 hours of boning.

4.2.5.4 Use of poultry carcasses and parts of carcasses containing kidneys (when the resulting product is not labelled as "containing kidneys") and lungs as raw material

Kidneys (for FTM and MSM which will not be labelled as containing kidneys), and lungs must be removed from poultry carcasses and portions prior to their use as material for mechanical separation.

In order to ensure proper removal of kidneys (when appropriate), and lungs in poultry carcasses and parts of carcasses used as raw material in the preparation of MSM or FTM, operators shall monitor this raw material as per the following protocol. This protocol is based on ISO Table #2859-1 at an inspection level of S-4, for a lot or batch size ranging from 1,201 to 10,000 units.

Upon arrival of the raw material to the establishment or prior to the processing of the material, the operator shall perform a random selection of 20 carcasses or units per combo or a lot of similar size.

- If the number of defects found is equal to or less than 1, the lot shall is acceptable for mechanical separation.
- If the number of defects found is equal to or greater than 4, the lot shall be rejected.
- If the number of defects found is between 1 and 4, a second sample of 20 units shall be evaluated. The number of defects in the first and second sample shall be totalled.
- If the cumulative number of defects found is equal to or less than 4, the lot is acceptable for mechanical separation.
- If the cumulative number of defects found is equal to or greater than 5, the lot shall be rejected.

One defect is defined as a carcass or unit with kidney (when not acceptable) and/or lung. The rejected product must be either reworked and resubmitted for sampling, or returned to the originator, or treated as inedible product.

The presence of kidney is defined as the presence of a part of a lobule or several lobules measuring at least 0.5 cm x 0.5 cm. The presence of lung is defined as a part of lung measuring at least 1 cm x 1 cm.

The inspection staff will monitor the compliance to these tolerances using the same protocol. The inspection service sampling will take place as deemed necessary based on previous compliance of the operator or of the supplier. It will also be incorporated in the inspection tasks for the plant. Any defective lots will be brought to the attention of the operator for appropriate corrective action.

4.2.5.5 Use of pork or poultry skin as raw material when producing Mechanically Separated Meat (MSM)

Mechanically Separated Pork or Poultry Meat will be deemed to contain skin unless the manufacturer indicates otherwise on the product’s label.

Only pieces which have **naturally adhering** skin can be used to make MSM; detached skin or pieces which have loose skin flaps cannot be used. For example, skin-on necks which have attached neck skin can be used to make MSM but necks to which flaps of breast or back skin have been left attached cannot be used.

When MSM is used in the manufacture of a formulated meat product, unless the MSM is free of skin and has been identified as such by the supplier, it is considered as containing the allowed eight percent (8%) skin as indicated in notes 2(h) and 2(j) of Schedule I of the *Meat Inspection Regulations, 1990* (MIR). MSM made from skinless raw material may be labelled as "Skinless - Sans peau". It is then possible to add, when formulating the product, up to 8% of skin from the concerned species as stipulated in the notes of the

MIR Schedule I. Please note that the added 8% can only be applied to products which have skin on them (for example, it would not apply to beef tongues or gizzards).

Examples: Determination of the quantity of pork skin which may be added to the following recipes:

a) 55 kg of skinless pork trim:
25 kg of pork MSM
20 kg of water
x kg of pork skin

As the MSM is not labelled as "skinless", the amount of skin that may added is calculated for the 55 kg of skinless pork trim only, which gives us an "x" value of 4.4 kg (8% of 55 kg). This gives us the following final recipe:

50.6 kg of skinless pork trim + 4.4 kg of pork skin
25 kg of pork MSM
20 kg of water

b) 55 kg of skinless pork trim:
25 kg of pork MSM without skin
20 kg of water
x kg of pork skin

As the MSM is labelled as "skinless", the amount of skin that may be added is calculated for both the pork trim **AND** the MSM which gives us an "x" value of 6.4 kg: 4.4 kg for the pork trim and 2 kg for the MSM (8% of 80 kg). This gives us the following final recipe:

50.6 kg of skinless pork trim + 4.4 kg of pork skin
23 kg of pork MSM without skin + 2 kg of pork skin
20 kg of water

4.2.5.5.1 Sampling procedure and tolerance for pork or poultry skin

In order to use the term "Skinless - Sans peau" the manufacturer must operate a raw material monitoring protocol in accordance with the following specifications:

For the purpose of this sampling plan the definition of a lot is the same as in the above item 4.2.5.4 Use of poultry carcasses and parts of carcasses containing kidneys (when the resulting product is not labelled as "containing kidneys") and lungs as raw material.

The total skin area of all sample units (up to 20) cannot exceed 25 cm^2 (i.e. 4 in^2).

- Select a 10 unit sample at random and examine for the presence of skin. A unit is an intact piece, e.g. front half shell, breast frame, shell, skinless backs or necks.
- If no skin is found, the mechanically separated meat may be identified as "Skinless - Sans peau".
- If the total skin on the first 10 units exceeds 25 cm^2, the lot cannot be used in the preparation of "Skinless - Sans peau" products unless it is reworked to remove the skin and presented for reevaluation.
- Any skin found in the first 10 sample units not exceeding the tolerance, requires random selection of a second 10 unit sample from the same lot. Product where the skin found in the total 20 unit sample does not exceed the tolerance may be used in the preparation of "Skinless - Sans peau" products. Products where the skin exceeds the tolerance must be reworked to remove the skin and presented for reinspection.

The inspection staff will monitor compliance using the same protocol. Monitoring by the inspection personnel will take place as deemed necessary based on previous compliance

of the operator and as prescribed by the inspection tasks for the plant. Any defective lots will be brought to the attention of the operator for appropriate action.

4.2.5.6 Handling of MSM and FTM

Unless MSM or FTM is used directly after the separation process as an ingredient of a meat product, it shall be:

- cooled to a temperature close to 0ºC (±2ºC) in conjunction with the deboning process or immediately afterwards;
- cooled to a temperature close to 0ºC (±2ºC) in conjunction with the deboning process or immediately afterwards and cured; or
- frozen immediately after the deboning process.

4.2.5.7 Shipment of mechanically separated meat (MSM) from one registered establishment to another for incorporation into a prepared meat product

MSM may be shipped from one registered establishment to another in the refrigerated, refrigerated and cured or frozen state. The operator is responsible to implement proper controls over the conditions under which the product is handled to ensure its wholesomeness.

Refrigerated MSM (cured or non-cured) should be maintained at temperatures close to 0ºC and should be closely monitored from production to utilization.

Cured MSM must be identified as such: **cured** mechanically separated (name of the species of meat).

Note: When cured refrigerated MSM is used, the operator must recalculate the nitrite input of the formulation to account for the nitrite contribution from the MSM. For this purpose, it is assumed that the maximum 200 ppm of nitrite salt has been added.

4.2.5.8 Quality control program and compliance monitoring for Mechanically Separated Meat and Finely Textured Meat

Operators are required to maintain a quality control program and appropriate records to demonstrate that the process is under control and that mechanically separated meat and finely textured meat are meeting the standards.

The operator shall submit a copy of their proposed quality control program to the CFIA Inspector in Charge who will comment and then forward to the Area program specialist, Animal Products Program Network, oversight review.

The operator may choose to use on-site laboratory facilities.

The Quality Control Program shall contain the elements listed below.

4.2.5.8.1 Cover letter

The cover letter must contain the following information:

- name of the company;
- establishment number;
- the objective of the program;
- the length of time data generated by the program is retained -- e.g., all records generated by this quality control (QC) program are retained for a minimum of one year;

- commitment to make all data, records and information, generated as a result of the program, readily available to CFIA officials;
- signature of the establishment's official responsible for the program -- e.g., Quality Control Manager; and
- a statement that the quality control personnel have the authority to halt production and restrict shipment of product if standards established in this program are not met.

4.2.5.8.2 Detailed information

A complete and effective quality control program must contain the following information:

4.2.5.8.2.1 Products covered

Name(s) of product(s) and approximate daily production.

Example: Mechanically separated pork (2,000 kg/day), Finely textured beef (1,000 kg/day), Regular ground chicken (2,000 kg/day).

4.2.5.8.2.2 Raw materials

- Source

  Provide names and establishment numbers of raw material suppliers. The date and time of production must be legibly printed on each container (combo bin or other). If the source of bones is an outside establishment, arrangements shall be made with the supplier(s) to print date and time of production on each container.

- Controls (including transportation if applicable):

  - Specify the bone mix or blend of bones used (%).
  - **Example:** 100% beef neck bone (previously deboned material)
  - Specify the handling and storage procedures.
  - Describe the method/means of recording times and temperatures.
  - A bone control is in place to make sure there is no spinal cord in bones from ruminant, equine and porcine carcasses.

4.2.5.8.2.3 Equipment

- Provide the name and model number for all equipment used in the process, including the heat exchanger if applicable.

- All sections of the sanitation and maintenance programs which are applicable to the equipment installed must be evaluated and approved by the inspection service before it is used in the establishment.

- Equipment specifications and operating parameters (where applicable):

  - Speed of raw material in feed and raw material batch load size (e.g. 5,000 kg of raw material is processed every hour, this represents 250 batches of 20 kg of raw material).
  - Yield (e.g. 30%, 3,000 kg of meat for every 10,000 kg of raw material).
  - Opening size of filters, perforated drums etc.
  - Maximum pressure applied to raw material (e.g. maximum roller pressure = 5 bars, maximum belt pressure = 40 bars, etc.).
  - Maximum dwell time in chamber.
  - Specify how each operating parameter (e.g. speed of process, batch load size, maximum cylinder pressure, pressure time, etc.) is adjusted and controlled. Indicate what the reading on the equipment's monitor should be. For example, visual indicator "A" will display the number 10 to indicate that the maximum dwell

time is 10 seconds; visual indicator "B" will display the number 2 when the maximum pressure applied to the product is 5 bars; etc.

4.2.5.8.2.4 Finished product controls

- Lot definition: Product produced from a single species in no more than one continuous shift of up to twelve hours.
- Specify the handling and storage procedures.
- Describe the method/means of recording times and temperatures for the product to reach the storage temperature of either chilled (4ºC) or frozen.

4.2.5.8.2.5 Finished product analysis

- Indicate analytical methods used.
- Explain method(s) of drawing samples.
- Sample size, sampling frequency and compliance limits:

4.2.5.8.2.6 Monitoring procedure

- Is monitoring done by Quality Control personnel? If not, then who is responsible?
  Example: One full-time Quality Control technician collects the samples, performs the tests (calcium, proteins and bone particles) and records all the results.
- How are retained products identified and controlled?
  Example: All retained product is tagged with a company tag and placed in the area designated for retained product. A CFIA inspector is notified.

4.2.5.8.2.7 Record keeping procedure

- Who are the personnel responsible for records?
  Example: Quality Control data and records are maintained by the Quality Control technician.
- All information and data generated by this program should be clearly and accurately recorded. Example copies of all forms, tags, and charts used must be included as part of the program.

4.2.5.9 Sampling and testing procedures for MSM and FTM

As a minimum the following procedure will be used by the operator to maintain assurance that the production process is delivering a product in compliance.

For purposes of this program, a lot shall consist of the mechanically separated meat or finely textured meat produced from a single species in no more than one continuous shift of up to 12 hours.
Samples and mixed sub-samples must not to be ground or crushed before the analysis.

4.2.5.9.1 Start-up plan

This plan is used when the equipment is first installed, when major components are replaced (e.g. a separating drum or filter, separating screens, screen plates or perforated screen, feeding screw [i.e. worm], etc.) or when major repairs are made.

Under this sampling plan the operator must test each lot for calcium, protein and bone particle until 10 consecutive lots are in compliance. Once this is achieved, the monitoring plan can be used.

The sample to be analysed shall consist of 20 sub-samples taken during the lot run. If the shift is 8 hours (480 minutes) sampling must be done every 24 minutes (480/20 = 24 minutes). Likewise, if the scheduled lot run is 6 hours (360 minutes) sampling must be done every 18 minutes (360/20 = 18 minutes).

The shift must be a minimum of 4 hours to be considered in this start-up plan. If the shift is less than 4 hours the total sample collected will be sent for analysis, however, this shortened shift will not be counted as part of the 10 consecutive lots that must be in compliance.

Each sub-sample should be about 30 grams. The samples may be placed in the same container (e.g. a plastic bag) so that at the end of the lot run it will contain about 600 grams of product.

The tested lots are to be held until receipt of an acceptable laboratory report.

4.2.5.9.2 Monitoring plan

This plan is uses after having successfully completed the start-up plan. Under this sampling plan the operator must test for calcium, protein and bone particle 1 lot out of 5 lots.

For the purpose of this monitoring plan a sample of at least 500 g shall be taken randomly from the production lot. The tested lots may move freely prior to receipt of the laboratory report. If a lot is found to be in non compliance for any of the prescribed standards the following procedure shall be followed.

4.2.5.9.3 Deviation procedures for noncompliant results

When a noncompliant result is reported, the lot shall be disposed of as described in section 4.2.5.9.4, Disposition of product not meeting the performance criteria. The operator shall sample subsequent lots using the start-up plan and shall document the preventive actions taken to prevent re-occurrences.

Performance Criteria and Tolerances for Results Analysis

Mechanically separated meat	Performance criteria	Tolerance
Bone particle	No bone particle larger than 2 mm	NONE
Calcium	No more than 0.027% of calcium for every 1% of protein	0.03%
Protein	Minimum of 10% or 14% according to declared use	NONE

Finely textured meat	Performance criteria	Tolerance
Bone particle	No bone particle larger than 1.5 mm and a maximum of 20% of the bone particles larger than 1 mm	NONE
Calcium	No more than 0.15%	0.03%
Protein	Minimum of 10% or 14% According to declared use	NONE

For FTM a lot is deemed out of compliance if the calcium content of any single analytical result is more than 0.18%, or if the protein content of any single analytical result is less than 10.0%. In the case of protein the results shall be rounded to the nearest 0.1% (e.g. 9.5% or 9.7% would not be rounded to 10%).

4.2.5.9.4 Disposition of product not meeting the performance criteria

- Receipt of test results indicating that the criterion for calcium is not met:
  - When the lot is still under the operator's control (it is still in the plant or in storage for example): provided the lot meets the standards for mechanically separated meat, re-label it as MSM. Otherwise send it for edible rendering/extraction or treat as inedible.
  - When the lot is no longer under the operator's control, it is not required to recall the product and it may remain distribution.
- Receipt of test results indicating that the criterion for proteins is not met:
  - When the lot is still under the operator's control:
    - In all cases where the product has a protein content of less than 10%, send it for edible rendering/extraction or treat as inedible.
    - If the product has been labelled for retail sale and has a protein content of less than 14%, it may either be re-labelled for further processing (i.e., not for retail) or treated in the manner described just above.
  - When the lot is no longer under the operator's control, it is not required to recall the product and it may remain in distribution.
- Receipt of test results indicating that the criteria for bone fragments are not met:
  - In **all cases** where there is a bone fragment greater than 2 mm - the product must be recalled by the manufacturer. The product may then be directed for edible rendering/extraction or be treated as inedible.
  - In cases where there is NO bone fragment greater than 2 mm:
    - When the lot is still under the operator's control, send if for edible rendering/extraction or treat as inedible.
    - When the lot is no longer under the operator's control, it is not required to recall the product and it may remain in distribution.

4.2.6 Defrosting or thawing

This may be performed in either air or water. Thawing of meat must be done as rapidly as possible given the defrosting process being used. The temperature of the meat is to be controlled to minimize the time that the temperature, in any portion of the meat, is above 4ºC. Acceptable **active** methods could be, for example, the use of microwaves, forced air, continuously circulating water, etc. that are operated under Good Manufacturing Practices (GMPs).

When air is used as a thawing medium, the product surface temperature shall not exceed 7ºC. Where meat products are thawed in water, the water must be cold, potable and continuously exchanged. Packaging material (e.g. boxes) shall be removed prior to thawing. However, meat products packaged in plastic bags may be thawed without removing these plastic bags.

Thawing shall be monitored to determine when all portions of the meat have thawed (i.e., have reached a temperature of 0ºC or greater). As soon as thawing is complete, product

is immediately processed or stored at a temperature of 4ºC or less. When water is used, it is directly drained before storage.

Thawing practices and procedures shall result in no net gain in weight over the frozen weight, when meat products are thawed for repackaging. Thawed meat products may be held in tanks of crushed ice with continuous drainage, pending further processing or packaging providing there is no net gain in weight.

When establishing the best before date of thawed products, operators must take into account the length of time elapsed before the product was completely frozen. Meat products which have been frozen and thawed for sale in a refrigerated state must be labeled in accordance with article B.01.080 of the *Food and Drug Regulations* as "previously frozen". This ***does not*** apply to ***prepared*** meat products.

4.2.6.1 Thawing meat products for immediate cooking

As an alternative to defrosting and thawing methods listed above, meat products that are thawed in water in preparation for immediate cooking in the establishment may be handled by one of the following methods. Cooking must be started within 2 hours from completion of the thawing process:

- in continuous running tap water of sufficient volume and for such limited time as is necessary for thawing - the thawing medium shall not exceed a temperature of 21ºC; and

- in re-circulated water, maintained at a temperature not in excess of 10ºC, for such limited time as is necessary for thawing.

Note: The placing of frozen meat into cooking kettles without prior thawing is permitted only when a representative sample of the entire lot has been thawed and found to be sound and unadulterated.

4.2.7 Rework

This is defined as the inclusion of a prepared meat product into another meat product. It is the responsibility of plant management to ensure that all the ingredients and components of the rework material are allowed into the meat product to which they are added. A special attention shall be paid to the list of ingredients of the resulting meat product; all ingredients added either directly or by the means of a rework product shall be accurately declared.

4.2.7.1 Curing aids

It should be noted that the presence of some curing aids may be found in significant amounts in the final product if their presence in the rework was not taken into consideration. In that respect, the level of nitrite/nitrate salts and of phosphates must be recalculated if the amount of rework material added to the formulation is in excess of 10%. Refer to Annex C of this chapter.

4.2.7.2 Meat products in edible artificial casings

Sausages in artificial edible casings (e.g. collagen) are allowed as rework material in the preparation of sausages wrapped in artificial edible casings or natural casings, to a limit of 3% in weight of the new meat product. The artificial edible casing does not have to be declared on the label of the product.

4.2.7.3 Meat products in natural casings

Sausages in natural casings are only allowed as rework material in the preparation of equivalent meat products (i.e. also wrapped in natural casing), to a limit of 3% in weight of the new meat product. When meat products in natural casings are reworked special attention must be paid to the animal species from which the casings were derived in order to verify that labelling requirements are met. All ingredients added either directly or by the means of a rework product shall be accurately declared in the ingredients list of the resulting meat product. For more information see Chapter 7.

4.3 COOKING

Operators are responsible for determining whether their meat product is RTE according to this section.

Definitions:

Cooked:
Subjected to heat for a time sufficient to produce the characteristics of a cooked meat product in respect of friability, colour, texture and flavour. The meat product must be ready-to-eat.

Ready-to-eat (RTE):
Means, in respect of a meat product, a meat product that has been subjected to a process sufficient to inactivate vegetative pathogenic microorganisms or their toxins and control spores of foodborne pathogenic bacteria *so that the meat product does not require further preparation before consumption except washing, thawing or moderate reheating.*

Thermal Lethality:
Ability of a given heating process to kill bacteria. It is most often expressed in quantitative terms, i.e., as the amount of heat energy that must be applied to a specific meat product to achieve a given $\log_{10}$ reduction of a particular microorganism.

Note: 1 $\log_{10}$ reduction = a tenfold reduction (1×10^1) = a 1D reduction
2 $\log_{10}$ reduction = a one hundredfold reduction (1×10^2) = a 2D reduction
3 $\log_{10}$ reduction = a one thousandfold reduction (1×10^3) = a 3D reduction etc.

Post-Cook Stabilization:
The set of measures applied to protect a cooked meat product against the possible outgrowth of heat shocked *Clostridium* spp. spores to dangerous levels during the interval following cooking. Refer to section 4.4 for these requirements.

Manufacturing Process:
The set of steps for cooking the meat product that ensures that the product receives enough thermal lethality to make it RTE.

4.3.1 Introduction

Cooking can render many foods digestible, palatable, bring them to enjoyable eating temperature, and kill or injure viruses, parasites or vegetative forms of bacteria. Microorganisms, however, may survive depending on time-temperature exposure, previous treatments and characteristics of contaminating organisms (e.g. *Salmonella*). Experience has shown that the main risk to public health from meat products is due to food-poisoning organisms such as salmonellae, staphylococci and *Clostridium perfringens*.

In order to avoid risks of this nature, the temperature and duration of the cooking process for heat treated meat products employed in registered establishments should be such

that the heat treatment alone or in combination with other preserving processes is sufficient to destroy all vegetative forms of these pathogens.

4.3.2 Requirements for operators manufacturing cooked RTE meat products

The operator of a federally registered establishment that manufactures a cooked RTE meat product must have all of the following:

- a **manufacturing process** specified in writing by the operator and used to cook a particular meat product;
- **validation data from a process authority and/or documentation** that suitably demonstrates compliance with point 1) above;
- **cooking equipment** which consistently (lot by lot) delivers the specified cooking process;
- **measuring and/or recording equipment** suitable to accurately and consistently measure and/or record the data used to verify that the control limits identified in the *manufacturing process* are being met;
- **equipment calibration procedures** to ensure that cooking equipment as well as measuring and/or recording equipment are continuing to perform in an acceptable manner; and
- **complete production records** for each lot manufactured to document the results of monitoring activities done for each of the control limits listed in the *manufacturing process*.

All establishments should meet these requirements. Under normal circumstance, establishments would need to make minimal adjustments to their existing procedures to ensure compliance.

4.3.2.1 Manufacturing process for a cooked RTE meat product - specific requirements

The manufacturing process **must be set out in writing** by the operator and must indicate how sufficient thermal lethality is being provided to the meat product.

It must indicate the **minimum internal temperature** reached during the process and, where applicable, the **minimum holding (or dwell) time at the minimum internal temperature.** The combination used must provide enough heat energy to achieve at least a:

- 6.5 $\log_{10}$ (6.5D) reduction in *Salmonella* spp. in meat products that contain no poultry[1];
- 7.0 $\log_{10}$ (7.0D) reduction in *Salmonella* spp. in meat products containing poultry.

It is the operator's responsibility to ensure that the minimum internal temperature of the cooked meat product meets regulatory requirements to ensure pathogen destruction.

The manufacturing process must also indicate in writing how the process is controlled. The operator's HACCP plan must provide the following information:

- what is measured, when, how and by whom;
- the limits used to decide if the process is acceptable or not;
- deviation procedures; and
- how controls are documented.

To be deemed acceptable, the manufacturing process must also be validated (see 4.3.2.2). If the operator has no validation that the process provides at least the minimum needed amount of thermal lethality, the product must be considered as a heat treated non RTE meat product. See section 4.3.3 for more information about these products.

4.3.2.2 Validation of the manufacturing process - specific requirements

"Validation" is done by a process authority to verify and demonstrate that the manufacturing process:

- is designed to deliver the necessary amount of thermal lethality to reach food safety; and
- that the operating procedures and equipment used to make meat products on a day-to-day basis will deliver the *manufacturing process* as designed.

4.3.2.2.1 Validation of the design of the manufacturing process

The operator must prove that the process used will be able to deliver the minimum amount of thermal lethality to reach food safety. All new or altered manufacturing process must be appropriately validated using scientific supportable data. This can be done in numerous ways:

- Referencing a combination of internal product temperature and minimum holding time known as safe. A list of these combinations is provided under Annex D. The operator needs to show that their manufacturing process includes at least one of the combinations provided in the Annex.
- Submission of a scientifically validated alternate manufacturing process sent to the area meat program processing specialist.

4.3.2.2.2 Verification that the manufacturing process is delivered as designed

The operator must verify that operating procedures will ensure that all lots of meat product are made according to the manufacturing process. The goal is to prove that in the "worst case", (i.e., coldest spot/product; measured at the limit of measurement error) receives thermal lethality in an amount equal or in excess to what the manufacturing process requires and that the monitoring procedures used during routine production ensure this. Validation activities done for HACCP plans typically fulfill this requirement.

The extent of this validation depends on the complexity of the manufacturing process itself and the tools used by the operator to monitor the process. Validating the manufacturing process for meat sauce cooked in a 100 litre kettle to temperatures far in excess of 70ºC and checked with a thermometer requires less effort than validating the manufacturing process for an automated cooking line with multiple chambers or a computerized smokehouse cooking roasts for an extended period of time at a temperature below 70ºC.

The operator needs to conduct tests to determine the "worst case" spot/product, i.e. the location that takes the longest amount of time to reach the internal product temperature set out in the manufacturing process. Multiple tests to identify the coolest spots of the cooking vessel for different product layouts (full house, half-full, 1 tree) are advised in the case of variable lot sizes. When the "worst case" spot or product is not where process monitoring is routinely done, the operator has to conduct tests to show how the surrogate location and values used will accurately predict that the "worst case" spot or product has been sufficiently heat treated.

4.3.2.3 Cooking equipment which consistently (lot by lot) delivers the specified cooking process

To be considered effective, the equipment must consistently deliver the intended thermal process in order to achieve proper cooking. The internal temperature of a cooked meat product must be taken at the coldest spot in the cooking device and in the center of the largest piece of meat. It typically involves identifying and controlling cold spots within the smokehouse or cooking vessel. Determination of the coldest spot of the cooking unit or cooking medium must be established beforehand by a competent authority in the field by the means of heat penetration tests on the equipment used. Any modification of the equipment will require a reevaluation of data (determination of the coldest spot) by the competent authority. When manufacturing food in hermetically sealed containers, the equipment and the instruments used along with the thermal treatment applied must meet the requirements of Chapter 15 of the Manual of Procedures.

When steam is generated, it must be properly vented out of the area and not allowed to permeate into adjoining rooms.

4.3.2.4 Measuring and/or recording equipment

Equipment used to monitor the process must be as accurate and reliable as is required for purposes of verifying the manufacturing process. When the process uses a reduced safety factor (for example, a minimum internal temperature of 63ºC for 200 seconds), the equipment needs to be much more accurate than what is used to verify a process with an inherently greater safety factor (e.g., a minimum internal temperature of 80ºC.)

The operator shall ensure that the monitoring limits used in their manufacturing process are adjusted by at least the amount of degrees or time specified by the equipment manufacturer as the acceptable measurement error.

Monitoring equipment capable of measuring within the following limits is provided:

- temperature ± 1.0ºC;
- time ± one minute; and
- relative humidity (where specified) ± 5%.

Temperature sensing devices are so placed as to monitor the temperature of the product and the heating environment *in the coldest part* of the cooking unit.

Also, if the operator is using time, relative humidity or another type of factor as a critical factor in the process, they must have automatic recording devices which can capture this data and that are capable of measuring within the following limits:

- temperature:
  - ± 1.0ºC

- time:
  - ± 1 minute when the minimum internal (dwell) time is at least 10 minutes (Note: the *manufacturing process* to build-in an extra 1 minute of dwell time to compensate for measurement error)
  - ± 5 seconds when the minimum internal (dwell) time is at least 200 seconds (Note: the *manufacturing process* to build-in an extra 10 seconds of dwell time to compensate for measurement error)
  - ± 1 second when the minimum internal (dwell) time is at less than 30 seconds (Note: the *manufacturing process* to build-in an extra 1 second of dwell time to compensate for measurement error)

- relative humidity:
  - ± 5%

If the operator is cooking a pork product in order to make it RTE, use of a recording thermograph is **required**.

4.3.2.5 Equipment calibration procedures

Calibration ensures that the process is delivered in a uniform manner. The equipment must be calibrated according to the manufacturer's specifications and these calibration activities need to be part of the operator's control programs.

Equipment used to monitor and record cooking data (e.g., thermograph devices, thermometers used to manually record internal temperatures) must be calibrated as often as is necessary to ensure the reliability of data. Thermograph devices must be calibrated at least annually. Thermometers need to be checked against a reference thermometer as often as is needed to ensure their accuracy - checks should be performed for the temperature range which is most often reported with the device. Calibration activities need to be part of the operator's control programs.

4.3.2.6 Complete production records - specified requirements

The operator must generate and retain records to document that they have suitable control over the cooking process. The cooking of each lot must be documented in the appropriate manner. Records are to include at least the following information:

- date and time;
- name of product;
- batch number (if more than one batch);
- quantity of product;
- cooking device (if more than one device);
- minimum internal temperature sought;
- minimum internal temperature achieved;
- initials of the responsible employees; and
- other critical factors cited for the process (e.g., relative humidity, minimum/maximum size of pieces, weight of product, minimum time at internal temperature, etc.).

The operator shall keep all processing control records for at least one year after the expiry (best before) date on the label or container.

4.3.3 Requirements for heat treated non ready-to-eat (NRTE) meat products

These meat products have been heated to improve their appearance or flavor but not to make them RTE. The actual amount of cooking may vary from minimal to extensive. In all cases, the products need to be cooked prior to consumption.

Unlike cooked RTE meat products, the operator is not required to verify at the time of manufacture that NRTE products have been subjected to a minimum amount of thermal lethality.

However, labelling of the product must comply with Section 94(6.1) of the MIR which stipulates:

> "If any meat product is not a ready-to-eat meat product but has the appearance of or could be mistaken for a ready-to-eat meat product, the meat product shall bear the following information on its label:
> - the words "must be cooked", "raw product", "uncooked" or any equivalent words or word as part of the common name of the product to indicate that the product requires cooking before consumption; and

- comprehensive cooking instructions such as an internal temperature-time relationship that, if followed, will result in a ready-to-eat meat product."

In order to meet these requirements, the operator must conspicuously label the meat product to prevent it from being mistaken for a cooked RTE product and provide clear preparation instructions that when followed by the consumer will fully cook the product (i.e. provide enough thermal lethality instructions to achieve a 6.5D or 7.0D reduction in *Salmonella* spp.).

The text will be the same size as the rest of the common name. Article B.01.006 of the *Food and Drug Regulations* requires that the common name of the food be shown on the **principal display panel**, therefore if re-packaged, heated NRTE meat products will have to display the appropriate NRTE qualifiers.

The manufacturer of the meat product must provide clear preparation instructions on the label to ensure that the consumer will adequately prepare the product to make it RTE. The cooking instructions will be such that when followed, the product is provided with the following thermal lethality by the end user:

- If the meat product contains no poultry: at least a 6.5 $\log_{10}$ (6.5D) reduction in *Salmonella* spp.
- If the meat products contains poultry: at least a 7.0 $\log_{10}$ (7.0D) reduction in *Salmonella* spp.

The manufacturer is responsible for validating the preparation instructions[1] i.e.:

- ensuring that they will yield the appropriate D reduction in *Salmonella* spp.; and
- ensuring that the instructions are representative of the cooking devices available to the consumer.

Note[1]: The minimum amount of thermal lethality must be received in a single dose, it is not acceptable to use a dose cumulative approach, i.e. add the amount of lethality provided at the manufacturing facility to the amount which will be added by end-user preparation as per instructions.

4.3.4 Other considerations for production of cooked or partially cooked meat.

Establishments should physically separate completely the handling of cooked, partially cooked and raw products to prevent recontamination.

Handling of cooked foods (e.g. slicing, portioning and combining components) is done by trained staff in such a way as to minimize product contamination. Processes should be supervised by technically competent personnel and any process deviation be brought to the attention of the Inspector in Charge at the time of occurrence.

Chilling begins immediately after the cooking cycle is completed and according to section 4.4 of this chapter.

Monitoring environmental and on-line samples for *Listeria* spp. / *Listeria monocytogenes* is recommended.

4.3.5 Cooking of specific perishable meats

Beef heated to an internal temperature of less than 60ºC retains a bright red internal colour (rare beef); that heated to an internal temperature of 60ºC - 70ºC develops a pink internal colour (medium cooked beef); and that heated to an internal temperature of 70ºC - 80ºC develops a grayish-brown colour throughout (well done beef).

Temperature in the range of 40ºC - 60ºC, especially of short duration, will not eliminate even relatively heat-sensitive vegetative bacteria. Thus, many microbes will survive including salmonellae, *C. jejuni/coli*, pathogenic strains of *E. coli*, *Yersina enterocolitica*, and parasites.

Industrially produced cooked meats and meat products include pre-cooked roast beef and corned beef, hot and cold meat pies (including pasties and sausage rolls) and prepared meat based RTE products and meals and meals components (including sous-vide).

In order to protect the consumer, specific heat treatments may be required. It is the operator's responsibility to ensure that the minimum internal temperature of the cooked meat product meets regulatory requirements to ensure pathogen reduction/destruction.

4.3.5.1 Definitions

- Roast beef or roasted beef shall be beef prepared in a manner which allows juices to drain away during the application of dry heat or steam.
- Moist cooked beef or cooked corned beef shall be beef prepared in a manner in which the draining away of juices is prevented during the application of heat.
- The term "cooked beef" may be used to describe beef which is cooked in any manner.
- In this context "dry heat" is defined as heat transferred from the source to the product via the medium of air as opposed to a liquid.

4.3.5.2 Procedures

In registered establishments, pre-cooked beef shall be prepared according to a process that achieves pathogen lethality and validated by a processing authority. The process must be done at all time in compliance with the validated conditions of production.

Uniformity of processing is controlled by restricting the variation in size and weight of individual pieces of raw product to not more than 1 kg, and not more than 5 cm in diameter.

4.3.6 Cooking of perishable cured meats

Cooked perishable cured meats contain not less than 100 ppm of nitrite or nitrate before heating, are fully cooked and require refrigerated storage. Some cured meats may be cooked in the container in which they are marketed, or they may be repacked after cooking. They include such products as pâté, pressed ham and emulsion-style sausages (frankfurters). They are distributed chilled and may, or may not, be heated before consumption.

Microorganisms may be distributed throughout the meat during cure injection, reforming or preparation of the emulsion. The heating process of cured meats should be sufficient to destroy vegetative forms of pathogens. Heating to 72ºC or maintaining temperatures above 60ºC for an adequate period of time generally achieves this purpose. Products which are mildly heated (e.g. bacon heated at 55ºC) may contain surviving pathogens.

Excessive contamination during preparation, or growth before cooking due to abuse temperature of the product, may result in increased numbers of heat-resistant vegetative bacteria and some may survive heat treatment. In order to minimize this, the products must be cooled according to the requirements set out in this chapter after cooking. Products of this category must also be stored and distributed under refrigeration (< 4ºC) to limit spoilage and prevent the growth of mesophilic pathogens.

To prevent growth of heat shocked pathogen spores (e.g.: *Clostridium perfringens*), cooked perishable meats (cured and uncured) shall be cooled according to section 4.4.

4.4 COOLING OF HEAT PROCESSED MEAT PRODUCTS

This section is intended to provide generic requirements for the cooling of heat processed meat products. The application of these generic requirements will contribute to the microbiological safety of meat products.

The processor is responsible for ensuring that all heat processed meat and poultry products are handled and chilled so the product is maintained in a wholesome and unadulterated state. A cooling schedule shall be developed and filed for every type of heat processed product. The chilling process shall be monitored to demonstrate that each lot complies with the validated established cooling schedules. Those records showing adherence to the schedule (product time/temperature) should be maintained on file for a period of at least 12 months beyond the shelf life (best before) of the product and made available to the inspector on request.

The actual section covers all heat processed meat and poultry products except:

- shelf stable products such as dried, semi-dried products or fully retorted (commercially sterilized) products; for the cooling of fully retorted products, please refer to Chapter 15 of the Meat Hygiene Manual of Procedures;
- cooked products shipped hot and labelled with a statement indicating that the product must either be maintained at no less than 60ºC up to its consumption or be discarded; and
- edible rendered products.

4.4.1 Cooling of heat processed meat products

Cooling must be continuous and begins immediately after the heating cycle is completed.

Most common food-poisoning bacteria can grow from 0ºC up to 54ºC; however, their range of rapid growth is from 27ºC to 54ºC. Thus, it is very important to cool product effectively but it is even more important to cool it quickly through this rapid growth range to prevent the outgrowth of heat shocked pathogen spores including the *Clostridium* species.

Processors must use one the following **cooling schedules**, appropriate to the product type, to cool all heat processed products in order to minimize growth of pathogenic bacteria in/on their products.

4.4.1.1 Slow cooling for specific heat processed products: cured / nitrites added / salted / reduced water activity

These generic requirements for slow cooling are applicable for a meat product that is formulated:

- with a water activity (a_w) of above 0.92, no less than 120 ppm of sodium nitrite (or its equivalent in KNO_2) **and** a salt concentration* of 3.5% in the finished product or more; **OR**
- with a water activity (a_w) above 0.92, no less than 40 ppm of sodium nitrite (or its equivalent in KNO_2) **and** a salt concentration* of 6% or more in the finished product; **OR**
- with a water activity (a_w) that is less than or equal to 0.92 at the beginning of the cooling process, with or without nitrite (such as dried products); **OR**

- with a water activity (a_w) of above 0.92, no less than 180 ppm of sodium nitrite (or its equivalent in KNO_2) **and** a salt concentration* of 2.3% in the finished product or more.

* Note:

$$\text{Brine concentration in the finished product} = \frac{\%\ \text{salt}}{\%\ \text{salt} + \%\ \text{moisture in end product}} \times 100$$

Example: If 2.8% of salt in the formulation and the end product has a moisture level of 72%, the brine concentration is:

$$\frac{(2.8/100)}{(2.8/100) + (72/100)} \times 100 = \frac{0.028}{(0.028 + 0.72)} \times 100 = \frac{2.8}{0.748} = 3.74\%$$

Requirement for slow cooling:

Please note that condition 1 and one of the two options in condition 2 must be met:

Condition 1.

The internal temperature does not remain between 49ºC and 4ºC for more than 20 hours; **AND**

Condition 2.

The cooling process:

- causes a continuous drop in product's temperature; **OR**
- controls the product's surface temperature so that it does not stay between 49ºC and 20ºC for more than 2 hours.

4.4.1.2 Rapid cooling rate:

To cool their products rapidly and continuously, processors shall use the following criteria:

During cooling, product's **maximum internal temperature** shall not remain between 54ºC and 27ºC for more than 2.0 hours nor from 54ºC to 4ºC for more than 7 hours.

As an option, products consisting of a piece of intact (excluding tenderized) muscle such as roast beef, moist cooked beef, turkey breast or pork loin, may be cooled to 4ºC within 7.5 hours from the initiation of the cooling process while taking no more than two hours for the 50ºC to 20ºC temperature zone.

4.4.1.3 Interrupted cooling rate:

The following applies to cooked product kept at intermediate temperatures. Cooked products that are cooled from 54ºC to 18ºC within 2 hours may be held for **up to 4 hours** if they are:

- kept below 18ºC during the 4 hours, **AND**
- protected from post cooking contamination (e.g., covered, wrapped, etc.), **AND**
- cooled to 4ºC within 2 hours **immediately** at the end of the 4 hour holding period.

4.4.2 Deviation from the approved cooling process

Any deviation from the approved process must be assessed by the operator/competent authority to validate its safety. If the product is deemed acceptable, there must be scientific evidence to support this decision.

Computer modeling may be used to evaluate the safety of the product. As any other results obtained by using modeling in predictive microbiology, the log increase is useful but it has to be treated with caution.

The level of estimated increase of *Clostridium perfringens* concentration (log increase) will depend on the quality of data obtained by an evaluator and input into the program. It is obvious that inadequate or poor quality data would give a misleading or unrealistic estimation. Another factor is that the initial concentration of heat resistant spores in raw ingredients is usually not known. The need to adhere to a very strict cooling guideline is a good incentive for the industry to monitor the raw products for *Clostridium perfringens* before processing. Characterization of heat resistance of spores recovered from raw products would further facilitate the assessment of the cooling process parameters. The "safe" increase in the concentration of viable cells of *Clostridium perfringens* during cooling depends on the concentration of heat resistant spores in the product. Further, as it is always the case when the predictive microbiology is used the values are estimated using the growth characteristics in the model matrix system; the behaviour in the actual food matrix could differ.

Review of the cooking process and product formulation must also be done. End product sampling for *Clostridium perfringens* (viable cells) can be done as an additional safety measure but is not sufficient on its own.

4.4.3 Alternate cooling process

Any alternate cooling process must be submitted by the Operator to the Responsible inspector who will consult with the Area Program Specialist. The protocol will then be evaluated by the national processing specialist in collaboration with the food safety group. The proposal must be supported by scientific data to validate the submission. Microbial testing alone is not sufficient for this purpose. This documentation package should include, but not be limited to, a recommendation from a process authority demonstrating that the alternate cooling process is as effective as the current performance standards.

Operators should be advised that the time required to review and accept an alternate cooling process will depend on the quality of the submission and could be lengthy. **The alternate cooling process cannot be used prior to having been accepted by the National Specialist, Meat Processing, Ottawa.**

4.4.4 Product storage temperatures of heat processed meat products

4.4.4.1 Cold product temperatures

Heat processed meat products, including cooked or partially cooked products, that require refrigeration, must be kept at 4ºC or less. Refrigerated meat products *which have been previously heat processed* must not be packaged until chilled to 4ºC unless it can be demonstrated, through a process validation, that packaging does not interfere with the cooling schedule or the product safety.

4.4.4.2 Hot product temperatures

If kept hot, cooked meat products should always be kept at 60ºC or above. Product temperature is to be taken and recorded on a regular or continuous basis during storage to monitor compliance with these guidelines.

4.5 EDIBLE RENDERING

Edible rendering is the heat treatment of edible animal tissues to extract fats and oils. The standards for lard, shortening and tallow are listed in Schedule I of the *Meat Inspection Regulations, 1990*. When carried out in enclosed equipment, it is difficult to visually monitor operations. Incoming material should be monitored for prohibited product, e.g., species, kidneys or improperly trimmed material (e.g., pork heads), and the operator must maintain sufficient records to demonstrate compliance of the final product to Schedule I of the MIR.

Adequate venting and proper air flow must be maintained to prevent contamination or the intrusion of odours into other areas of the establishment.

4.6 CANNING

Canned food means commercially sterile low-acid or acidified low-acid food packed in hermetically sealed containers. This includes the use of cans, glass jars, retortable pouches or other containers. For production specifications please consult Chapter 15 of the MOP.

Further information and visual inspection protocol can be found at the following site:

http://www.inspection.gc.ca/english/fssa/meavia/man/ch10/annexp-5e.shtml

4.7 AGING AND TENDERIZING

Aging of beef has traditionally been used to increase tenderness and flavour and involves holding a carcass for 7-14 days under refrigeration. Where carcasses are aged in this manner, attention must be paid to temperature and humidity, to avoid the development of mould.

To speed up the tenderization process, other methods have been developed and these include:

- treatment with enzymes (enzymes that are approved for use in Canada as defined in the *Food and Drug Regulations* - Division 16, Table 5);
- electrical stimulation;
- holding muscles in traction during *rigor mortis*;
- use of fibre breakers or delicatizers (needles, blades);
- manufacture of flaked-formed meats; and
- curing.

Wherever management wishes to introduce an alternative process or new technologies to achieve tenderness, the inspector should verify that it has been approved by the CFIA for use in a registered establishment.

4.8 DRYING TREATMENTS

4.8.1 Dehydration

This is accomplished by drying-in air, the application of heat or by freeze-drying (lyophilization). This form of preservation depends on a lowering of the water activity (a_w) of the product to inhibit the growth microorganisms. The lowering of the water activity may also be accomplished by the addition of sugars or salt (NaCl). It must be remembered that a reduction in water activity neither destroys microorganisms nor toxins; it only retards the growth of microorganisms.

When the a_w of product is a critical limit set out in the manufacturing process for a meat product, accurate measurement devices shall be employed. It is most important that the manufacturer's instructions for use, maintenance and calibration of the instrument as well as recommended sample preparation and testing be followed. If a dehydrated product that is not cooked is sold as shelf-stable (i.e., there is no "keep refrigerated" statement), it has to meet the same applicable controls as shelf-stable fermented meat products (see section 4.11.4.7).

Additional control points include, as applicable:

- meat quality (microbial load);
- microbial specification for ingredients/regular testing;
- process deviation/corrective action plan; and
- trichinosis control.

As dried beef products may pose a hazard associated with *E. coli* O157:H7, these products must be submitted to a heat treatment before the drying process.

See section 4.8.4 for details.

4.8.1.1 Facility and equipment requirements

The following controls shall be in place during the processing:

- The temperature in the drying chamber/room shall be uniform and controlled to prevent any fluctuation that could impact on the safety of the final product.
- The drying chamber/room shall be equipped with a shatter resistant indicating thermometer (or equivalent), with graduations of 1ºC or less. All thermometers shall be located such that they can be easily read.
- Indicating thermometers shall be checked for accuracy against a standard thermometer (validated) at least annually and records shall be kept.
- Drying and aging rooms shall be equipped with humidity recorders in order to prevent uncontrolled fluctuations of the relative humidity. The only alternative to an automatic humidity recorder in these rooms would be for the company to manually monitor and record ambient humidity twice a day (morning and afternoon) every day with a properly calibrated portable humidity recorder.
- a_w measurement.
- The recording thermometer shall be adjusted to agree with the indicating thermometer.
- The recording charts shall contain the following information:
  - date and time started - date and time concluded;
  - identification of recorder (if more than one used);
  - batch number;
  - processing time;
  - reading of the temperature of the indicating thermometer and the relative humidity at a specific time within the processing period;
  - name of product and batch size;
  - record of unusual occurrences (process deviation); and
  - signature or "initials" of operator or responsible person designated by him.

4.8.2 (Reserved)

4.8.3 Salted and dried products

Products used for the production of RTE meat products that do not receive a thermal lethality to control pathogens (e.g. prosciutto hams) must use processes validated to ensure food safety. The initial microbial load should be as low as possible and therefore the incoming product should be assessed for microbiological quality.

4.8.4 Cooked and dried products

Escherichia coli O157:H7 is a hazard deemed reasonably likely to occur in beef products. If a dehydrated product is made with beef, e.g. beef jerky, the manufacturing process must include a kill step for
E. coli O157:H7 prior to dehydration. The following methods have been found acceptable for this purpose:

- cooking the product so it reaches an internal temperature of 71° C for 15 seconds before starting the drying process;
- use of a process validated as achieving a 5D reduction in *E. coli* O157:H7. Refer to section 4.11.4.6 for recognized processing parameters; and
- an alternative challenge study of a design acceptable to the CFIA and Health Canada achieving a 5D reduction in *E. coli* O157:H7 can be used.

4.9 FORMULATION, CURING, SALTING AND PICKLING

Unless otherwise validated through the operator's HACCP system:

- Where spices and other condiments are prepared, mixed or measured into units, a separate room, meeting all structural and sanitary requirements, shall be provided.
- Curing rooms shall be equipped with refrigeration facilities capable of maintaining a temperature of 6ºC or less.

4.9.1 Formulation of meat products

The formulation of all prepared meat products shall be controlled as part of the operators HACCP system.

The *Food and Drug Regulations* (Divisions 14 and 22) and the *Meat Inspection Regulations, 1990* (Schedule I) prescribe the standards for meat products manufactured in Canada. Operators and inspectors must ensure that all ingredients and processes are permitted under the appropriate standard. Furthermore, all food additives including curing aids used in meat product formulations must be listed in the Tables of Division 16 of the *Food and Drug Regulations* and used according to the provisions in those tables.

*Note: The *Food and Drug Regulations* have separate Divisions for meat and for poultry products. The *Meat Inspection Regulations, 1990* include all species of food animals in references to meat products.

Refer to Annex C of this chapter for information on the use of phosphates and nitrites in meat products.

4.9.2 Curing

Cured (MIR):
Means, in respect of an edible meat product, that salt together with at least 100 ppm of sodium nitrite, potassium nitrite, sodium nitrate or potassium nitrate or any combination thereof, was added to the meat product during its preparation.

Nitrite or nitrate salts or both, in combination with salt (NaCl) and other curing aids are added to meat products to improve colour, texture and flavour and to prevent or delay undesirable microbial growth and toxin production.

Cured meat are made from intact muscles and cuts of meat (e.g. ham, bacon), from pieces of meat that have been massaged and tumbled and then formed in casings or moulds (e.g. pressed shoulders), or from fully comminuted meats that extruded into casings or moulds (e.g. emulsion-style sausages, pâtés). The cure is added to the meat

by injection of brine, soaking in brine, or blending during emulsion preparation. Most cured meat products are subsequently heated, i.e. cooked and/or smoked (wieners, loaves, bologna, bacon, etc.). Please refer to cooking specifications.

With the exception of shelf stable meat products such as commercially sterile meat products in hermetically sealed containers, fermented, acidified and dried meat products, cured meat products rely on refrigeration for preservation.

It is advisable to conduct microbiological testing of meat products of unknown quality prior to subjecting them to a curing process which does not involve heating.

Additional explanation on nitrate/nitrite and phosphate calculations for formulated products is provided in Annex C of this chapter.

4.9.3 Salting

This is the preservation of meat products by the addition of ingredients and additives that reduce the water activity (a_w). Meat products packed in salt or saturated salt solution are considered shelf stable. A saturated salt solution has a salt content of 26.4% and a Salinometer reading of 100.

4.9.4 Pickling

Pickling, the addition an acidulant, lowers the pH value of the meat product. Products such as pickled sausages must be kept under refrigeration until it can be determined that the centre of the sausage has achieved a shelf stable parameter for pH. Pickled products are preserved products and must comply with section B 14.031 of the *Food and Drug Regulations*.

4.9.5 Meat particles injection in solid meat cuts

The incorporation of ground meat or poultry pieces with intact muscle cuts is accomplished by either mixing or tumbling the ground meat with the larger pieces. The cure or brine can be added to the tumbler mixer and be incorporated into the product by the physical action of tumbling. Another method that is currently used is the incorporation of the cure or brine by injecting the solution into large meat pieces then by mixing the ground meat with the injected meat. To improve the appearance of the finished product some tumbler mixers have been modified by adding blades or spikes in the tumblers so that during the tumbling action, the ground meat and cure is pushed into the solid meat cuts. This process accelerates the cure process and enhances the appearance of the finished product.

A third process can be used. That process consists in emulsifying trimmings or ground pork, beef or poultry, and injecting this meat particle suspension into solid muscle cuts along with the brine and then placing these meat pieces into a mixer or tumbler.

1. The ground or emulsified trimmings originate from like cuts of meat (e.g., emulsified round trimmings used in a "Boneless roast beef round" or emulsified turkey breast meat trimmings injected into "Boneless roasted turkey breast", etc.). The exact source and quantities of ground meat must be indicated in the product formulation on label submittals.

2. That the amount of ground or emulsified trimmings may be injected in a quantity up to 15% of the fresh (green) weight at the time of formulation (e.g. 170 kg of intact muscle and 30 kg of trimmings) without having to be declared on the label. Products containing more than 15% of ground or emulsified trimmings **must be labelled** to indicate the presence of ground trimmings into the whole muscle piece of meat. (See Chapter 7 for labelling information).

3. This emulsified suspension cannot be stored overnight i.e. must be used during the same production day unless the safety of the stored emulsion is validated.

4.10 SMOKING

This is achieved by the use of smoke generated from hardwood, hardwood sawdust, or vaporized liquid smoke derived from the aforementioned sources.

Smoking is used mainly for flavouring and development of surface colouring in meat products. Smoking also has a bacteriostatic effect. Smoking can be used with heat to achieve a cooking effect or as a cold smoke. Cold smoke temperatures are generally less than 30°C. Products that are cold smoked and have the appearance of being RTE must be labelled as per section 94(6.1) of the MIR.

Smoke racks (trees) and the interiors of smokehouses must be adequately cleaned to prevent the contamination of meat products with soot. If wood chips or sawdust are used for smoke generation, their storage and use must not pose a sanitary hazard. Smokehouses must be adequately vented.

When smoking of pork products is used with heat to destroy *Trichinella*, the temperatures maintained must be carefully monitored. Recording thermometers must be present and properly functioning. The accuracy of these must be checked periodically against a mercury thermometer. The Operator shall ensure the heat process is sufficient to destroy trichinae.

4.11 FERMENTED MEAT PRODUCTS

4.11.1 Introduction

pH:
pH is the negative logarithm of the hydrogen ion or proton concentration. The pH measures acidity or alkalinity on a scale of 0 to 14 with 7 as the neutral point. The lower the pH the higher the acidity.

a_w:
The water activity (a_w) of a food is the ratio of the water vapour pressure of the food to that of pure water at the same temperature. It is measured at a scale of 0.00 to 1.00 with 0.00 indicating total dryness and 1.00 pure water.

Preservation of meat products by fermentation has been used for hundreds of years. Like other processes used in the preparation of ready-to-eat meat products, the manufacturing process for fermented meat products achieves a reduction of micro-organisms of concern to human health by creating an environment unsuitable for their survival. Fermentation also imparts a particular flavour to meat products.

The manufacture of fermented meat products relies on good control over a complex and precise combination of time, temperature, nitrites, salt concentration, pH and a_w factors to ensure food safety.

4.11.1.1 Requirements for shelf stable fermented meat products:

Many different types of manufacturing processes exist for making fermented meat products. Not all of these processes allow the finished product to be stored at ambient temperature.

In order to be considered "shelf-stable" and not require refrigeration, a fermented meat product must meet one of the following sets of specific requirements. Fermented products which do not meet these requirements must be labeled with a refrigeration statement.

- The pH of the finished product is of 4.6 or less, regardless to its final a_w.
- The a_w of the finished product is 0.85 or less, regardless of its final pH.
- The pH is 5.3 or lower at the end of the fermentation period and the end product has an a_w of 0.90 or lower.

For *all* fermented meat products:
To minimize the danger of outgrowth of *Clostridium botulinum* spores and development of the botulinal toxin in fermented product, nitrite/nitrate shall be added at a minimum level of 100 ppm *along with a minimum of 2.5% of salt*. The level of nitrate-nitrite should not interfere with the process of fermentation.

Note: For any fermented products, degree-hours requirements must be met (refer to sub-section 4.11.4.5)

4.11.1.2 Food borne pathogens of special concern

All food borne pathogens which have been linked to the consumption of a ready-to-eat meat product can affect fermented meat product. However, a number of organisms are considered to be of particular importance and establishments which manufacture dry or semi-dry fermented meat products **must** have corresponding controls in place to address each of these hazards. In addition, when a_w or pH is a critical factor in the manufacture of product, each production lot must be tested for these factors (refer to section 4.11.4.7).

Organism	Refer to
Trichinella spiralis	Part 4.11.4.4 of this section
Enterotoxic *Staphylococcus aureus*	Part 4.11.4.5 of this section
Verotoxinogenic *E. coli* (e.g., *E. coli* O157:H7) and *Salmonella* in fermented sausages	Part 4.11.4.6 of this section

To be assessed as complete, an operator's HACCP plan for the manufacture of dry or semi-dry fermented meat products must have Critical Control Points in place which address these specific organisms in accordance to the requirements set out in this section. Other food borne pathogens and hazards such as *Salmonella* and *Listeria monocytogenes* must also be analyzed and addressed in an appropriate manner. Facility and equipment requirements for the manufacture of fermented meat products are outlined in section 4.11.3 must also be met.

Operators of registered establishments who wish to market a meat product without a refrigeration declaration and which does not meet the "shelf stable" criteria set out above, must submit a request for the acceptance of their proposal to the responsible inspector. The submission must be accompanied by detailed recipe, formulation and processing information for the product. Submissions will be sent to the Area Program Specialist - Meat Processing for review with Food Safety Micro specialist and Health Canada. A formal letter of response will be returned to the operator.

4.11.2 Manufacture of dry and semi-dry fermented sausages

Dry or semi-dry fermented sausages are prepared by mixing ground meat with various combinations of spices, flavourings, salt, sugar, additives and bacterial cultures. The mixtures, in bulk or after stuffing, are allowed to ferment at different temperatures for varying periods of time. Following fermentation, the product may be smoked and/or dried under controlled conditions of temperature and relative humidity.

4.11.2.1 Types of sausages made with a fermentation process

There are many ways to classify or define the various types of sausages which are manufactured using a fermentation process. We have retained the following definitions:

- **Dry Sausages:** Dry sausages are made with chopped or ground meat products that, as a result of bacterial action, or chemical acidification, reach a pH of 5.3 or less at the end of the fermentation period. Subsequently they are dried in a drying room to reduce their a_w to 0.90 or less.

- **Semi-Dry Sausages:** Semi-dry sausages are made with chopped or ground meat products that, as a result of bacterial action, or chemical acidification, reach a pH of 5.3 or lower. Their a_w is reduced during the process but only to values above 0.90. This means they have to be kept refrigerated. In general, the semi-dry sausages are not subsequently dried in a drying room but are packaged soon after the fermentation/heating process is completed. They are generally smoked during the fermentation cycle.

4.11.2.2 Importance of ingredients and raw materials

Because of the complex nature of the fermentation process, it is critical that ingredients be especially well controlled and that the microbiological load of the meat used be as low as possible. The use of mechanically separated meat or finely textured meat in the manufacturing of fermented meat products is strongly discouraged for this reason.

4.11.2.3 Fermentation and chemical acidification

4.11.2.3.1 Fermentation

- The fermentation process involves the growth of lactic acid bacteria in order to acidify the product. Providing raw materials are of excellent microbiological quality, during fermentation the combined effect of curing salts, curing aids and temperature encourages the gradual replacement of the contaminating flora including pathogens (such as *Salmonella, Campylobacter* and *Staphylococcus*) by *lactobacilli*, *pediococci* and *micrococci*.

- While it was once necessary to rely on environmental conditions for natural fermentation to occur, or to inoculate new batches with a portion of raw mixture from a previous batch (commonly referred to as "back slopping"), these methods were not always successful and represented significant risks. Commercial starter cultures are most often used today as they offer a degree of consistency and safety not found in other methods.

- Contamination by pathogenic organisms at the outset of the process may have a critical effect on finished product. Bacterial competition, pH and a_w values are important factors in the control of the development or die-off of pathogenic organisms.

- *Lactobacilli* and *pediococci* are primarily responsible for converting sugars into lactic acid thereby lowering the pH of the meat product. Where nitrate salts are used for curing in slow cured sausages, *micrococci* present convert nitrate salts to nitrite salts.

- *Lactobacilli* with or without *micrococci* are components of starter cultures available for use in slow fermentation (25°C) whereas *pediococci* with or without *micrococci* are used in starter cultures for rapid fermentation at higher temperatures (25°C to 37°C). *Pediococci* do not occur in fresh meat products in numbers large enough to be a significant factor in traditional slow fermentation and therefore are only important in meat product fermentation if they are added in starter cultures.

- When fermented cured sausages are subjected to an extended drying period, *lactobacilli* act to significantly reduce the number of undesirable microorganisms including pathogens.

- The predominant type of fermenting organism combined with the formulation and process schedule will give a product its characteristic flavour.

4.11.2.3.2 Chemical Acidification

Chemical acidification may be used to help lowering the pH. Citric acid or glucono-delta-lactone are commonly used for this purpose.

4.11.2.4 Drying

Most fermented products are also subject to a drying process which reduces the amount of available water (a_w) and thus further limits the survival or growth of pathogenic bacteria and spoilage organisms. This drying takes place during the fermentation process itself or as a separate activity after fermentation has been completed. Heat can also be used during drying.

The physical characteristics of the meat and fat particles (such as particle size, product temperature, etc.) are important in achieving a reduced a_w. The meat particles must be of such size that would efficiently allow release of moisture and the cut edges must be without fat smearing. Sharp and efficient grinding or chopping equipment and mixers are necessary.

4.11.2.4.1 Water activity (a_w) measurement:

The growth and metabolism of microorganisms demands the presence of water in available form. The most useful measurement of the availability of water in meat products is water activity (a_w). The a_w may be reduced by adding solutes (salt, sugar) or removing moisture.

Approximate minimum levels of a_w (if considered alone) for the **growth** of:

molds:	0.61 to 0.96	
yeasts:	0.62 to 0.90	
bacteria:	0.86 to 0.97	
	Clostridium botulinum:	0.95 to 0.97
	Clostridium perfringens:	0.95
	Enterobacteriaceae:	0.94 to 0.97
	Pseudomonas fluorescens:	0.97
	Salmonella:	0.92 - 0.95
	Staphylococcus aureus:	0.86
parasites:	*Trichinella spiralis* will survive at an a_w of 0.93 but is destroyed at an a_w of 0.85 or less.	

The above levels are based on the absence of other inhibitory effects such as nitrite, competitive growth, sub-optimum temperatures, etc., which may be present in meat products. In normal conditions, enterotoxin formation by *Staphylococcus aureus* has not been observed at a_w below 0.92.

4.11.3 Facility and equipment requirements

The following controls shall be in place during the processing:

- Temperature in the fermentation, drying and smoking chambers shall be uniform and controlled to prevent any fluctuation that could impact on the safety of the final product.

- Fermentation, drying and smoking chambers shall be equipped with a shatter resistant indicating thermometer, (or equivalent), with graduations of 1ºC or less. If mercury thermometers are used, their mercury columns shall be free from separations. All thermometers shall be located such that they can be easily read.
- Indicating thermometers shall be checked for accuracy against a standard thermometer (validated) at least annually and records shall be kept.
- Fermentation and smoking chambers shall be equipped with a recording thermometer for determining degree-hours calculations in a reliable manner. Recording thermometers are also preferable in drying and aging rooms but, in these rooms, it may be sufficient to read and record the temperatures 2 times a day.
- Drying and aging rooms shall be equipped with humidity recorders in order to prevent uncontrolled fluctuations of the relative humidity. The only alternative to an automatic humidity recorder in these rooms would be for the company to manually monitor and record ambient humidity twice a day (morning and afternoon) every day with a properly calibrated portable humidity recorder.
- The recording thermometer shall be adjusted to agree with the indicating thermometer.
- The recording charts shall contain the following information:
  – date and time started - date and time concluded;
  – identification of recorder (if more than one used);
  – batch number;
  – processing time;
  – reading of the temperature of the indicating thermometer and the relative humidity at a specific time within the processing period; and
  – name of product and batch size.
- Record of unusual occurrences (process deviation)
- Signature or initials of operator or responsible person designated by him

4.11.3.1 pH measurement devices

For routine monitoring, accurate measurement electronic pH meters (± 0.05 units) should be employed. It is most important that the manufacturer's instructions for use, maintenance and calibration of the instrument as well as recommended sample preparation and testing be followed.

4.11.3.2 a_w measurement devices

When the a_w of a product is a critical limit set out in the HACCP plan for a meat product, accurate measurement devices shall be employed. It is most important that the manufacturer's instructions for use, maintenance and calibration of the instrument be followed.

4.11.4 Operator controls on ingredients and the manufacturing process

4.11.4.1 Ingredients and raw materials

The operator must have physical and microbiological specifications for **ALL** ingredients that may represent a hazard when used in the preparation of a fermented meat product. To ensure that the initial bacterial load is acceptable, microbiological specifications will be maintained for meat, starter culture and, where back slopping is used, the raw batter used for new batches. Records of microbiological tests performed to ensure compliance to determine specifications shall be available to the inspector on request.

4.11.4.2 Inoculum used to begin the fermentation process

- If **commercial starter cultures** are used, they shall have been listed in Annex G of this chapter. There must be microbiological specifications for the cultures.

Commercial cultures shall be stored according to the culture manufacturer's directions.

In order for a new commercial starter culture to be added to the list, details of commercial starter cultures for use in registered establishments must be submitted for review by the CFIA.

- "**Back Slopping**" is the process of using inoculum from a previous batch to initiate the fermentation process of a new batch. Because of the risk of transmitting pathogens from the inoculum to the new batch, strict controls are required when using this technique.

  Inoculum used for back slopping shall be carefully handled and stored to avoid any contamination. The storage temperature for that inoculum shall be maintained at 4°C or less and a pH of 5.3 or less. Samples for microbiological analysis shall be taken to ensure that the process is in line with the specifications. The frequency of that sampling is to be adjusted according to compliance to specifications. Each batch of inoculum which will have a pH > 5.3 shall be analysed to detect at least *Staphylococcus aureus*. Only on satisfactory results will this inoculum be allowed to be used for back slopping.

- "**Natural fermentation**" is a process which relies on the fermentation process self-initiating without the help of commercial starter culture or inoculum from a previous batch. Because of the high potential for process failure, this process **is not considered acceptable.**

4.11.4.3 Chemical acidification

If product is chemically acidified by addition of citric acid, gluconodelta-lactone or another chemical agent approved for this purpose, controls shall be in place and records kept to ensure that pH of 5.3 or lower is achieved by the end of the fermentation process.

4.11.4.4 Controls to ensure the destruction of viable *Trichinella spiralis*

Refer to Annex A or Annex B of this chapter.

4.11.4.5 Controls to address hazards related to enterotoxic *Staphylococcus aureus*

Certain strains of the bacteria *Staphylococcus aureus* are capable of producing a highly heat stable toxin that causes illness in humans. Above a critical temperature of 15.6ºC, *Staphylococcus aureus* multiplication and toxin production can take place. Once a pH of 5.3 is reached, *Staphylococcus aureus* multiplication and toxin production are stopped. Processors are required to control this hazard by verifying that their product attains a pH of 5.3 within pre-defined degree-hours limits.

As part of their control, processors shall verify the pH of each lot and record the time that it took from the moment of formulation until the pH of the sausage achieved a pH of 5.3 or less. This normally is done when each batch of product leaves the "green room".

When a process has not met degree-hours limits, the lot shall be dealt with in accordance with sub-section 4.11.4.5.4.

4.11.4.5.1 Degree-hours defined

A process can be judged acceptable as long as the product consistently reaches a pH of 5.3 using:

- fewer than 665 degree-hours when the highest fermentation temperature is less than 33ºC;

- fewer than 555 degree-hours when the highest fermentation temperature is between 33º and 37ºC; and
- fewer than 500 degree-hours when the highest fermentation temperature is greater than 37ºC.

Degree-hours are the product of time as measured in hours at a particular temperature multiplied by the "degrees" measured in excess of 15.6ºC (the critical temperature at which staphylococcal growth effectively begins). Degree-hours are calculated for each temperature used in the process. The limitation of the number of degree-hours indicated in points (1), (2) and (3) above depends upon the highest temperature in the fermentation process prior to the time that a pH of 5.3 or less is attained.

Manufacturers are encouraged to measure temperatures at the surface of the product. Where this is not possible, manufacturers should utilize fermentation room temperatures. The table and examples are based on fermentation room temperatures. Temperature and humidity should be uniform throughout the fermentation room.

4.11.4.5.2 Fermentation done at a constant temperature (constant temperature process)

When fermentation is done at a constant temperature, operators can either use the following table or the calculation method (see examples below) for determining degree-hours limits and maximum time for fermentation at a given room temperature.

Degree-hours limit for the corresponding temperature	Fermentation room temperature (ºC)	Maximum allowed hours to achieve a pH of 5.3 (based on guideline)
665	20	150.0
665	22	103.4
665	24	78.9
665	26	63.8
665	28	53.6
665	30	46.2
665	32	40.5
555	33	31.8
555	34	30.1
555	35	28.6
555	36	27.2
555	37	25.9
500	38	22.3
500	40	20.5
500	42	18.9
500	44	17.6
500	46	16.4
500	48	15.4
500	50	14.5

Examples of how to use the calculation method for constant temperature processes:

Process A:

Fermentation room temperature is a constant 26ºC. It takes 55 hours for the pH to reach 5.3.

Degrees above 15.6°C:	26°C - 15.6°C =	**10.4°C**
Hours to reach pH of 5.3:		**55**
Degree-hours calculation:	(10.4°C) x (55) =	**572** degree-hours

The corresponding degree-hours limit (less than 33ºC) is 665 degree-hours.

Conclusion: Process A **meets** the guideline because its degree-hours are less than the limit.

Process B:

Fermentation Room temperature is a constant 35ºC. It takes 40 hours for the pH to reach 5.3.

Degrees above 15.6°C:	35°C - 15.6°C =	**19.4°C**
Hours to reach pH of 5.3:		**40**
Degree-hours calculation:	(19.4°C) x (40) =	**776** degree-hours

The corresponding degree-hours limit (between 33 and 37ºC) is 555 degree-hours.

Conclusion: Process B **does not meet** the guideline because its degree-hours exceed the limit - hold the product and refer to sub-section 4.11.4.5.4.

4.11.4.5.3 Fermentation done at different temperatures (Variable Temperature Processes)

When the fermentation takes place at various temperatures, each step in the progression is analysed for the number of degree-hours it contributes. The degree-hours limit for the entire fermentation process is based on the highest temperature reached during fermentation.

Process C:

It takes 35 hours for product to reach a pH of 5.3 or less. Fermentation room temperature is 24ºC for the first 10 hours, 30ºC for second 10 hours and 35ºC for the final 15 hours.

Step 1

Degrees above 15.6ºC:	24°C - 15.6°C =	**8.4°C**
Hours to reach pH of 5.3:		**10**
Degree-hours calculation:	(8.4°C) x (10) =	**84** degree-hours

Step 2

Degrees above 15.6ºC:	30°C - 15.6°C =	**14.4°C**
Hours to reach pH of 5.3:		**10**
Degree-hours calculation:	(14.4°C) x (10) =	**114** degree-hours

Step 3

Degrees above 15.6ºC:	35°C - 15.6°C =	**19.4°C**
Hours to reach pH of 5.3:		**15**
Degree-hours calculation:	(19.4°C) x (15) =	**291** degree-hours

Degree-hours calculation for the entire fermentation process = 84 + 144 + 291 = **519**

The highest temperature reached = 35ºC
The corresponding degree-hour limit = 555 (between 33°C and 37ºC)

Conclusion: Process C **meets** the guideline because its degree-hours are less than the limit.

Process D:

It takes 38 hours for product to reach a pH of 5.3 or less. Fermentation room temperature is 24ºC for the first 10 hours, 30ºC for the second 10 hours and 37ºC for the final 18 hours.

Step 1		
Degrees above 15.6ºC:	24°C - 15.6°C =	**8.4°C**
Hours to reach pH of 5.3:		**10**
Degree-hours calculation:	(8.4°C) x (10) =	**84** degree-hours
Step 2		
Degrees above 15.6ºC:	30°C - 15.6°C =	**14.4°C**
Hours to reach pH of 5.3:		**10**
Degree-hours calculation:	(14.4°C) x (10) =	**114** degree-hours
Step 3		
Degrees above 15.6ºC:	37°C - 15.6°C =	**19.4°C**
Hours to reach pH of 5.3:		**18**
Degree-hours calculation:	(19.4°C) x (18) =	**385.2** degree-hours

Degree-hours calculation for the entire fermentation process = 84 + 144 + 385.2 = **613.2**

The highest temperature reached = 37ºC
The corresponding degree-hour limit = 555 (between 33°C and 37°C)

Conclusion: Process D **does not meet the guidelines** because its degree-hours exceed the limit; hold the product and refer to sub-section 4.11.4.5.4.

4.11.4.5.4 Disposition of lots which have not met degree-hours limits:

The Inspector in Charge must be notified of each case where degree-hours limits have been exceeded. Such lots must be held and samples of product submitted for microbiological laboratory examination after the drying period has been completed. Analyses should be done, **at least** for *Staphylococcus aureus* and its enterotoxin, and for principal pathogens such as *E. coli* O157:H7, *Salmonella*, *Listeria monocytogenes*, etc.

- If the bacteriological evaluation proves that there are fewer than 10^4 *Staphylococcus aureus* per gram, that neither enterotoxin nor other pathogens are detected, then the product may be sold provided it is labelled as requiring refrigerated storage.
- In the case of an *Staphylococcus aureus* level higher than 10^4 per gram but there is no enterotoxin present, or if other pathogens are present in very low numbers, the product may be used in the production of compatible cooked product but only if the heating process destroys **all** of the pathogens present.
- In the case where *Staphylococcus aureus* enterotoxin is detected in the product, irrespective of the level of viable *S. aureus* cells, the product shall be destroyed.

4.11.4.6 Controls to address hazards related to verotoxinogenic *E. coli* (e.g. *E. coli* O157:H7) and to *Salmonella* in fermented sausages

Outbreaks of human illness associated with the consumption of fermented sausages which were found to contain verotoxinogenic *E. coli* and *E. coli* O157:H7 have been reported in the United States (1994), Australia (1995) and Canada (1998, 1999).

Following the 1994 US outbreak, work by the United States Department of Agriculture (USDA) and a task force composed of US industry and academia scientifically confirmed that some fermentation processes used by industry were effective (5 D reduction - A unit which expresses the lethality of a process. This is the time required to destroy 90% of the organisms present. Hence, a 5 D reduction would destroy 99.999% of the organisms or

10^5 organisms) against *E. coli* O157:H7 but others were only partially effective (between 2 and 5 D reduction). The task force recommended five possible ways to minimize the risk of *E. coli* O157:H7 in fermented sausages. At the same time, it has been established that Salmonella may also be found in the resulting product.

In order to suitably control these hazards and prevent incidents of food borne disease, registered establishments who manufacture fermented sausages are required to use one of the five following options for the control of verotoxinogenic *E. coli* and *E. coli* O157:H7 when they make this type of product.

To date, outbreaks of *E. col*i O157:H7 reported in association with dry/semi-dry fermented sausages have been linked to beef meat ingredients. The following establishments must therefore use one of the five (5) options outlined in this section when manufacturing a dry or semi-dry fermented meat sausage product:

- establishments which use beef as an ingredient in a dry or semi-dry fermented meat sausage;
- establishments which store or handle uncooked beef on site; AND
- establishments which obtain raw meat from a supplying establishment which stores or handles uncooked beef on site.

Other establishments (for example establishments which only handle pork and who do not obtain meat ingredients from establishments which handle beef) are therefore not currently obliged to use one of the five options for the control of *E. coli* O157:H7 in dry/semi-dry fermented sausages. However, they must validate through a microbiological testing program that their process will not result in the presence of *E. coli* O157:H7 or *Salmonella* in the finished product. They are not required to use the testing protocol outlined under Option 3.

To ensure that all of the requirements corresponding to the selected option are met, and to suitably demonstrate this, operators of registered establishments who fabricate a dry/semi-dry fermented sausage are required to:

- compile a list of all the types of dry and semi-dry fermented sausages made at the establishment or which have a current label registration on file with the CFIA; and
- complete a copy of Annex K "Option used for the control of *E. coli* O157:H7 in dry and semi-dry fermented sausage" for each different product and attach all the required information.

This material will be screened by the Inspector in Charge and forwarded to the area CFIA program specialist for verification.

If an establishment does not follow one of the other available options, they are automatically considered to be using Option 3, end product testing. If an establishment which has to do end product testing as per Option 3 refuses to do the required testing on the finished product, they are creating a situation whereby the CFIA inspector must take action to deal with a potential health hazard. In such a case, the CFIA inspector shall formally detain the affected product, take measures to prevent cross-contamination of other product and inform the establishment that, if they do not provide the necessary test results within 60 days, the affected product will be treated as inedible and condemned.

4.11.4.6.1 Option 1:

Include as part of the manufacture of the sausage, one of the following heat process which is recognized as controlling *E. coli* O157:H7.

Under this option, it is not required to test for *E. coli* O157:H7. Time and temperature controls will be documented in the same manner as is required for other similar cooking processes (refer to section 4.3 of this chapter).

Minimum internal temperature maintained during the entire process		Minimum processing time in minutes after the minimum temperature has been reached
(°F)	(ºC)	
130	54.4	121
131	55	97
132	55.6	77
133	56.1	62
134	56.7	47
135	57.2	37
136	57.8	32
137	58.4	24
138	58.9	19
139	59.5	15
140	60	12
141	60.6	10
142	61.1	8
143	61.7	6
144	62.2	5
145	62.8	4[1]

[1] This table is identical to the roast beef cooking table with one exception: the minimum processing time for a minimum internal product temperature of 145°F/62.8ºC is 4 minutes instead of "instantaneous". This difference is because the sausage product's smaller size results in a much quicker cooling and decreased cumulative lethality.

4.11.4.6.2 Option 2:

Use a manufacturing process (combination of fermentation, heating, holding and/or drying) which has already been scientifically validated to achieve a 5 D reduction of *E. coli* O157:H7.

Manufacturing processes used to make fermented sausages are only considered effective against *E. coli* O157:H7 if it is shown that they achieve a 5D reduction or more of *E. coli* O157:H7. The manufacturing process used must be evaluated in a scientific manner consistent with the challenge study recommendations (refer to Option 5) of this section.

Under this option, it is not required to test each lot for *E. coli* O157:H7 or *Salmonella*. The operator shall nevertheless conduct some degree of testing for these organisms as a verification procedure for their process.

The operator must maintain suitable records to demonstrate that all of the critical control points (CCP) for the process have been met (for example, casing diameter, fermentation room (green room) thermographs, pH at the end of the fermentation step of the process, a_w, etc.)

The following processes have been scientifically validated as achieving a 5D or greater reduction of *E. coli* O157:H7.

Fermentation chamber temperature		pH at the end of fermentation process	Casing diameter	Subsequent process (dry, hold or cook)	Reference
°F	ºC				
70	21	>5.0	< 55 mm	HEAT (1hr @ 110°F and 6hrs @ 125°F)	[1]
90	32	<4.6	< 55 mm	HOLD @ 90°F for > 6 days	[1]
90	32	<4.6	< 55 mm	HEAT (1hr @ 110°F then 6 hrs @ 125°F)	[1]
90	32	<4.6	56 to 105 mm	HEAT (1hr @100°, 1hr @110°F, 1hr @120°F, then 7hrs @ 125°F)	[1]
90	32	>5.0	56 to 105 mm	HEAT (1hr @100°, 1hr @110°F, 1hr @120°F, then 7hrs @ 125°F)	[1]
96	36	<5.0	< 55 mm	HEAT (1hr @128°F internal product temperature) and DRY (at 55°F and 65% Relative Humidity to a Moisture Protein Ration of < 1.6:1)	[2]
110	43	<4.6	< 55 mm	HOLD @ 110°F for > 4 days	[1]
110	43	<4.6	56 to 105 mm	HOLD @ 110°F for > 4 days	[1]
110	43	>5.0	56 to 105 mm	HOLD @ 110°F for > 7 days	[1]

[1] Nicholson, R., et al, *Dry fermented sausage and Eshcerichia coli O157:H7*. National Cattlemen's Beef Association, Research Report Number 11-316, Chicago, Illinois, 1996.

[2] Hinkens, J.C., et al, *Validation of Pepperoni Processes for Control of Escherichia coli O157:H7*, Journal of Food Protection, Volume 59, Number 12, 1996, pp. 1260-1266.

4.11.4.6.3 Option 3:

Where the manufacturing process does not correspond to one of the processes set out under options 2 or 4 of this section and has not been assessed in accordance to option 5 of this section, do **microbiological end-product testing of each production lot and hold the lots pending reception of results**.

- Definition of "lot": The definition of "lot" for purposes of sampling must be statistically sound and must correspond to product manufactured under the same conditions. A lot cannot exceed a single day's production.
- Sampling plan: For each lot, the operator shall take **30** samples of finished product and submit them for analysis. The sample plan must be representative of the lot.
- Sample size: Each sample shall consist of at least **25 g** of product. Samples must be taken in accordance to standard microbiological techniques to avoid contamination of product and sampling of intact product packages is strongly recommended. It is unacceptable to take multiple sample from one intact package as this is not considered statistically representative of the lot.
- Compositing of samples by the laboratory for analysis: It is acceptable to combine a **maximum of three (3) samples** into a composite for purposes of analysis when testing is done for *E. coli* O157:H7 and *Salmonella*.

- Organisms to be tested: At a minimum, each composite sample shall be tested for the presence of *E. coli* O157:H7 and *Salmonella*.
- Laboratory requirements: **CAUTION!** - Since *E. coli* O157:H7 are pathogenic to humans, the tests should be conducted by appropriately trained personnel.
- Method used: The method used to analyse the end product samples shall be one of the methods listed in Health Canada's Compendium of Analytical Methods, Volume 3, Laboratory Procedures for the Microbiological Analysis of Foods (ISBN 0-921317-17-4).
- Reporting of results: Results shall be reported in writing. Results shall be identified to the lot of product being tested and shall include individual results for each test performed, method used, minimum sensitivity of the test used, lot for which these results apply.
- Release of product: Product will be held under the control of the operator until the written results of analysis have been received. In order to be released, all tests must be negative for the presence of *E. coli* O157:H7 and *Salmonella* and any other pathogens tested.
- In case of a positive result for either *E. coli* O157:H7 or *Salmonella* or another pathogen: the entire lot must be held and either submitted to a 5D reduction process or be destroyed. Possible cross-contamination of other lots shall also be assessed.
- Keeping of records: Records of test results shall be kept for a minimum of 24 months beyond the release date of the product.

4.11.4.6.4 Option 4:

Implement a HACCP system at the establishment which includes testing of raw meat and batter, and use a manufacturing process (fermentation and holding, heating and/or drying) which has been scientifically validated as achieving at least 2D reduction of *E. coli* O157:H7.

To be eligible to use this option, the operator must have implemented a HACCP system which is meeting CFIA's FSEP approach. Sampling of raw batter must be done in accordance to the requirements set out in items (a) to (l) of this section.

Manufacturing processes used to make fermented sausages are considered partially effective against *E. coli* O157:H7 if it is shown that they achieve 2D to 5D reduction of *E. coli* O157:H7. The manufacturing process used must be evaluated in a scientific manner consistent with the challenge study recommendations (refer to Option 5, sub-section 4.11.4.6.5). A number of manufacturing processes have been scientifically demonstrated as achieving a 2D to 5D reduction.

(a) Definition of "lot": The definition of "lot" for purposes of sampling must be statistically sound and must correspond to like production practices. Provided that effective controls for tracing product are in place and all corresponding dry fermented sausage manufacturing processes have been validated as achieving at least a 2D reduction of *E. coli* O157:H7, it would be acceptable to conduct one single series of sampling on batter which is used in different sausages. A lot cannot exceed one day's production of raw batter.
(b) Sampling plan: For each lot, the operator shall take 15 samples of raw batter and submit them for analysis. The sample plan must be representative of the lot.
(c) Sample size: Each sample shall consist of at least **25 g** of product. Samples must be taken in accordance to standard microbiological techniques to avoid contamination of product. It is unacceptable to take multiple samples from one site as this is not considered statistically representative of the lot.
(d) Compositing of samples by the laboratory for analysis: It is acceptable to combine a **maximum of three (3) samples** into a composite for purposes of analysis when testing is done for *E. coli* O157:H7 and *Salmonella*.
(e) Organisms to be tested: At a minimum, each composite sample shall be tested for the presence of *E. coli* O157:H7 and *Salmonella*.

(f) Laboratory requirements: **CAUTION!** - Since *E. coli* O157:H7 are pathogenic to humans, the tests should be conducted by appropriately trained personnel.
(g) Method used: The method used to analyse the end product samples shall be one of the methods listed in Health Canada's Compendium of Analytical Methods, Volume 3, Laboratory Procedures for the Microbiological Analysis of Foods (ISBN 0-921317-17-4).
(h) Reporting of results: Results shall be reported in writing. Results shall be identified to the lot of product being tested and shall include individual results for each test performed, method used, minimum sensitivity of the test used, lot for which these results apply.
(i) Release of product: Product will be held under the control of the operator until the written results of analysis have been received. In order to be released, all tests must be negative for the presence of *E. coli* O157:H7 and *Salmonella*.
(j) In case of a positive result for either *E. coli* O157:H7 or *Salmonella*: the entire lot must be held and either submitted to a 5D reduction process or be destroyed.
(k) Keeping of records: Records of test results shall be kept for a minimum of 24 months beyond the release date of the product.
(l) Methods which have been scientifically documented as achieving a minimum 2D reduction in *E. coli* O157:H7.

Fermentation chamber temperature		pH at the end of fermentation	Casing diameter	Subsequent process (dry, hold or cook)	Reference
°F	°C				
70	21	>5.0	56 to 105 mm	EAT (1hr @ 110°F and 6 hours @ 125°F)	[1]
90	32	<4.6	56 to 105 mm	HOLD @ 90°F for 7 days then dry	[1]
90	32	>5.0	56 to 105 mm	HOLD @ 90°F for 7 days then dry	[1]
110	43	>5.0	< 55 mm	HOLD @ 110°F for 7 days then dry	[1]
110	43	>5.0	56 to 105 mm	HEAT (1hr @ 110°F and 6 hours @ 125°F)	[1]

[1] Nicholson, R., et al, *Dry fermented sausage and Eshcerichia coli O157:H7.* National Cattlemen's Beef Association, Research Report Number 11-316, Chicago, Illinois, 1996.

4.11.4.6.5 Option 5:

Use an alternative manufacturing process which is scientifically validated against *E. coli* O157:H7.

(a) Establishments which elect to use this option may choose to demonstrate that:
- their method achieves a 5D reduction of *E. coli* O157:H7, in which case they will be able to manufacture product according to the requirements of Option 2 (e.g., not be required to test each lot of product for *E. coli* O157:H7 and *Salmonella*); or alternatively their method achieves a 2D reduction of *E. coli* O157:H7, in which case they will be able to manufacture product according to the requirements of Option 4 (e.g., HACCP system and testing of raw batter)

(b) The manufacturer shall make a request for the evaluation of the alternative manufacturing process to the Chief, Program development and evaluation, Food Borne Pathogen Unit, Laboratory Services Division. To allow the process to be evaluated, manufacturers shall use the challenge protocol developed by the USDA

for such purposes and which is listed under part (d) below. Because of the complex nature of the protocol, it is strongly recommended that the services of an experienced food technology centre be retained.

(c) Upon completion of a successful evaluation, the operator shall be provided in writing, with a letter stating that the CFIA has evaluated the process for its ability to control *E. coli* O157:H7 and that it does not object to the manufacturer using the process. Until such confirmation is received, the operator will have to manufacture product in accordance to one of the other 4 options outlined in this section.

(d) Challenge protocol for the evaluation of a fermented sausage manufacturing process ability to control *E. coli* O157:H7.

4.11.4.6.6 General Requirements

- *Biosafety requirements*: **CAUTION! - This protocol is a laboratory-based validation procedure that employs cultures that are pathogenic to humans. THE VALIDATION SHOULD NOT BE CONDUCTED WITHIN AN ACTUAL FOOD MANUFACTURING FACILITY.** Work should be conducted in a Biosafety level II facility by appropriately trained personnel. Following use, autoclave all inoculated product and sanitize processing equipment. Follow appropriate procedures for the disposal of waste.

- Types and numbers of strains of *E. coli* O157:H7 to use as an inoculum: at least five (5) strains of *E. coli* O157:H7 should be used including representatives of strains associated with human illness and strains isolated from meat and poultry products. One isolate from an outbreak associated with a dry fermented sausage product must be included.

- Methods of production, enumeration and standardization of inoculum: Individual cultures of each strain should be prepared by inoculating an appropriate growth media, such as Tryptic Soy or Trypticase Soy broth, supplemented with 1% glucose and incubating for 18 to 24 hours at 37ºC to obtain stationary phase cells. The additional glucose is added to ensure that the inoculum is pre-adapted for acid tolerance. Cultures should be grown the day prior to product inoculation with a minimum holding period prior to actual use. Each strain should be centrifuged, washed and resuspended in 0.1% peptone broth. Dilutions of each strain should be made to yield approximately equal numbers of each of the five strains. The five strains should be thoroughly mixed prior to being used as an inoculum. After the mixed working inoculum is prepared, the viable count of the mixture should be determined by direct surface plating on MacConkey sorbitol agar (MSA). Each of the individual strains in the inoculum should contribute about 20 percent of the total Inoculum.

- Size of inoculum to be used: the final concentration of *E. coli* O157:H7 in the meat mixture should be no less than 2.0×10^7 CFU/g of meat mixture. The actual inoculum level in the meat mixture should be confirmed by sampling the inoculated meat mixture immediately after the inoculation using the above media. At this concentration, product can be serially diluted and direct plated without the need for enrichment to recover low levels of inoculum. The initial inoculum level was chosen to allow direct enumeration of at least a 5 log reduction in the level of the inoculum between the initial count in the meat mixture and the finished product.

- Method of inoculation to be used: the inoculum must be added to the meat and mixed prior to the addition of the other ingredients or a starter culture to the meat mixture. The use of a non-inhibitory, food grade, green dye added to the inoculum may aid in determining the uniform distribution of inoculum. The following procedure is recommended:

  – add inoculum to meats while grinding or chopping the meats to the desired consistency;

  - mix in cure (if used), salt and spices;
  - blend in starter culture (if used) near end of mixing cycle; and
  - stuff batter into casings.

- Stuffing product into casings: Inoculated product should be stuffed into casing as usual to approximate normal production procedures. A shorter length may be used as long as the length is approximately twice the diameter of the stuffed casing.

- Sample size, sampling time, sampling location and number of samples to test: Select two sausage sticks at the end of the drying period (finished product). From each stick selected, cut multiple cross-sectional slices from multiple locations on each stick to a final analytical sample weight of 25 g per stick.

- Methods of microbial analysis: Blend each of the two 25 gram samples (one per stick) in separate 225 ml portions of buffered peptone water. Serially dilute the homogenates in buffered peptone water and surface plat 0.1 ml portions from the dilutions onto MSA plates in duplicate. Count plates after incubation at 42ºC overnight. Confirm 5-10 randomly selected colonies by serological and biochemical methods as necessary. Report count per gram of finished product. Report initial Inoculum level.

- Number of replicates: a minimum of three replicates of the study should be performed. Three separate formulation batches can, however, be processed concurrently following stuffing.

  Therefore, total number of samples for microbiological analysis:

  Time zero (0) = 2
  After fermentation = 0
  During drying = 0
  End drying = 2
  Total = 4
  Number of replicates x 3
  Total samples = 12

- Measurement of process parameters used to determine when a product is finished at each stage of production (control program criteria): Duplicate uninoculated samples of the product which are collected after stuffing and at each production stage should be assayed for moisture, fat, protein, salt content, pH, a_w, and titratable acidity.

  Therefore, total number of samples for additional analysis:

  Time zero (0) = 2
  After fermentation = 2
  During drying = 2
  End drying = 2
  Total = 8
  Number of replicates x 3
  Total samples = 24

4.11.4.7 Controls for the a_w and pH of product

a_w and pH values are critical for processes used to ensure the control of pathogens in all semi-dry and dry fermented meat products as well as to ensure shelf-stability of certain of these products. a_w and pH values may vary greatly between individual production lots. Consequently, if a_w or pH value is a identified as a critical factor in the manufacture of dry fermented meat products, **each production lot** must be tested for a_w and/or pH in order to verify that the critical limits are met.

With the exception of products with a pH of 4.6 or less, fermented dry sausages and fermented meat products sold as shelf-stable must have an a_w value of 0.90 or less before release. Even though a_w measurement is mandatory only for shelf stable products, it is strongly recommended that the operator determine the norm for a_w values achieved for each product type they manufacture and for each production line (room). Once this has been established, frequent regular checks should be made.

4.11.5 Inspectional control

The inspector will monitor the production of fermented meat products and the critical controls points of the HACCP plan through the CVS system. The inspector should verify if all applicable controls are in place. The Operators determination of pH and a_w values should be verified, periodically, by observing the operator doing actual a_w and pH measurements and by observing the operators calibration activities for a_w and pH measuring equipment. Any discrepancy should be checked by repeating the sampling and testing procedures. Any product found in non compliance shall be held pending further evaluation.

4.11.6 Summary of the control points applicable to dry/semi-dry fermented meat products

- meat quality (including microbiological load);
- microbial specification for ingredients/regular testing;
- acidification;
- commercial starter cultures/back sloping;
- time/temperature control (degree-hours);
- indicating thermometer;
- thermometer, verifications;
- recording thermometer, correlation
- recording charts (temperature - relative humidity);
- relative humidity control;
- relative humidity recorder in greenrooms and smokehouses (recommended in drying rooms);
- pH monitoring;
- process deviation/ planned corrective action;
- a_w monitoring;
- nitrate/Nitrite salt levels;
- trichinosis control; and
- controls for *E. coli* O157:H7 and *Salmonella* in dry and semi-dry fermented sausage and completion of the checklist in Annex K of this chapter for each different type of such product made at the establishment.

4.12 POST PROCESS PASTEURIZATION OF RTE MEAT PRODUCTS

Pasteurization of packaged RTE meat products may be used as an adjunct to GMPs to extend shelf life and to prevent pathogen growth in RTE meat products. Post packaging pasteurization may not be used to replace GMPs.

Packaging materials used for this purpose must be specifically designed to withstand the pasteurization process. The operator must keep records of all products pasteurized. The process may be designed to achieve a surface heating only however they must be immediately cooled to 4ºC within the requirements of section 4.4 of this chapter.

4.13 HIGH PRESSURE PROCESSING FOR RTE MEAT PRODUCTS

High pressure processing is an approved post-lethality, post-packaging intervention step for RTE meats for the control of *Listeria monocytogenes*. This additional intervention step is to enhance the microbiological safety of these products.

The process is run in batch mode for pre-packaged foods. Batch high hydrostatic pressure units consist of a pressure chamber and a tray for the packaged food to be treated. Prior to pressurization, packaged foods are loaded in the tray, which is itself loaded into the chamber. The chamber is then sealed and pressurized by injecting water in to the chamber until a defined pressure specific for the food to be treated is reached. The packaged food is thus immersed in the pressurized water and is submitted to high hydrostatic pressure.

The mode of action of the high hydrostatic pressure attained in the treated food is theorized to be that high hydrostatic pressure inactivates the microbial flora by inactivating overall enzyme activity in the living cells, thus interrupting all cellular functions during the high pressure phase. The length of this phase determines the efficacy of the inactivation. The high hydrostatic pressure does not affect any of the structural components of the food itself (structural proteins, fibres, fats, etc.), nor does it affect the structural integrity of the package used, as the pressure is applied uniformly on the food and the package. Any food which has a sufficiently high water activity can be treated with this technology. In addition to meats, this includes juices, sauces, purées, seafood, fruits and vegetables.

4.13.1 Process parameters applicable to RTE meats

- The chamber must be pressurized to 87,000 PSI* (or 600 MPa**).
- The pressure must be maintained for three (3) minutes.
- The pressure is released and the treated containers are packed and ready for shipping.

* PSI: Pounds per square inch
** MPa: Megapascal

4.13.2 Packaging material

The safety of all materials used for packaging foods is controlled under Division 23 of the *Food and Drug Regulations*, Section B.23.0001 which prohibits the sale of foods in packages that may impart harmful substances to their contents. This regulation puts the onus clearly on the food seller (manufacturer, distributor, etc.) to ensure that any packaging material that is used in the sale of food products will meet that requirement.

Operators must provide evidence that the packaging material used is appropriate to undergo high pressure processing treatment. Concerning the acceptability of packaging material to high pressure processing, packaging material companies should send their requests to the CFIA's Food Safety Risk Analysis.

The following link provides additional information on the submission process:
http://www.inspection.gc.ca/english/fssa/reference/sube.shtml

4.13.3 Additional considerations

- Treated packages still require refrigeration.
- As the high pressure processing does not cause a significant compositional change in the meat, there are no mandatory labelling requirements associated to its use.

4.14 PACKAGING

4.14.1 Packaging materials

Packaging material includes cartons, wrapping materials, films, synthetic casings, nettings, trays, pouches, bags, and any other material which may come into contact with the meat product. This also includes gases used in modified atmosphere packaging. Packaging material shall not impart any undesirable substance to the meat product,

either chemically, physically or microbiologically and shall protect them sufficiently to avoid their contamination. Each new material must be evaluated in regard to its suitability for the intended purpose.

In order to demonstrate to the inspector that the materials used satisfy the above criteria, the operator shall maintain a listing of all the packaging materials used in the establishment. The packaging material, excluding gases, shall appear in the "Reference Listing of Accepted Construction Materials, Packaging Materials and Non-food Chemical Products" published by the CFIA or if not yet listed in this manual, a CFIA approval letter. Gases used in modified atmosphere packaging must be medical grade.

For further information on packaging material approvals, refer to the following site: www.inspection.gc.ca/english/fssa/reference/refere.shtml

4.14.2 General considerations

Packaging operations shall be conducted in a sanitary manner. Contact surfaces such as tables, knives, equipment, aprons, etc. shall be kept in a suitably sanitary condition at all times during operations. To prevent product contamination adequate segregation between bulk packaging material and exposed product shall be maintained.

Incompatible product packaging operations (RTE versus NRTE meats) must be segregated physically or operationally. If segregated operationally (by time of production) documented operational controls must be included in the FSEP system. All packaging material that contacts meat products must be approved as described above and be functionally suitable for the intended packaging method.

4.14.3 Preparation of corrugated packaging materials

Corrugated containers should be made up in a separate area from the exposed product area. This ensures package preparation does not contaminate meat products with dust, dirt, plastic or pieces of cardboard.

4.14.4 Use of packaging material in packaging rooms

Only enough packaging material from one complete clean-up to another is allowed in a product packaging room. Packaging materials such as rolls of plastic film must be removed prior to clean-up of these rooms.

In new establishments, or during renovations, operations should be designed (e.g. conveyors, chutes, etc.) to allow assembled corrugated packaging to enter product packaging areas as individual assembled units. This eliminates the need to store assembled packaging in product packaging areas. For RTE products, it is recommended that packaging of the exposed meat product into prepackaged units be conducted in a separate room from corrugated shipping carton forming and filling operations.

During operations, packaging material must be protected from potential contamination. Protection from contamination can be accomplished by adequate physical separation from meat processing, covering with plastic or other methods that will control the hazards. Packaging material cannot be placed directly on the floor or floor equivalent (stands, platforms, etc. that employees walk on).

When packaging exposed meat products into unwaxed cardboard containers, liners must be used. Every effort must be made to prevent the meat products from coming into contact with the exposed surfaces of any shipping containers during filling.

4.14.5 Containers with open hand holes or ventilation holes

Both open hand holes and ventilation holes are permitted in corrugated cartons provided the meat products are prepackaged or contained in sealed liners. This protection is required in both waxed and unwaxed containers.

4.14.6 Combo bins

Acceptably constructed combo bins may be used for storage of refrigerated or frozen meat products. Whenever combo bins are used for the storage of meat products in freezers or for the shipment of refrigerated or frozen meat products from a registered establishment, the meat products shall be protected by adequate lids or covers to prevent contamination and freezer burn. Combo bins shall be stored, assembled and/or filled off the floor. To prevent leakage the operator must ensure plastic liners in combo bins are not punctured.

4.14.7 Reusable shipping containers

Accepted reusable shipping containers may be used in registered establishments provided the following conditions are met:

- In the case of an accepted shipping container with lid qualifying for direct food contact:
  - There is a suitable room adequately equipped for the washing of containers before reuse. The washing and rinsing must ensure that the containers are visibly clean. The state of these containers should be maintained in a condition that will be acceptable as a food contact surface. Washing of reusable containers in outside facilities will be considered on an individual basis. Applications are to be made to the Chief of Plants and Equipment.
  - There are separate facilities in the registered establishment for the storage of cleaned and non-cleaned, reusable containers. The cleaned containers shall be stacked on cleaned non-absorbent pallets. Once dry they may be stored in a dry storage area along with other new material as long as they are dry and protected against contamination of any kind. Storage should be in accordance with Chapter 3 of the Manual.
  - Reusable shipping containers are of sufficient strength to support the weight of the ones above. They can not have perforations; if perforated, a liner must be used. The lid must be adequately designed to prevent contamination of the product.

- In the case of an accepted container without a lid, the following requirement apply in addition to the previous conditions:
  - The bottom of stacked shipping containers will not be supported by the packaged product in the lower shipping container; the bottom of the container cannot have drainage holes or perforations.
  - Only product packaged in sealed bags may be shipped in these shipping containers without lids.

4.14.8 Reuse of cardboard boxes

Cardboard containers may be reused by the operator provided that concerns regarding sanitary handling of the boxes, prevention of cross-contamination and labelling of the boxes are addressed in a satisfactory manner.

The operator shall have in place written protocols and procedures as part of their FSEP system. **The procedures must ensure that:**

- **Containers have not left federal inspectional control.**

  Containers must either have remained in the establishment or have been shipped directly to the establishment from another registered establishment or registered storage. Returned containers from retailers, hotels, restaurants, institutions or non-registered processing/slaughter establishments are not eligible for reuse.

- **Containers reused:**

  – are clean with no visible contamination;
  – are in good condition with no physical damage liable to weaken the container's structure; and
  – have remained completely dry at all times (even in the case of waxed corrugated cardboard boxes).

  Provisions for the prompt removal of all unsuitable containers must be included as part of the operator's procedure.

- **Containers destined for re-use are stored and handled in such a way as to prevent any possible contamination of product and/or of the plant environment.**

  When stacked, containers must not enter into contact with the insides of box liners, product contact surfaces or employees handling exposed product.

- **New liners are required when boxes are reused for packaging exposed products.**

  Fibre containers may be reused without liners for fully packaged product.

- **All applicable labelling requirements for the container are met.**

  Reused cardboard containers must be relabelled as necessary to reflect labelling requirements of the container contents.

4.14.9 Handling procedures for meat and food containers

Assembled cardboard cartons, either waxed or with plastic liners, shall be stacked to prevent contact of product surfaces with the outside of containers. The outside of shipping containers shall not come in direct contact with meat products.

Non-meat ingredient containers should not contaminate ingredients or meat products during opening. Paper bags containing such products as spices, binders, fillers, etc. shall have the **outer layer of paper peeled off** prior to placing their ingredients into meat formulations or transferring the ingredients into storage containers. The **uncontaminated** inner layer of paper can then be opened to transfer the ingredients to a storage container or into a meat product formulation. All storage containers for food ingredients must be labeled with the name of the ingredient. Food ingredient bags and storage containers are not to be stored on floors or floor equivalents (stands or platforms that employees walk on). Equipment used to transfer ingredients to meat formulations from storage containers/bags (e.g. shovels, augers, and scoops) must be stored so they too do not become contaminated.

Employees handling the outside of shipping containers should not handle meat products or food ingredient surfaces without a complete cleanup. A complete cleanup includes washing hands and change of outer clothing or washing apron. This ensures contamination from outer surfaces of shipping containers is not transferred to food products.

All plastic liners must be removed from frozen meat products prior to grinding. This may require tempering of the meat product to enable removal of plastic from frozen meat products.

4.14.10 Shelf life

All meat products must contain a best before date as required by as per Section 94 of the MIR. Refer to Chapter 7 of the MOP for information on requirements for Best Before dating of meat products.

4.15 STORAGE OF PALLETIZED MEAT PRODUCTS

Rooms used for the storage of palletized meat products should be provided with suitable shelving when pallets are stored in superposition. The stacking must not result in contamination of boxes or containers. Separators or other means acceptable to the inspector must be used to prevent contamination. The product should be stored so that boxes or containers at the bottom are not damaged by the weight of containers they support. Canned meat products must be stored in accordance with the can manufacturer's and Chapter 15 specifications.

Wood pallets must be stored in an area where they will not be contaminated. This is usually a dry storage area free of moisture and other contaminants. Pallets that are not in good repair should be removed from the establishment to prevent contamination of other packaging material or food products with wood splinters or nails.

Wood pallets cannot be stored in meat processing rooms. A pallet may be used to bring meat or food ingredients into a processing room. As soon as these products have been used the pallet must be removed from the area. Wood pallets used to accumulate finished meat product (e.g. combo bins or cartons of product) shall be removed from the processing room to a storage room (cooler or freezer) as soon as the pallet is full. Wood pallets can be used to store product in coolers and freezers. The pallets should be dry, in good repair and free of contamination to prevent contamination of product containers. Employees should not walk on wood pallets as they then become floor equivalents and are no longer suitable for the storage of food products.

Reusable pallets that can be cleaned (e.g.: plastic or metal) may remain in use in processing rooms as long as they are clean and in good repair. At the end of the production day, they should be washed and stored in rooms for reusable containers. The same requirements as those for storage, care and cleaning of reusable containers apply.

4.16 NON-MEAT FOOD PRODUCTS

4.16.1 General Information

Products under this category refer to those ingredients that are normally added in the preparation of a meat product (e.g. spices, fillers, extenders, curing agents, etc.) Basically, they can be divided into 2 groups:

- restricted non-meat food product, e.g. nitrite and nitrate salts; and
- non-restricted non-meat food product, e.g. spices, fillers, extenders, etc.

Non-meat food products shall be stored in a suitable dry storage room or in a cooler meeting all structural and sanitary requirements that apply in registered establishments.

The operator is responsible for maintaining non-meat food products and the premises in which they are stored, in good sanitary conditions. The operator is responsible in ensuring that handling of the non-meat products do not pose a hazard to the meat products subsequently prepared.

Vegetables must be stored, washed and prepared in a separate room to avoid risk of contamination.

4.16.2 Use of eggs in registered establishments

The operator of the registered establishment may use pasteurized processed egg which originates from a registered processed egg station or may purchase grade "Canada A" shell eggs from a registered egg station.

The major concern with the use of eggs is the possible presence of *Salmonella* bacteria, particularly *Salmonella enteritidis*.

Pasteurized processed eggs are considered the lowest risk form of eggs and continue to be the safest and preferred option, especially if the prepared food may be consumed by people particularly vulnerable to infection.

In the case of products which are fully cooked or intended to be cooked by the consumer before eating, the risk associated with the use of fresh uncracked (i.e. in the shell) grade Canada A eggs should be minimal if Good Manufacturing Practices (GMPs) are met during food preparation.

A summary of the GMPs for the breaking of eggs is as follows:

- Egg holding: Shell eggs are to be held in a cooler at 4ºC (40°F).
- Eggs may be tempered prior to breaking for better yield. Tempering may be done at room temperature; however, tempering shall be done in a way that the does not result in time-temperature abuse of the eggs. The quantity of eggs tempered should not exceed the amount needed for the production lot. Eggs should be used as soon as, or before reaching room temperature and should not be held for extended periods of time at room temperature.
- Stainless steel equipment shall be used for the breaking of eggs. Any shell in contact with the egg meat shall be removed immediately. The egg should be broken in a manner that allows the person breaking the eggs to visually examine each egg for defects and to detect any odours which may be developing. Defective eggs, i.e. leakers, off odour, blood rejects, etc., must not be used for human consumption.
- The breaking equipment shall be maintained in good working condition. Equipment shall be effectively cleaned and sanitized as per the establishment's written sanitation program.
- Egg shells and any inedible eggs (leakers) shall be identified and promptly removed from the processing area. Control of inedible eggs should be maintained in an appropriate manner.
- The liquid product must be used immediately or cooled to 4ºC (40°F) for holding purposes.
- Holding tanks shall be constructed of stainless steel or other approved material; they should be equipped with agitators, and refrigerated, if they are to be used for holding liquid eggs.
- No fresh or frozen liquid egg is to leave the premises unless it is marked "Inedible egg - unfit for human consumption", as it does not meet federal or provincial requirements.

Storing, tempering and breaking of shell eggs shall be done in a manner which does not result in cross-contamination of meat products.

4.16.3 Preparation of fillers, spices and preservatives

Where these products are purchased in bulk form, mixing and preparation must take place in a separate room. The operator is responsible to execute these operations under acceptable sanitary conditions. A hand wash sink should be provided. Special attention must be given to handling and storage of potential allergens.

4.16.4 Control over the use of restricted non-meat food products

Restricted non-meat food products are described in Division 16 of the *Food and Drug Regulations*.

Registered establishments that store bulk restricted curing agents shall keep those under lock and key and account for their use to prevent an accidental misuse of those potentially dangerous compounds. The company shall maintain a log book for nitrates/nitrites. The log should contain information such as: quantity on hand, quantity used, date, signature of employee. Binder units must have curing salts packaged separately in a coloured bag.

4.17 NON-FOOD PRODUCTS

Refer to Chapter 3 section 3.6.3.5.

Annex A – CURING

APPROVED CURING METHODS TO ENSURE THE DESTRUCTION OF *TRICHINELLA* IN SAUSAGES AND OTHER MEAT PRODUCTS CONTAINING STRIATED PORK MUSCLE TISSUES

WARNING: The curing methods described in this annex are designed only to ensure that viable *Trichinella* are destroyed in sausages and meat products containing striated pork muscle tissues. These methods do not guarantee the safety of product in terms of other pathogens such as *Salmonella spp., Toxoplasma gondii, E. coli* and *L. monocytogenes*, etc. When any of these methods are used in the production of ready-to-eat meat products, it is the operator's responsibility to undertake all other additional manufacturing procedures required to ensure product safety.

A.1. SAUSAGES

Sausage may be stuffed in animal casings, hydrocellulose casings, or cloth bags. Except as specified in method # 5, casings are **not to be coated** with paraffin or a like substance at any stage during the *Trichinella* destruction process, nor shall they be washed during any prescribed period of drying. Several curing methods are acceptable. They are:

A.1.1. Method # 1 (Cured and Dried Sausages)

Meat shall be ground or chopped into pieces of no more than 1.9 cm (¾ inch) maximum in diameter. A minimum of 3.33% of salt per weight of unstuffed sausage material shall be mixed thoroughly with the ground or chopped meat.

Pepperoni sausages stuffed into casings of 3.5 cm (1 3/8 inches) diameter or less as measured at the time of stuffing shall be held in a drying room for a minimum of 15 days at a temperature not lower than 7.3°C. In no case however, shall the sausage be released from the drying room less than 20 days from the time the curing materials are added.

- Sausage having a diameter not exceeding 8.8 cm (3½ inches) measured at the time of stuffing shall be held in a drying room for a minimum of 20 days at a minimum temperature of 7.3°C. In no case, however, shall the sausage be released from the drying room less than 25 days from the time the curing materials are added.

- Sausage in casings exceeding 8.8 cm (3½ inches) but not exceeding 10.2 cm (4 inches) in diameter at the time of stuffing shall be held in a drying room for a minimum of 35 days at a minimum temperature of 7.3°C. In no case shall the sausage be released from the drying room less than 40 days from the time the curing materials are added to the meat.

A.1.2. Method # 2 (Cured, Smoked and Dried Sausages)

Meat shall be ground into pieces of 1.9 cm (¾ inch) maximum diameter or less. A dry-curing mixture containing a minimum of 3.33% of salt per weight of **unstuffed** sausage material shall be mixed thoroughly with the ground or chopped meat. After stuffing, sausage **shall be smoked** a minimum of **40 hours** at a temperature not lower than **26.7°C**.

After smoking, sausage having a diameter not exceeding 8.8 cm (3½ inches), measured at the time of stuffing, shall be held in a drying room for a minimum of 10 days at a minimum temperature of 7.3°C. In no case, however, shall the sausage be released from the drying room less than 18 days from the time curing materials are added to the meat.

After smoking, sausage in casings exceeding 8.8 cm (3½ inches) but not exceeding 10.2 cm (4 inches) in diameter at the time of stuffing shall be held in a drying room for a minimum of 25 days at a minimum temperature of 7.3°C. In no case shall the sausage be released from the drying room less than 33 days from the time the curing materials are added to the meat.

A.1.3. Method # 3 (Cured and Smoked Sausages)

Meat shall be ground or chopped into pieces of 1.9 cm (¾ inch) maximum diameter or less. A dry-curing mixture containing a minimum of 3.33% of salt per weight of **unstuffed** sausage material shall be mixed thoroughly with the ground or chopped meat.

Total curing time shall be no less than six days; this **six-day** period must include:

- a minimum **36-hour** holding period before stuffing of casings (calculated from the admixture of salt and curing material), where the mixture is held at a temperature not lower than 1.2°C;

- an additional period of time, after stuffing, sufficient to attain the minimum curing period of six days. During this period, sausages shall either be held at a temperature not lower than 1.5°C **OR** placed in a pickle-curing medium of a minimum strength of 50° (salimeter reading) at a minimum temperature of 6.7°C.

Smoking of sausages is mandatory in this process:

- Sausages having a diameter of 8.8 cm (3½ inches) or less, measured at the time of stuffing, shall be smoked after the prescribed curing, for a minimum period of **12 hours** during which time:

  - the temperature shall be maintained at **32.3°C** minimum; **and**
  - the temperature shall be gradually raised **(over a period of no less than four hours) and maintained for at least four consecutive hours at a minimum temperature of 53.4°C**.

- Sausage in casings exceeding 8.8 cm (3½ inches) but not exceeding 10.2 cm (4 inches) in diameter, measured at the time of stuffing, shall be smoked, following the prescribed curing, for a minimal period of **15 hours** during which time:

  - the temperature shall be maintained above a minimum of **32.3°C; and**
  - the temperature shall be gradually raised **(over a period of no less than four hours) and maintained for at least seven consecutive hours at a minimum temperature of 53.4°C**.

A.1.4. Method # 4 (Cured and Dried Sausages with Optional Cooking or Smoking)

Meat shall be ground or chopped into pieces of 0.6 cm (¼ inch) maximum diameter. A dry-curing mixture containing a minimum of **2.5%** of salt per weight of **unstuffed** sausage material shall be mixed thoroughly with the ground or chopped meat.

After admixture with the curing salts and before stuffing, the ground or chopped meat shall be held as a compact mass of a depth of 15.2 cm (6 inches) or less at a minimum temperature of 2.3°C for a minimum of ten days. At the end of this holding period, the sausage shall be stuffed in casings or cloth bags not to exceed a maximum diameter of 8.5 cm (3 $^{1}/_{3}$ inches), as measured at the time of stuffing.

At any time after stuffing, if the operator so wishes, the product may be heated in a water bath for a period not to exceed three hours at a temperature no lower than 29.5°C, or may be smoked at a minimum temperature of 26.7°C during a period not to exceed three hours, or may be both heated and smoked as specified.

After stuffing, the sausage shall be held in a drying room at a minimum temperature of 7.3°C for the remainder of a **35-day** period, measured from the time curing materials were added to the meat. **The time spent smoking or heating the sausage shall not be included in the 35 day holding/drying period calculation.**

A.1.5. Method # 5 (Sausages with Coated Casings or Coverings)

Meat shall be ground or chopped into pieces of 1.9 cm (¾ inch) maximum diameter. A dry-curing mixture containing a minimum of 3.33% of salt per weight of **unstuffed** sausage material shall be mixed thoroughly with the ground or chopped meat.

After stuffing, the sausage shall be held in a drying room at a temperature no lower than 7.3°C for a minimum period of 65 days.

The casings or coverings for sausages prepared according to this method may be coated, before or during the drying period, with paraffin or other substance listed in the "Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products".

A.1.6. Method # 6 (Dry Cured Sausage; Optional Cooking or Smoking; Optional Reduced Salt Formulation)

A.1.6.1. General Requirements:

Meat shall be ground or chopped into pieces of 1.9 cm (¾ inch) maximum diameter. A dry-curing mixture containing a minimum of 3.33% salt per weight of unstuffed sausage material, ***excluding the weight of dry ingredients***, shall be mixed thoroughly with the ground or chopped meat. Salt concentration for this method is calculated with the following formula:

$$\text{Salt concentration} = \frac{\text{weight of salt in sausage formula}}{\text{weight of sausage formula - weight of dry ingredients}} = X\ 100$$

The **result is rounded down to the next lowest 0.1%**

Example:

Formula: 120 kg pork, 3.56 kg salt, 2 kg spice, 0.5 kg wine, 1 kg water and starter culture, 0.8 kg sugar, 0.012 kg sodium nitrite.

$$\text{Salt concentration} = \frac{\text{Weight of salt (3.56 kg)}}{\text{weight of formula (127.872kg) - weight of dry ingredients (6.372kg)}} = X\ 100$$

$$= 0.0293 \text{ or } 2.93\%; \rightarrow \mathbf{2.9\%}$$

After mixing, the sausage **shall be held for two time periods**:

- a minimum 48-hour holding period in a room maintained at a temperature of no lower than 1.7°C; and
- a drying period, in a room maintained at a temperature no lower than 10.0°C, of a duration equal to, or greater than, the minimum number of drying days obtained by the following formula:

Baseline value for minimum number of drying days for the type of sausage (ref. Table A.1.6.1)

-	Number of days which can be reduced from the drying period because of a smoking or fermentation of the sausage during the holding period (ref. section A.1.6.2)
+	Number of days which must be added to the drying period because of a sausage formulation which has a reduced salt content (ref. section A.1.6.3)
=	Minimum number of drying days

Note: The 48-hour holding period can take place entirely or partially before the beginning of the drying period; if the holding period is not completed before the beginning of the drying period, that part which remains must be completed either after the end of the drying period or as an extension of the drying period.

TABLE A.1.6.1
SAUSAGE DRYING TIMES BY METHOD # 6
(baseline table)

Maximum diameter of casing at time of stuffing[1] in cm (inches)	Minimum holding time in drying room (temperature≥1,7°C)	Minimum number of days in drying room (Room temp. ≥10°C)
2.5 cm (1.0")	48 hours	14 days
3.8 cm (1.5")	48 hours	15 days
5.0 cm (2.0")	48 hours	16 days
6.3 cm (2.5")	48 hours	18 days
7.6 cm (3.0")	48 hours	20 days
8.8 cm (3.5")	48 hours	23 days
10.1 cm (4.0")	48 hours	25 days
11.4 cm (4.5")	48 hours	30 days
12.7 cm (5.0")	48 hours	35 days
13.4 cm (5.5")	48 hours	43 days
15.2 cm (6.0")	48 hours	50 days

1. The drying time for flattened or oval sausages shall be calculated from a diameter derived by measuring the circumference and divided by 3.14 (pi π).

A.1.6.2. Reduction in the number of Drying Days for sausages which are smoked or fermented during the holding period:

Sausages fabricated according to the methods outlined in section A.1.6.1 and A.1.6.3 may be smoked or fermented between the time curing materials are added and the time drying commences. If the internal temperature of the product is increased to 21.1°C or higher during the 48 hours holding period and ***maintained*** according to one of the time/temperature combinations described in Table A.1.6.2 below, the drying time prescribed for the product may be reduced.

No interpolation of values is permissible.

TABLE A.1.6.2
SAUSAGES MANUFACTURED ACCORDING TO METHOD 6 WHICH ARE SMOKED OR FERMENTED DURING THE HOLDING PERIOD - REDUCTION (%) OF THE DRYING PERIOD ACCORDING TO THE TEMPERATURE AND THE DURATION OF THE SMOKING OR FERMENTATION PERIOD

MINIMUM NUMBER OF HOURS DURING WHICH THE SAUSAGE IS HELD AT A TEMPERATURE NO LOWER THAN:										
Minimum period	INTERNAL TEMPERATURE OF PRODUCT[1] (minimum)									
	21.1°C 70°F	23.9°C 75°F	26.7°C 80°F	29.5°C 85°F	32.2°C 90°F	35.0°C 95°F	37.9°C 100°F	40.6°C 105°F	43.3°C 110°F	48.9°C 120°F
24 hrs.	4%	5%	8%	10%	15%	23%	37%	57%	90%	100%[2]
48 hrs.	9%	12%	18%	25%	35%	49%	88%	100%[2]	100%[2]	100%
72 hrs.	14%	19%	28%	39%	55%	74%	100%[2]	100%	100%	100%
96 hrs.	19%	26%	38%	53%	75%	98%	100%[2]	100%	100%	100%
120 hrs.	24%	33%	48%	67%	95%	100%[2]	100%	100%	100%	100%

[1] Internal product temperature shall be used for all types of sausages with the exception of dry cured fermented sausages (e.g. sausages with a pH ≤ 5.3 at the end of the fermentation period and an a_w of 0.90 or less at the end of drying); in these cases room temperature or product temperature shall be used.

[2] *Trichinella* will be destroyed during fermentation or smoking at the temperature and length of time indicated. Therefore, no drying room period is required for *Trichinella* destruction for products so treated. However, the total holding period must last at least 48 hours.

How to use Table A.1.6.2:

1. Determine how long and at which temperature the sausage will be fermented or smoked (Note: the heat treatment must take place during the holding period);
2. Identify the appropriate row and column for these values in the table: when the time and/or temperature values used in the preparation of the product are not listed, select the **next lowest value(s)**. (see following example);
3. Find the % in reduction time using the table above;
4. To obtain the number of days by which the minimum drying period can be reduced, multiply the % in reduction value by the baseline minimum number of drying days for the type of sausage (ref table 1.6(a)) and round this value to the **next lower integer** number of days;

Example:

A 7.6 cm (3 inches) diameter sausage fermented at 29 C for 60 hours.

1. The exact temperature is not in the table; the next lowest value in the table is *26.7°C*
2. The exact time is not in the table; the next lowest value in the table is *48 hours*.
3. The percentage of reduction found in the table with 26.7°C and 48 hours is *18%*.
4. According to table 1.6(a), the baseline number of minimum drying days for the type of sausage of 7.6 cm diameter, is 20 days. The number of days by which the minimum drying period can be reduced is:

20 days X 18% = 3.6 days → round to 3 days (nearest lowest number)

Therefore, a reduction of three days to the number of drying days is allowed; the minimum number of drying days for this type of sausages is 20 days - 3 days = **17 days**.

A.1.6.3. Reduced Salt Content: Increase in Drying Room Times

Sausages prepared according to the general requirements in 1.6.1 but with a recipe using less than 3.33% of salt per weight of ***unstuffed sausage material*** **excluding the weight of dry ingredients** (such as salts, sugars and spices) may be permitted provided the drying time is increased according to the schedule contained in Table A.1.6.3.

TABLE A.1.6.3
Increase in Drying Room Times for Reduced Salt Content Sausages Prepared according to Method 1.6.1

Minimum % of Salt in Sausage[1]	Increase in Drying Room Time (%)
3.3 %	1 %
3.2 %	4 %
3.1 %	7 %
3.0 %	10 %
2.9 %	13 %
2.8 %	16 %
2.7 %	19 %
2.6 %	22 %
2.5 %	25 %
2.4 %	28 %
2.3 %	31 %
2.2 %	34 %
2.1 %	37 %
2.0 %	40 %

[1]Calculated on the base of the weight of sausage materials excluding dry ingredients (see section A.1.6.1.

How to use Table A.1.6.3:

1. Calculate the percentage of salt in the sausage with the formula in section A.1.6.1;
2. With Table A.1.6.3 above, find the percentage by which the drying period must be extended;
3. To obtain the number of days by which the drying period must be extended, multiply the % by the baseline minimum number of drying days specified in Table A.1.6.1 for the type of sausage in question and round this value to the ***nearest greater integer***.

Example:

A 5.0 cm (2 inches) diameter sausage with 2.0% salt requires a 40% increase in drying time according to Table A.1.6.3.

1. & 2. According to Table A.1.6.3, an increase of 40% in the drying time is required for sausages containing 2.0% salt.
3. The formula used: 40% X 16 days = 6.4 days → (round to next **highest** integer) **7 days.**

(The baseline number of drying days for a 2 inch sausage (ref. Table A.1.6.1) is 16 days).
Therefore an extension to the drying period of 7 days is required; the minimum number of drying days for the sausage in this example is 16 days + 7 days = **23 days**.

A.1.7. Method # 7 (Dry Sausages)

Meat shall be ground or chopped into pieces of a maximum 0.6 cm (¼ inch) diameter or less. A minimum of **2.7% of salt per weight of *sausage meat*** shall be uniformly mixed with the ground or chopped meat.

Depending on the size of the sausages, the treatment shall be as follows:

A.1.7.1. Sausages with a diameter of 10.5 cm (4 1/8 inches) or less

Sausages with a diameter of 10.5 cm (4 1/8 inches) or less
at the time of stuffing shall be subjected to the following 23 hour process schedule after stuffing.

TABLE 1.7.1
PROCESS SCHEDULE FOR HEAT TREATED DRY SAUSAGE OF A DIAMETER OF 10.5 CM (4 1/8 INCHES) OR LESS

Step	Minimum Room temperature	Minimum time (hours)
1	10.0°C / 50°F	12 hours
2	32.2°C / 90°F	1 hour
3	37.8°C / 100°F	1 hour
4	43.3°C / 110°F	1 hour
5	48.9°C / 120°F	1 hour
6	51.7°C / 125°F	7 hours
TOTAL TIME:		23 HOURS

The sausages shall then be **dried** at a minimum temperature of 10°C for not less than 7 days.

A.1.7.2. Sausages with a diameter of 5.5 cm (2 1/8 inches) or less

Alternatively, sausages with a diameter of 5.5 cm (2 1/8 inches) or less at the time of stuffing, are to be subjected to the following 19-hour process schedule:

TABLE 1.7.2
PROCESS SCHEDULE FOR HEAT TREATED DRY SAUSAGE OF A DIAMETER OF 5.5 CM (2 1/8 INCHES) OR LESS

Step	Minimum Room temperature	Minimum time (hours)
1	10.0°C / 50°F	12 hours
2	37.8°C / 100°F	1 hour
3	51.7°C / 125°F	6 hours
TOTAL TIME:		19 HOURS

The sausages shall then be **dried** at a minimum temperature of 10°C for not less than 4 days.

SUMMARY TABLE OF APPROVED CURING METHODS FOR SAUSAGE TO ENSURE THE DESTRUCTION OF TRICHINELLA IN SAUSAGES CONTAINING STRIATED PORK MUSCLE

Method	Maximum diameter of meat particles (cm)	Minimum % of salt per weight of sausage material	Diameter of sausage at time of stuffing (cm)	Minimum curing time cure room temperature ≥ 3°C (days)	Minimum smoking period		Minimum holding time in drying room temperature ≥7.3°C (Days)	Minimum time between addition of cure and release from the drying room (Days)
					Time (Hrs)	Smokehouse temperature (°C)		
1	1.9	3.33	< 3.5[1]	N/A	N/A	-	15	20
1	1.9	3.33	< 8.8	N/A	N/A	-	20	25
1	1.9	3.33	8.8 - 10.2	N/A	N/A	-	35	40
2	1.9	3.33	< 8.8	N/A	40	≥26.7°C	10	18
2	1.9	3.33	8.8 - 10.2	N/A	40	≥26.7°C	25	33
3	1.9	3.33	< 8.8	6[2]	12	≥32.3°C [3]	N/A	N/A
3	1.9	3.33	8.8 - 10.2	6[2]	15	≥32.3°C [4]	N/A	N/A
4	0.6	2.5	< 8.5	10[5]	SEE[6]	-	N/A	35[6]
5[7]	1.9	3.33	N/A	N/A	N/A	N/A	65	N/A
6	1.9	SEE[8]	2.5 -15.09	2[10]	SEE[11]	-	SEE[12]	N/A
7	0.6	SEE[13]	< 10.5	N/A	SEE[14]	-	7	N/A
7	0.6	SEE[13]	< 5.5	N/A	SEE[15]	-	4	N/A
N/A	Not applicable OR no minimum standard specified.							

1. Sausages of the Pepperoni variety.

2. This 6-day curing period includes a minimum 36-hour period, prior to stuffing, where the mixture shall be held at a temperature of 1.2°C or higher; sausage may either be held at 1.5°C or more OR placed in a pickle-cure of 50° (salimeter reading) or more at a temperature of 6.7°C or more for the remainder of the 6 days.

3. During this 12-hour period, the smokehouse temperature shall be gradually raised (over a minimum period of
4 hours) and maintained (for a minimum of 4 additional hours) at 53.4°C or higher.

4. During this 12-hour period, the smokehouse temperature shall be gradually raised (over a minimum period of
4 hours) and maintained (for a minimum of 7 additional hours) at 53.4°C or higher.

5. This 10-day curing period must take place **before** stuffing; product must be stored at 2.3°C or more as a compact mass of a depth not to exceed 15.2cm.

6. A maximum of 3 hours cooking in a 29.5°C water bath and/or maximum 3 hours smoking at 26.7°C is permitted; if either option is used, the drying time must be extended by a period of time equivalent to the time taken to cook and/or smoke the sausage.

7. The coverings of these sausages may be coated with paraffin or other substance listed in the "Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products" before or during the drying period.

8. Salt content (%) is calculated on the basis of the unstuffed sausage weight, **exclusive of the weight of the dry ingredients**. The baseline value of salt % is 3.33%. Salt content may be reduced; see section A.1.6.3.

9. See section A.1.6.1 for specific information regarding this method.

10. The 48 hour holding period at 1.7°C may be partly or entirely completed before the end of the drying period, if the holding period is not entirely completed before the drying period, the remainder can be completed after the end of drying, or as an extension of the drying process.

11. Smoking of sausage is optional and may be used to lower the drying time; ref. section A.1.6.2.

12. This value is to be determined in accordance to the exact process used; ref. section A.1.6.

13. This percentage is calculated on the basis of the sausage **meat** only (2.7%).

14. Sausage must be processed according to the method prescribed in table 1.7.1.

15. Sausages must be processed according to the method prescribed in table 1.7.2.

A.2. CAPICOLA (CAPOCOLLO CAPACOLA) AND COPPA

Capicola, Capocollo and Capacola are dry-cured **smoked** boneless pork shoulder butts.

Coppa is a dry-cured **unsmoked** boneless pork shoulder butt.

Boneless pork butts used for coppa or capicola (or Capocolo or Capacola) shall be dry-cured using a mixture containing a minimum 4.5kg of salt per 100kg of fresh meat (weight before curing). Product must be cured and dried according to the schedule set out in Table A.2 below.

If curing materials are applied by the "churning" process, a small amount of pickle may be added. During the curing period, butts may be overhauled, e.g. turned over for application of additional pickle or dry salt, during the process.

In addition, capicola, capocollo and capacola shall be smoked for a minimum temperature of 26.7°C for a minimum period of 30 hours.

Butts shall not be treated in any manner designed to remove salt from the meat during or after curing; superficial washing of the butts may however be permitted.

TABLE A.2
***Minimum* treatments for ensuring the destruction of *Trichinella* in Coppa, Capicola, etc.**

Type of Product	**Curing** period at temperature not lower than 2.3°C (36°F) (days)	**Smoking** time at temperature not lower than 26.7°C (80°F) (hours)	**Drying** time at temperature not lower than 7.3°C (45°F) (days)
Capicola, Capocollo, Capacola	25	30	20
Coppa	18	N/A	35

A.3. HAMS AND PORK SHOULDERS PICNICS

In the curing of hams and pork shoulder picnics, one of the following methods shall be used to destroy *Trichinella*.

A.3.1. 3.1 Method #1

Hams and pork shoulder picnics shall be laid down in salt, in a ratio of at least 4.0kg of salt for each 100kg of fresh meat (before curing) for a minimum of 40 days in a room maintained at a temperature not lower than 2.3°C.

Salt is to be applied in a thorough manner to the lean meat of each item. When placed in cure, product may be pumped with pickle. At least once during the curing process, products are to be overhauled (turned over for application of additional cure) and additional salt applied, if required, to thoroughly cover the lean meat of each item.

At the end of the curing period, product may be soaked up to a maximum of 15 hours in water at a temperature not to exceed 21°C (70°F). The water may be changed only once during this 15 hour period. The product shall not be treated, except for superficial washing, in any other manner designed to remove salt from the meat.

Product shall finally be dried or smoked at a time and temperature as specified in Table A.3.4 which is in section A.A.3.4.

A.3.2. Method # 2 [Reserved]

A.3.3. Method # 3

A.3.3.1. Traditional Dry Curing:

Hams and shoulders shall have all exposed muscle tissue covered and the hock region packed with a cure mixture containing a minimum of 70% salt (by weight of the curing mixture).

Curing shall consist of:

A **mandatory cure contact time** of a minimum 28 days but no less than 3.3 days/kg of uncured product (whichever period is longest) at a room temperature between 1.7°C and 7.3°C; **and**

An optional **cure equalization time** at a room temperature no lower than 1.7°C and no higher than 15.6°C to permit the cure mixture to penetrate deeply into the muscle tissues of the product.

The number of days obtained using days/kg, is calculated by multiplying the value of *#days/kg* by the weigh in kilograms of the ***heaviest*** piece of the lot (as weighed prior to the addition of cure materials).

The total curing time (between application of cure and entry into the drying room) shall be at least 40 days and in no case less than 4.4 *days/kg* of uncured ham or shoulder.

During the mandatory cure time, exposed muscle tissue must stay coated with the cure mixture. After this period, the operator may remove excess cure from the product's surface either mechanically or by a water rinse of a maximum duration of 60 seconds, and allow the product to rest in order to permit salt to permeate the product's inner tissues (equalization). Soaking of hams to remove cure is not permitted.

Product is to be dried in accordance with Table A.3.4.

A.3.3.2. Bag curing:

Hams and cure mixture are wrapped together in uncoated kraft paper and hung individually. Reapplication of salt is not necessary since the wrapping keeps the cure mixture in close contact with the product.

Exposed muscle tissue shall be rubbed and hocks packed with a cure mixture containing at least 6kg of salt for each 100kg of uncured meat (weighed before the addition of curing material), any remaining cure mixture shall be used in wrapping the product in the paper bag.

Product shall remain wrapped during a minimum curing period of at least 40 days but not less than 4.4 days per kg of uncured ham or shoulder (which ever period is longest) at a room temperature between 1.7°C and 7.3°C. It may be unwrapped during the drying period.

The number of days obtained using *days/kg*, is calculated by multiplying the value of *#days/kg* by the weigh in kilograms of the ***heaviest*** piece of the lot (as weighed prior to the addition of cure materials).

Product is to be dried in accordance with Table A.3.4.

A.3.4. Method # 4

Hams and shoulders shall be cured with a cure mixture containing a minimum of 71.5% salt by weight. The operator may substitute potassium chloride (KCl) **for up to half of the required salt** on an equal weight basis.

Cure shall be applied at a minimum rate of 5.72 kg of cure for each 100kg of fresh meat (weighed before addition of the curing materials). The hock region is to be packed and all exposed muscle tissue covered. The cure shall be applied in either three or four approximately equal amounts (three or four overhauls) at separate times during the first 14 days of curing.

The product shall be kept in contact with the cure mixture at a minimum temperature of 1.7°C for a minimum period of 4.4 *days/kg* of uncured product but for at least 30 days, whichever period is longest.

The number of days obtained using *days/kg*, is calculated by multiplying the value of *#days/kg* by the weigh in kilograms of the ***heaviest*** piece of the lot (as weighed prior to the addition of cure materials).

At the end of the cure contact period, excess cure mixture may be removed either by rinsing for a maximum of 60 seconds with water or by mechanically removing the excess from the products surface; soaking is not allowed.

After the cure contact period has ended and the excess cure has been removed, an additional period of a minimum 2.2 days/kg of uncured product but at least 14 days, whichever period is longest, shall be provided to allow the cure to permeate the deeper muscle masses. Additional cure contact days may be substituted for an equal number of equalization days.

Drying cannot begin until the end of the equalization period. Drying is to be performed according to one of the methods described in Table A.3.4.

Table A.3.4 ***Minimum* Drying Time/Temperature Combinations to Ensure the Destruction of *Trichinella*** **in Dry Cured Hams**			
Minimum Drying Temperature		Minimum Days at Drying Temperature	Fractional Period/ Drying Day
(°F)	(°C)		
≥130	≥54.4	1.5	0.67
≥125	≥51.7	2	0.50
≥120	≥48.9	3	0.33
≥115	≥46.1	4	0.25
≥110	≥43.3	5	0.20
≥105	≥40.6	6	0.17
≥100	≥37.8	7	0.14
≥95	≥35.0	9	0.11
≥90	≥32.2	11	0.091
≥85	≥29.4	18	0.056
≥80	≥26.7	25	0.040
≥75	≥23.9	35	0.029

How to use Table A.3.4:

- Drying at a single constant temperature:
  - Determine the lowest temperature attained/which will be attained during the drying period. Using the table, select the appropriate row (if the drying room temperature is not in the table, select the row with the next lowest temperature value) and determine the "Minimum Days at drying temperature" in column 3.
- Drying at two or more different temperatures:
  - Using the drying schedule, determine, for each day of drying, the lowest temperature reached/which will be reached. With the table, determine the fractional period contributed by each drying day using the lowest drying temperature for each day. In order for the process to be acceptable, the sum of these fractions must be greater than 1.5.

Interpolation of these times or temperatures is not acceptable.

A.4. BONELESS PORK LOINS AND LOIN ENDS

In lieu of heat or cold treatment, curing may be used to ensure the destruction of *trichinella* in boneless loins.

Loins are cured for a minimum period of 25 days at a temperature not lower than of 2.3°C using one of the following methods:

- Application of a dry-salt curing mixture containing a minimum of 5kg of salt per 100 kg of fresh meat (weighed prior to the addition of curing materials);
- Application of a pickle solution (minimum 80° strength on the salimeter) at a ratio of 60 kg of pickle for each 100 kg of fresh meat (weighed prior to the addition of curing materials);

- Application of a pickle solution added to the dry-salt cure prescribed as method i) above, provided the pickle solution is not less than 80° strength (salimeter).

Loins may be soaked in maximum 21°C temperature water for a maximum duration of one hour, or washed under a spray. Product shall not be subjected, during or after curing, to any other treatment designed to remove salt.

Loins shall be smoked for a minimum of 12 hours. The smokehouse temperature shall be maintained above a minimum temperature of 37.8°C during the entire smoking process. **In addition**, within the 12 hours smoking period, the smokehouse temperature shall be maintained at a minimum temperature of 51.7°C for at least four consecutive hours.

Smoked product shall then be held in a drying room maintained at a temperature of not less than 7.3°C for a minimum period of 12 days.

Annex B

Trichinella spiralis control options for pork

B.1 General requirements and information

All smokehouses or other cooking devices, freezers, and any other room/device, used for the destruction of *Trichinella* in pork or pork products shall be equipped with accurate automatic devices that **continuously** record time/ temperature.

Time/temperature recorders and thermometers used in registered establishments shall be tested for accuracy against a known accurate standard thermometer and clock. Such tests shall be performed just prior to installation and at least once a year thereafter or more frequently as may be necessary to ensure their accuracy. A dated record of such tests shall be kept, along with the responsible person, and the necessary information on deviations and appropriate corrective actions.

For freezing, heating and curing methods used to ensure the destruction of viable *Trichinella* in striated pork muscle or meat product containing striated pork muscle, the operator is responsible for keeping current and accurate records which document all parameters required for process control (e.g. lot identification, time/temperature records, % salt, casing diameter, etc.), the critical limits which must be respected as well as the actual measurements confirming that the critical limits were met and, when a process deviation has occurred, the corrective action taken.

The controls for the freezing of product to ensure the destruction of *Trichinella* are described under section B.3 of this annex.

All operator control records shall be verified on a regular basis and kept at the establishment for at least one year or for the duration of the shelf life of the product if the latter is greater than one year. Records shall be available to the inspector upon request.

The inspector is responsible to maintain a freezing log book in addition to the operator's control records.

B.2 Heating

All parts of the pork muscle tissue shall be heated according to one of the time/temperature combinations listed in Table B.2

Table B.2
Thermal treatments to ensure the destruction of *Trichinella* in Pork Meat

Minimal Internal Temperature (ºC)	Minimum time[1]
49	21 hrs.
50	9.5 hrs.
52	4.5 hrs.
53	2.0 hrs.
54	1.0 hr.
55	30 min.
56	15 min.

Table B.2 Thermal treatments to ensure the destruction of *Trichinella* in Pork Meat	
Minimal Internal Temperature (ºC)	**Minimum time[1]**
57	6 min.
58	3 min.
59	2 min.
60	1 min.[2]
62	1 min.[2]
63	Instant[2]

1 - The time to raise internal product temperature from15ºC to 49ºC shall not exceed 2 hours unless the product is cured or fermented.

2 - Time, when in combination with internal product temperatures of 59ºC to 62ºC, does not need to be monitored if the product's minimum thickness exceeds 5.1 cm and refrigeration of the product does not begin within 5 minutes of attaining 59ºC.

The operator shall use procedures which ensure the proper heating of all parts of the product. It is important that each piece of sausage, ham, and other product treated by heating in water be kept entirely submerged throughout the heating period; and that the largest pieces in a lot, the innermost links of bunched sausage or other massed articles, and those pieces placed in the coolest part of a heating cabinet, compartment or cooking vat be included in the temperature test.

Temperature monitoring shall therefore be conducted at the center of the largest pieces and at the coldest spot of the vat, heating cabinet or smokehouse. The operator shall keep records of their monitoring procedures including results, process deviations and corrective actions. Both the operators monitoring procedures and records should be routinely verified by the inspector as per the Compliance Verification System (CVS) program.

B.3 Freezing

Freezers or floor to ceiling cages used for the destruction of *Trichinella* shall be kept locked by the Inspector-in-Charge to ensure that product is not tampered with.

The keeping of a freezing log book is the inspectors's responsibility. Before product can be put in or be removed from the locked freezing area, the log book (refer to section B.6 of this annex) shall be completed by the inspector. After having checked that the lot has met critical limits, the inspector will sign the log book and allow product to be removed from the freezing area.

After completion of the prescribed freezing, boxed product shall be stamped on the main panel of each box "Frozen for the control of *Trichinella*". The letters of the stamp shall be of a minimum of 5 mm. These stamps shall be kept under the inspector's control at all times. In the case where the treated product is intended for export, the inspector will complete the attestation of freezing (refer to section B.7 of this annex) and will send the completed form with the CFIA/ACIA 1454 to the veterinarian who will sign the export documents.

Highlights of the various approved freezing methods for destroying trichinae

- In methods #1 and #2, room temperature is controlled for the purposes of establishing that the process for destroying trichinae is compliant. Products are put in the freezer after chilling (i.e., once they have reached a temperature no higher than 4°C without being frozen). Owing to these two factors, spacers must be used. The boxes may not be shrink-wrapped.

- In method #3, products are already frozen when the treatment for destroying trichinae begins. The entire treatment needs to be monitored using a properly installed thermocouple. Spacers are not required in this method and the boxes may be shrink-wrapped.

- Method #4 uses both types of monitoring (i.e., first the thermocouple, then room temperature) to ensure the destruction of trichinae. Spacers are not required and the boxes may be shrink-wrapped.

- Method #5 has been developed for meat products frozen in bulk containers according to a specific protocol; the trichinae destruction treatment uses the time/temperature combinations adopted in method #3. Given the size of the containers, spacers cannot be used. Boxes may not be shrink-wrapped.

Freezing Method #1:

When this method is used, pork striated muscle or products containing pork striated muscle tissue, after preparatory chilling to a temperature of 4ºC or less, shall be kept frozen at the indicated temperature for an **uninterrupted** length of time equal or longer to the one specified in the following table.

Table B.3.1
Freezing method #1 to ensure the destruction of *Trichinella* (Temperature -25°C)

Group 1 pork products with maximum thickness of 25 cm	10 days
Group 2 pork products with thickness between 25 - 50 cm	20 days

Insulating packaging material shall be removed prior to the commencement of the freezing process. Boxes shall be stacked in such a way as to permit air circulation and to permit product to reach the freezing room temperature as quickly as possible **(spacers required and no shrink wrap)**.

Freezing time calculation shall begin only from the moment that the freezer's temperature reaches the specified value. In cases where the freezer temperature exceeds the specified maximum temperature indicated in the freezing schedule, the operator shall either use a different time-temperature schedule which allows for the higher temperature or shall restart the counting of the number of uninterrupted freezing days from the moment that the freezer temperature returns below the specified maximum.

Freezing method # 2:

When this method is used, pork muscle or products containing pork muscle tissue, after preparatory chilling to a temperature of 4°C or less, shall be kept frozen at the indicated temperature for an **uninterrupted** length of time equal or longer to the one specified in Table B.3.2.

Insulating packaging material shall be removed prior to the commencement of the freezing process. Boxes shall be stacked in such a way as to permit air circulation and to permit product to reach the freezing room temperature as quickly as possible **(spacers required and no shrink wrap)**.

Freezing time calculation shall begin only from the moment that the freezer's temperature reaches the specified value. In cases where the freezer temperature exceeds the specified maximum temperature indicated in the freezing schedule, the operator shall either use a different time-temperature schedule which allows for the higher temperature or shall restart the counting of the number of uninterrupted freezing days from the moment that the freezer temperature returns below the specified maximum.

Table B.3.2
Freezing Method # 2 to Ensure Destruction of *Trichinella*

Freezer Temperature	**Minimum Number of Days (uninterrupted)**	
(°C)	**Group 1**	**Group 2**
-15	20	30
-23	10	-
-25	-	20
-29	6	12

Group 1: 15 cm thickness or less
Group 2: 15 to 50 cm thickness

In case of doubts, the documented case should be submitted to the Chief, Meat Processing, Meat Programs Division (MPD).

Freezing Method # 3:

In lieu of the methods prescribed in sections Freezing Method # 1 and Freezing Method # 2 above, products containing pork striated muscle may be treated by means of commercial freeze drying or controlled freezing.

When using this method # 3, **there is no obligation to use spacers and the use of shrink wrap around pallets is acceptable.**

Product brought in already frozen shall be treated in accordance with one of the time/product internal temperature combinations specified in Table B.3.3. For **each lot**, the **internal temperature** is to be monitored by a thermocouple placed in the CENTRE of the thickest piece of meat and in the warmest location of the freezer (not close to cooling equipment). The temperature shall be measured with properly calibrated thermoelectric instruments (recording thermometers) and continuously recorded. The charts shall include pertinent information and, at least, the lot number, its description, the number of boxes, date in, date out, and the signature of the inspector.

Table B.3.3 Freezing Method # 3 to Ensure Destruction of *Trichinella*	
Product Internal Temperature(ºC)	**Minimum Time (hours)**
-18.00	106
-21.00	82
-23.50	63
-26.00	48
-29.00	35
-32.00	22
-35.00	8
-37.00	½

Temperature, when measured in degrees Celsius, shall be measured to the next lowest tenth of a degree Cº or, in the case of temperature measuring devices unable to attain such a degree of accuracy, to the next lowest degree C. For example, if a thermometer is not accurate enough to read -23.5ºC, the meat shall be frozen to -24ºC.

Freezing method # 4:

For methods # 1 and # 2, the control of the freezing temperature is accomplished by monitoring the freezer's ambient temperature. For method # 3, the same control is exerted through the use of a thermocouple in the centre of the warmest piece of meat.

A fourth method has been found acceptable. This method is based on both types of controls to ensure the destruction of trichina.

When using this method # 4, **there is no obligation to use spacers and the use of shrink wrap around pallets is acceptable.**

This method is done in two steps.

Step 1:

The purpose of this first step is to ensure that the temperature of all products of the lot to be treated has attained a temperature equilibrium with the freezer' temperature. For **each lot**, the **internal temperature** is to be monitored by a thermocouple placed in the CENTRE of the thickest piece of meat and in the warmest location of the freezer (not close to cooling equipment). For doing so, as soon as the product is brought into the freezer, a thermocouple is placed at the centre of the warmest box of the lot. This box is then placed at the centre of the largest pallet. The temperature shall then be measured with properly calibrated thermoelectric instruments (recording thermometers) and continuously recorded until product temperature at the centre of this box is the same as the freezer's ambient temperature.

Step 2:

At this time, the thermocouple may be removed. The freezing time calculation may begin. The treated products shall be kept frozen at the indicated temperature for an **uninterrupted** length of time equal or longer to the one specified in Table B.3.1 or B.3.2.

For each lot treated, the operator shall keep the charts of the two steps to clearly demonstrate the control that is exerted. Records for the two steps shall be kept on file for each lot. The charts shall include all pertinent information and, at least, the lot number, its description, the number of boxes, date in, date out, the freezing method used and the signature of the inspector. In any case, the official log book shall be completed.

Freezing method # 5

This method is based on the protocol for freezing meat products in bulk containers (refer to Annex P, Chapter 4) and Table B.3.3. It **applies only to big cuts of meat** in bulk containers (e.g., a ham with bone) and has two steps.

Step 1:

The first step consists in ensuring that all refrigerated products that will be put in bulk containers will reach a temperature of -18°C or lower, according to a protocol that has been validated and approved by the CFIA.

From the outset of the freezing process, **core temperature** must be monitored for **each lot** to be treated using a thermocouple inserted in the MIDDLE of the biggest cut of meat located in the warmest part of the freezer (not close to a refrigeration unit). Temperature must be recorded on a continuous basis using properly calibrated thermoelectric instruments (recording thermometers).

A protocol must be submitted, validated and approved in compliance with Annex P of this chapter.

Step 2:

Freezing time for the treatment to destroy trichinae starts now. Treated products must be kept at the prescribed temperature without interruption for the amount of time specified in Table B.3.3.

The thermographs for each lot processed in each step should be preserved to clearly demonstrate that the proper controls have been applied. The temperature recordings for both steps must be kept, along with all pertinent information, notably the lot number, lot description, number of bulk containers, date of entry and removal, and the inspector's signature. The official logbook (section B.6 of this annex) must always be completed.

B.4 Curing:

Acceptable curing methods to ensure the destruction of *Trichinella* in striated pork muscle and meat products containing striated pork muscle are provided in Annex A of this chapter.

B.5 Other Processes:

Subject to approval by the Director, Meat Programs Division, treatment processes for the destruction of infective *Trichinella* in pork striated muscle and meat products containing pork striated muscle, other than those identified in this Annex, may be used. Proposed methods must be demonstrated to the satisfaction of the Director to be safe and to be verifiable by inspection staff. Data must be collected for assessment according to an experimental protocol which has been previously reviewed and accepted by the Director.

B.6 ***Trichinella*** **Control Log**

TRICHINELLA **CONTROL LOG**

Establishment number:
Freezer room/cage number:

PAGE NUMBER: /

Line Number	Lot Number	Product Name	No. Of Boxes In Lot	Slaughter Est. Numbers*	Cut Up Est. Numbers	Beginning Of Freezing Treatment (Yy/Mm/Dd)	End Of Freezing Treatment (Yy/Mm/Dd)	Time/Temp Regime Used (Specify)	Thermo-Graph Chart Reviewed (Requirements Met) Y/N	Number Of Boxes Removed	Date Of Removal (Yy/Mm/Dd)	Number Of Boxes Remaining	Sub-Total (Boxes Remaining) Carried To Line Number:	Export Certif. Number & Destination (Country)	Inspector Signature
001															
002															
003															
004															
005															
006															
007															
008															
009															
010															
ETC...															

B.7 Attestation of Freezing

Canadian Food Inspection Agency | Agence canadienne d'inspection des aliments

Attestation of Freezing
Attestation de congélation

Date:		
Name & Establishment number where product was frozen/ Nom & No. d'établissement où le produit a été congelé :		Product description / Description du produit :
Lot number / Numéro du lot :	Number of containers / Nombre de contenants :	Lot weight / Poids du lot :
Export Certificate number (if applicable)/ Numéro de du certificat d'exportation (le cas échéant) :		Establishment number appearing on boxes / No. d'établissement figurant sur les boîtes :
I hereby certify that the above described product was frozen to destroy *Trichinella* using the following approved freezing method:		Je, soussigné, certifie que le produit décrit ci-dessus a été congelé pour détruire *Trichinella* selon la méthode approuvée suivante:

	Group/ Groupe	Temp. (°C)	Days/Jours
Method / Méthode **1**			
Method / Méthode **2**			

Method / Méthode **3**	Internal temperature / Température interne (°C)	Hours / Heures

Method / Méthode **4**	Product Temperature at equilibrium with freezer's temperature / Température du produit en équilibre avec celle du congélateur (✓)	Method/ Méthode	Group/ Groupe	Temp. (°C)	Days/ Jours
	❒				
	❒				

Inspector /Inspecteur
(Signature)

Inspector /Inspecteur
(Print / Lettres majuscules)

Annex C

Use of Phosphate Salts and Nitrites in the Preparation of Meat Products

C.1 Use of Phosphate Salts and/ or Water in the Preparation of Meat Products

The *Food and Drug Regulations* (B.01.090, B.01.091 and B.01.092) permit the addition of phosphate salts and /or water in meat products. The permitted forms of phosphates are listed in the FDR: Division 16 Table XII. The maximum permitted level of use is 0.5% calculated as sodium phosphate dibasic added to the product. The operator shall verify as part of the HACCP system that recipe and method of production will result in product compliant with the permitted level of use.

The composition and labelling requirements for meat products which contain phosphate salts and/or water are described in the Guide to Food Labelling and Advertising.

The following chart is used to convert other permitted forms of phosphates to sodium phosphate dibasic when calculating the amount of phosphates in a meat product formulation. The synonyms of each form are provided:

Form & Common Synonym	Chemical formula	Molecular weight	Factor
Disodium phosphate -sodium phosphate dibasic	Na_2HPO_4	141.98	1.0
Monosodium phosphate -sodium phosphate monobasic	NaH_2PO_4	119.98	1.18
Sodium hexametaphosphate -sodium polymetaphosphate	$(NaPO_3)_6$	611.17	1.39
Sodium tripolyphosphate -sodium triphosphate	$Na_5P_3O_{10}$	367.85	1.16
Tetrasodium pyrophosphate -sodium pyrophosphate, tetrabasic	$Na_4P_2O_7$	265.94	1.07
Sodium acid pyrophosphate -disodium dihydrogen pyrophosphate	$Na_2H_2P_2O_7$	221.97	1.28
Potassium phosphate, dibasic - dipotassium phosphate	K_2HPO_4	174.18	0.82
Potassium pyrophosphate, tetrabasic -potassium pyrophosphate	$K_4P_2O_7$	330.34	0.86
Potassium phosphate, monobasic -potassium biphosphate	KH_2PO_4	136.09	1.04

Calculation of phosphate salts input levels

Example: Calculation of phosphate salt input levels in a product that is pumped or immersed in brine containing phosphate salts.

Cure unit:	
Sodium tripolyphosphate:	6.41 kg
Sodium nitrite:	0.28 kg
Sodium erythorbate:	0.84 kg
Spices:	0.70 kg
Total Cure Unit	8.23 kg

Brine preparation:

Cure unit:	8.23 kg
Water:	134.00 kg
Salt:	40.00 kg
Total Brine	182.23 kg

% Pump (gain) = 15

Formula 1: % added disodium phosphate

$$\left(\frac{\text{weight of phosphate (kg) } (\textit{in disodium phosphate equivalent})}{\text{weight of brine (kg)}} \right) \times 100 \times \left(\frac{\text{gain}}{(\text{gain} + 100)} \right)$$

Calculation

$$\left(\frac{7.43 \text{ kg } (\textit{6.41 kg x 1.16})}{182.23 \text{ kg}} \right) \times 100 \times \left(\frac{15}{115} \right)$$

= .53% added disodium phosphate

Formula 2:

1. Determine initial % phosphate in brine (in disodium phosphate equivalent)

$$= \left(\frac{(\text{weight phosphate x conversion factor})}{\text{weight of brine}} \right) \times 100$$

Calculation

$$= \left(\frac{6.41 \text{ kg} \times 1.16}{182.23 \text{ kg}} \right) \times 100 = 4.08\% \text{ disodium phosphate in brine}$$

2. % of phosphate based on initial wt of product:

$$= \frac{100 \times \% \text{ pump} \times \% \text{ phosphate}}{100 \times 100}$$

Calculation

$$= \left(\frac{100 \times 15 \times 4.08}{100 \times 100} \right) = 0.612\%$$

3. % Yield:

$$= \frac{(\text{weight final product} - \text{weight initial product}) \times 100}{\text{weight of initial product}}$$

Calculation

$$= \frac{(115 - 100) \times 100}{100} = 15\%$$

4. % added disodium phosphate in final product

$$= \frac{\text{\% phosphate based on initial weight of product x 100}}{\text{weight of initial product + \% yield}}$$

Calculation

$$= \frac{0.612\% \times 100}{100 + 15} = 0.53\% \text{ added disodium phosphate}$$

Notes

It is not necessary to make adjustments for the addition of “rework” containing phosphates, provided the quantity of "rework" material is not more than 10% of the batch weight.

In the case of bone-in meat cuts, the pumping percentage will be calculated on a boneless basis. The amount of bone in a bone-in ham is approximately 15% by weight.

In the case of injected products with rind on (ham, bacon, etc.), no consideration is necessary for the weight of the rind. Rind may be considered as meat.

Fillers (e.g.: soy) are not permitted to be injected into solid meat cuts.

Labelling Requirements for meat product containing added phosphates and/or water

Refer to the Guide to Food Labelling and Advertising.

C.2 Use of Nitrites in Prepared Meat Products

Cured Meat products

“Cured” (MIR) means, in respect of an edible meat product, that salt together with at least 100 ppm of sodium nitrite, potassium nitrite, sodium nitrate or potassium nitrate, or any combination thereof, was added to the meat product during its preparation.

The use of these nitrite or nitrates together with salt is therefore required when “cured“ is listed as a mandatory process in Schedule 1 of the MIR. The nitrite and nitrate salts may also be used as preservatives where permitted in Schedule 1 and in accordance with the *Food and Drug Regulations* Division 16, Table XI Part 1.

In the curing of meat products other than side bacon, the maximum input level of sodium nitrite salts is 20 g per 100 kg of meat product, i.e. 200 ppm. In the curing of side bacon, the maximum input level of sodium nitrite salts is 12 g per 100 kg of pork bellies, i.e. 120 ppm. The operator shall verify as part of the HACCP system that recipe and method of production will result in product compliant with the permitted level of use.

In the production of slow cured meat products, sodium nitrate salt at a maximum input level of 20 g per 100 kg of meat products, i.e. 200 ppm, may be used in addition to the nitrite salts.

In the production of dry rub cured meat products on racks, the maximum level of use is 62 g of sodium nitrite salts and 186 g of nitrate salts per 100 kg of meat product. Operators which use alternate processes for production of dry cured meat products must submit a validated study documenting compliance to the *Food and Drug Regulations* for use of nitrites or nitrates.

In the formulation of a cured meat product, the use of a previously cured meat product as ingredient in excess of 10% will necessitate recalculation of the nitrite/nitrate input to account for the contribution from those ingredients.

Registered establishments that store bulk nitrite or nitrate salts rather than Prague powder or similar premixes shall keep those salts under lock and key and account for their use to prevent an accidental misuse of those potentially dangerous compounds. The company shall maintain a log book for restricted ingredients such as nitrates/nitrites. The log should contain information such as: quantity on hand, quantity used, date, signature of employee. Inspection staff should review the log book periodically and initial it at the time of review. Binder units must have curing salts packaged separately in a coloured bag.

Calculation of nitrite/nitrate salt input levels

Calculation of nitrite in sausage emulsion

Example A:

Formulation: 114 kg sausage mix $\left(\frac{\text{23 g sodium nitrite (bulk)}}{\text{114.023 kg emulsion}} \right)$

Formula 1: ppm nitrite $= \frac{\text{sodium nitrite (g) x 1000 mg/g}}{\text{weight of emulsion (kg)}}$

Calculation: $= \frac{\text{23 g x 1000 mg/g}}{\text{114.023 kg}}$

$= \frac{\text{23,000 mg}}{\text{114.023 kg}}$

$=$ 201.71 mg/kg

$=$ 201.71 ppm

Formula 2: ppm nitrite $= \frac{\text{sodium nitrite (kg) x } 10^6}{\text{wt of emulsion (kg)}}$

Calculation: $= \frac{\text{.023 kg x } 10^6}{\text{114.023 kg}}$

$= \frac{\text{23,000 kg}}{\text{114.023 kg}}$

$=$ 201.71 ppm

Example B:

Formulation: 114 kg sausage mix $\left(\frac{\text{350 g Prague Powder}}{\text{114.35 kg emulsion}} \right)$

Note Prague Powder = 6.25% sodium nitrite
$\therefore$ 350 g Prague Powder = 21.875 g sodium nitrite

Formula 2: ppm nitrite $= \frac{\text{sodium nitrite (kg) x } 10^6}{\text{weight of emulsion (kg)}}$

Calculation: $= \frac{\text{.021875 kg x } 10^6}{\text{114.35 kg}}$

$= \frac{\text{21875 kg}}{\text{114.35 kg}}$

$=$ 191.30 ppm

Calculation of nitrite in injected product

Example:

Formulation:

Cure unit:

Sodium tripolyphosphate:	6.41 kg +
Sodium nitrite:	0.28 kg +
Sodium erythorbate:	0.84 kg +
Spices	0.70 kg
Total	8.23 kg Cure unit

Brine preparation:

Cure Unit	8.23 kg +
Water	134.00 kg +
Salt	40.00 kg
Total	182.23 kg Brine

% Pump (gain) = 15

Formula 1: ppm nitrite $= \left(\frac{\text{wt of nitrite (kg)}}{\text{wt of brine (kg)}} \right) \times \left(\frac{\text{gain} \times 10^6}{(\text{gain} + 100)} \right)$

Calculation: $= \left(\frac{0.28 \text{ kg}}{182.23 \text{ kg}} \right) \times \left(\frac{15 \times 10^6}{115} \right)$

$= 0.0015365 \times 0.130 \times 10^6$

$= 200$ ppm

Formula 2: ppm nitrite $= \left(\frac{\text{wt of nitrite (g)} \times \text{gain (kg)}}{\text{wt of brine (kg)}} \right) \div (100 \text{ (kg)} + \text{gain (kg)})$

Note Assume weight before injection = 100 kg
gain = 15 kg
weight after injection = 115 kg (weight before injection + gain)

Calculation: $= \left(\frac{280 \text{ g} \times 15 \text{ kg}}{182.23 \text{ kg}} \right) \div 115 \text{ kg}$

$= \frac{23.047 \text{ g}}{115 \text{ kg}}$

$= .200$ g/kg

$= 200$ mg/kg

$= 200$ ppm

Annex D

Cooking Time/Temperature Tables

The following tables are derived from the USDA document “Draft Compliance Guidelines for Ready-to-Eat Meat and Poultry Products”.

- If the meat product contains NO poultry[1] species meat, use table 1
- If the meat product contains poultry[1] species meat other than turkey, use table 2
- If the meat product contains turkey species meat, but no other poultry[1] meat, use table 3

[1] For the purposes of this table, “Poultry” is defined as meat coming from chicken, duck, goose, guinea fowl, ostrich, including emu and rhea, partridge, pheasant, pigeon, quail, or turkey.

Table 1 - Times for a given temperature, minimum holding time at that temperature (minimum dwell time) needed to obtain a 6,5D lethality of *Salmonella* spp

Degrees Celsius	Minimum Time to 6,5D reduction	Degrees Celsius	Minimum Time to 6,5D reduction
54.4	112 min	63.3	169 sec
55	89 min	63.9	134 sec
55.6	71 min	64.4	107 sec
56.1	56 min	65	85 sec
56.7	45 min	65.6	67 sec
57.2	36 min	66.1	54 sec
57.8	28 min	66.7	43 sec
58.4	23 min	67.2	34 sec
58.9	18 min	67.8	27 sec
59.5	15 min	68.3	22 sec
60	12 min	68.9	17 sec
60.6	9 min	69.4	14 sec
61.1	8 min	70	Instant
61.7	6 min	70.6	Instant
62.2	5 min	71.1	Instant
62.8	4 min	-	-

Table 2- PRODUCTS CONTAINING CHICKEN MEAT - Times for a given temperature, fat level - minimum holding time at that temperature (minimum dwell time) needed to obtain a 7,0D lethality of *Salmonella* spp

Minimum internal temp.	FAT (%)											
˚C	1%	2%	3%	4%	5%	6%	7%	8%	9%	10%	11%	12%
58	63.3 min	64.5 min	65.7 min	67.0 min	68.4 min	69.9 min	71.4 min	73.0 min	74.8 min	76.7 min	78.9 min	81.4 min
58	50.1 min	51.0 min	52.1 min	53.2 min	54.3 min	55.5 min	56.8 min	58.2 min	59.7 min	61.4 min	63.3 min	65.5 min
59	39.7 min	40.5 min	41.3 min	42.2 min	43.2 min	44.2 min	45.3 min	46.4 min	47.7 min	49.2 min	50.9 min	52.9 min
60	31.6 min	32.2 min	32.9 min	33.6 min	34.4 min	35.2 min	36.2 min	37.2 min	38.3 min	39.6 min	41.1 min	43.0 min
60	25.2 min	25.7 min	26.2 min	26.8 min	27.5 min	28.2 min	29.0 min	29.8 min	30.8 min	32.0 min	33.4 min	35 min
61	20.1 min	20.5 min	21.0 min	21.5 min	22.0 min	22.6 min	23.2 min	24.0 min	24.9 min	25.9 min	27.1 min	28.7 min
61	16.1 min	16.4 min	16.8 min	17.2 min	17.6 min	18.1 min	18.7 min	19.4 min	20.1 min	21.0 min	22.1 min	23.5 min
62	13.0 min	13.2 min	13.5 min	13.8 min	14.2 min	14.6 min	15.1 min	15.6 min	16.3 min	17.1 min	18.1 min	19.3 min
62	10.4 min	10.6 min	10.8 min	11.1 min	11.4 min	11.8 min	12.2 min	12.6 min	13.2 min	13.9 min	14.8 min	15.9 min
63	8.4 min	8.6 min	8.7 min	8.9 min	9.2 min	9.5 min	9.8 min	10.2 min	10.7 min	11.3 min	12.1 min	13.0 min
63	6.8 min	6.9 min	7.0 min	7.2 min	7.4 min	7.6 min	7.9 min	8.2 min	8.6 min	9.1 min	9.8 min	10.6 min
64	5.5 min	5.5 min	5.6 min	5.7 min	5.9 min	6.1 min	6.3 min	6.6 min	6.9 min	7.4 min	7.9 min	8.6 min
64	4.4 min	4.4 min	4.5 min	4.5 min	4.7 min	4.8 min	5.0 min	5.2 min	5.5 min	5.8 min	6.3 min	6.8 min
65	3.5 min	3.5 min	3.5 min	3.6 min	3.6 min	3.8 min	3.9 min	4.1 min	4.3 min	4.6 min	4.9 min	5.4 min
66	2.7 min	2.7 min	2.7 min	2.7 min	2.8 min	2.9 min	3.0 min	3.1 min	3.3 min	3.5 min	3.8 min	4.2 min
66	2.1 min	2 min	2 min	2.1 min	2.1 min	2.1 min	2.2 min	2.3 min	2.5 min	2.6 min	2.9 min	3.1 min
67	1.5 min	1.5 min	1.5 min	1.6 min	1.6 min	1.6 min	1.7 min	1.7 min	1.8 min	1.9 min	2.1 min	2.3 min
67	1.2 min	1.2 min	1.2 min	1.2 min	1.3 min	1.3 min	1.3 min	1.3 min	1.4 min	1.4 min	1.4 min	1.6 min
68	55.9 sec	56.9 sec	58.0 sec	59.1 sec	1.0 min	1.0 min	1.0 min	1.1 min	1.1 min	1.1 min	1.1 min	1.1 min
68	44.2 sec	45.0 sec	45.9 sec	46.8 sec	47.7 sec	48.6 sec	49.5 sec	50.4 sec	51.4 sec	52.4 sec	53.4 sec	54.4 sec
69	35.0 sec	35.6 sec	36.3 sec	37.0 sec	37.7 sec	38.4 sec	39.2 sec	39.9 sec	40.7 sec	41.4 sec	42.2 sec	43.0 sec
69	27.7 sec	28.2 sec	28.7 sec	29.3 sec	29.8 sec	30.4 sec	31.0 sec	31.6 sec	32.2 sec	32.8 sec	33.4 sec	34.0 sec
70	21.9 sec	22.3 sec	22.7 sec	23.2 sec	23.6 sec	24.0 sec	24.5 sec	25.0 sec	25.4 sec	25.9 sec	26.4 sec	26.9 sec
71	17.3 sec	17.6 sec	18.0 sec	18.3 sec	18.7 sec	19.0 sec	19.4 sec	19.8 sec	20.1 sec	20.5 sec	20.9 sec	21.3 sec
71	13.7 sec	14.0 sec	14.2 sec	14.5 sec	14.8 sec	15.0 sec	15.3 sec	15.6 sec	15.9 sec	16.2 sec	16.5 sec	16.9 sec
72	10.8 sec	11.0 sec	11.2 sec	11.5 sec	11.7 sec	11.9 sec	12.1 sec	12.4 sec	12.6 sec	12.8 sec	13.1 sec	13.3 sec
72	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	9.6 sec	9.8 sec	10.0 sec	10.2 sec	10.3 sec	10.5 sec
73	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec
73	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec

Table 3 - PRODUCTS CONTAINING TURKEY MEAT - Times for a given temperature, fat level - minimum holding time at that temperature (minimum dwell time) needed to obtain a 7,0D lethality of *Salmonella* spp

Minimum internal temp.	FAT (%)											
˚C	1%	2%	3%	4%	5%	6%	7%	8%	9%	10%	11%	12%
57.8	64.0 min	64.3 min	64.6 min	64.9 min	65.3 min	65.8 min	66.3 min	66.9 min	67.6 min	68.4 min	69.5 min	70.8 min
58.4	51.9 min	52.2 min	52.4 min	52.8 min	53.2 min	53.6 min	54.1 min	54.7 min	55.3 min	56.2 min	57.2 min	58.5 min
58.9	42.2 min	42.5 min	42.7 min	43.0 min	43.4 min	43.8 min	44.2 min	44.8 min	45.4 min	46.2 min	47.2 min	48.5 min
59.5	34.4 min	34.6 min	34.9 min	35.1 min	35.4 min	35.8 min	36.2 min	36.7 min	37.3 min	38.1 min	39.1 min	40.4 min
60	28.1 min	28.3 min	28.5 min	28.7 min	29.0 min	29.3 min	29.7 min	30.2 min	30.8 min	31.5 min	32.5 min	33.7 min
60.6	23.0 min	23.2 min	23.3 min	23.5 min	23.8 min	24.1 min	24.4 min	24.9 min	25.5 min	26.2 min	27.1 min	28.2 min
61.1	18.9 min	19.0 min	19.1 min	19.3 min	19.5 min	19.8 min	20.1 min	20.5 min	21.1 min	21.7 min	22.6 min	23.7 min
61.7	15.5 min	15.6 min	15.7 min	15.9 min	16.1 min	16.3 min	16.6 min	17.0 min	17.4 min	18.0 min	18.8 min	19.8 min
62.2	12.8 min	12.8 min	12.9 min	13.0 min	13.2 min	13.4 min	13.7 min	14.0 min	14.4 min	15.0 min	15.7 min	16.6 min
62.8	10.5 min	10.6 min	10.6 min	10.7 min	10.8 min	11.0 min	11.3 min	11.5 min	11.9 min	12.4 min	13.0 min	13.8 min
63.3	8.7 min	8.7 min	8.7 min	8.8 min	8.9 min	9.0 min	9.2 min	9.5 min	9.8 min	10.2 min	10.8 min	11.5 min
63.9	7.1 min	7.1 min	7.1 min	7.2 min	7.3 min	7.4 min	7.5 min	7.7 min	8.0 min	8.4 min	8.8 min	9.4 min
64.4	5.8 min	5.8 min	5.8 min	5.8 min	5.9 min	6.0 min	6.1 min	6.3 min	6.5 min	6.8 min	7.2 min	7.7 min
65	4.7 min	4.7 min	4.7 min	4.7 min	4.7 min	4.8 min	4.9 min	5.0 min	5.2 min	5.4 min	5.8 min	6.2 min
65.6	3.8 min	3.7 min	3.7 min	3.7 min	3.7 min	3.8 min	3.9 min	4.0 min	4.1 min	4.3 min	4.5 min	4.9 min
66.1	3.0 min	2.9 min	2.9 min	2.9 min	2.9 min	2.9 min	3.0 min	3.1 min	3.2 min	3.3 min	3.5 min	3.8 min
66.7	2.3 min	2.3 min	2.3 min	2.3 min	2.3 min	2.3 min	2.3 min	2.3 min	2.4 min	2.5 min	2.7 min	2.8 min
67.2	1.8 min	1.8 min	1.9 min	1.9 min	1.9 min	1.9 min	1.9 min	1.9 min	1.9 min	1.9 min	1.9 min	2.1 min

Minimum internal temp.	FAT (%)											
˚C	1%	2%	3%	4%	5%	6%	7%	8%	9%	10%	11%	12%
67.8	1.5 min	1.5 min	1.5 min	1.5 min	1.5 min	1.5 min	1.5 min	1.5 min	1.5 min	1.6 min	1.6 min	1.6 min
68.3	1.2 min	1.2 min	1.2 min	1.2 min	1.2 min	1.2 min	1.2 min	1.3 min	1.3 min	1.3 min	1.3 min	1.3 min
68.9	59.0 sec	59.3 sec	59.5 sec	59.8 sec	1.0 min	1.0 min	1.0 min	1.0 min	1.0 min	1.0 min	1.0 min	1.0 min
69.4	47.9 sec	48.1 sec	48.3 sec	48.5 sec	48.8 sec	49.0 sec	49.2 sec	49.5 sec	49.7 sec	49.9 sec	50.2 sec	50.4 sec
70	38.8 sec	39.0 sec	39.2 sec	39.4 sec	39.6 sec	39.8 sec	40.0 sec	40.1 sec	40.3 sec	40.5 sec	40.7 sec	40.9 sec
70.6	31.5 sec	31.7 sec	31.8 sec	32.0 sec	32.1 sec	32.3 sec	32.4 sec	32.6 sec	32.7 sec	32.9 sec	33.0 sec	33.2 sec
71.1	25.6 sec	25.7 sec	25.8 sec	26.0 sec	26.1 sec	26.2 sec	26.3 sec	26.4 sec	26.6 sec	26.7 sec	26.8 sec	26.9 sec
71.7	20.8 sec	20.9 sec	21.0 sec	21.1 sec	21.2 sec	21.3 sec	21.4 sec	21.5 sec	21.6 sec	21.7 sec	21.8 sec	21.9 sec
72.3	16.9 sec	16.9 sec	17.0 sec	17.1 sec	17.2 sec	17.3 sec	17.3 sec	17.4 sec	17.5 sec	17.6 sec	17.7 sec	17.7 sec
72.8	13.7 sec	13.7 sec	13.8 sec	13.9 sec	13.9 sec	14.0 sec	14.1 sec	14.1 sec	14.2 sec	14.3 sec	14.3 sec	14.4 sec
73.3	11.1 sec	11.2 sec	11.2 sec	11.3 sec	11.3 sec	11.4 sec	11.4 sec	11.5 sec	11.5 sec	11.6 sec	11.6 sec	11.7 sec
73.9	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec

Annex F

Lot Sampling and Inspection/Examination Procedures for Fresh Meat

F.1 Raw meat products other than poultry

F.1.1 Sampling

The number of sample units required is determined using the sampling plans provided. These sampling plans are based on 5.5 kg units.

Once the number of sample units has been determined, a random selection of the samples is made by the inspector or plant employee. (For random sampling procedures, see Chapter 10.

Only 1 sample per box should be selected. When dealing with product in combo bins, the required number of 5.5 kg sample units are to be withdrawn from at least 25% of the total number of combo bins in the shipment.

It should be noted that some of the sampling plans indicate steps A and B. In making the initial sample selection, step A is used. The inspection findings will determine if step B is to be used.

F.1.2 Inspection Procedures

- Boneless meat should be carefully examined for the presence of pathological conditions such as abscesses, etc., spoilage, contamination with ingesta, faecal material, hair, grease, rail dirt, foreign material, presence of spear-grass, blood clots, pieces of hide, and bone or cartilage (gristle) pieces. Cuts should be checked for correct stamping, if appropriate.

- The plant employee or inspector will examine/inspect the product thoroughly and classify defects found according to the appropriate defect criteria table.

F.1.3 Disposition

A decision to accept or reject is made on the defects found. One or more critical defects means the shipment is rejected. With respect to major and minor defects, the decision criteria given in the sample tables are to be used.

If upon completing inspection on the basis of Step A, the lot can be clearly accepted or rejected no further sampling and examination/inspection is required. If the number of major defects or the total number of defects (minor alone or combination of major and minor) falls between the accept and reject numbers, a second sampling and examination/inspection as per step B is done. The defects found are added to those found at Step A and the total numbers are then used to accept or reject the lot.

Note: Total defects are only used if the reject level for major defects has not been exceeded.

F.1.4 Sampling plan and decision criteria

PLAN NO.	SHIPMENT SIZE (kilos)	STEP NO.	NO. SAMPLE UNITS SELECTED AND EXAMINED	NO. DEFECTS FOUND AND ACTION TO BE TAKEN			
				MAJOR		TOTAL (major and minor)	
				ACCEPT	REJECT	ACCEPT	REJECT
1.	454 or less	A	3	0	1	1	2
2.	3629 or less	A	6	0	1	5	6
3.	3630 to 10885	A	9	0	2	4	8
		B	3				
	Total of A + B		12	1	2	8	9
4.	10886 to 27271	A	15	0	3	6	12
		B	15				
	Total of A + B		30	2	3	18	19
5.	27272 to 108861	A	22	0	4	9	16
		B	25				
	Total of A + B		47	3	4	26	27
6.	108862 and over	A	27	0	4	10	19
		B	40				
	Total of A + B		67	4	5	35	36

F.1.5 Examples

F.1.5.1 Lot weighing 18,144 kg packed in 27 kg boxes.

Sampling plan 4 is selected, which means that 15 boxes are to be randomly chosen and a 5.5 kg sample examined from each box.

Findings are as follows:

critical	=	0
major	=	3
minor	=	3
total	=	6

The lot is rejected on the basis of 3 major defects, even though the total number of defects is acceptable.

F.1.5.2 Lot weighing 9,999 kg packed in 9 kg boxes.

Sampling plan 3 is selected which means that 9 - 5.5 kg sample units are required from 9 different boxes.

Findings are as follows:

critical	=	0
major	=	1
minor	=	3
total	=	4

The lot can not therefore be accepted or rejected at this point since the number of major defects lies between 0 and 2. Step B is therefore followed, which means that another 3 units must be selected.

Findings are as follows:

critical	=	0
major	=	0
minor	=	4
total	=	4

These defects are added to those found at step A giving totals as follows:

critical	=	0
major	=	1
minor	=	7
total	=	8

The lot is accepted.

F.1.6 Defect Criteria for Meat from Cattle and Calves

DEFECT	MINOR	MAJOR	CRITICAL
BLOOD CLOTS	40 - 150 mm (GD)	>150 mm (GD); or >5 minor clots *	Any clot(s) that would seriously affect product use
BONE FRAGMENTS	Hard bone <40 mm (GD); bone slivers (from rib) <75 mm x 6 mm	>40 mm (GD); or >5 minor fragments *	Any fragment(s) that would seriously affect product use
BRUISES	25 - 60 mm (GD); or 13 - 25 mm deep	>60 mm (GD); or >25 mm deep; or >5 minor bruises *	Any bruises that would seriously affect product use
DETACHED CARTILAGE LIGAMENTS	>25 mm long and free from muscle tissue	>5 minor defects that would not seriously affect product use	Any cartilage or ligament that would seriously affect product use
FAECAL MATERIAL			Any amount
HAIR, WOOL, HIDE	Hide <10 mm (GD); 5 - 10 strands of hair or wool. The number of minor defects is derived by dividing the number of hairs by 10. Hair cluster in single area	Hide >10 mm (GD); or >25 strands of hair or wool; or >5 clusters of hair provided not affecting product usability *	Hair, hide or wool that seriously affect product use - 100 single strands of hair in one sample unit
HARMFUL EXTRANEOUS MATERIAL		Any substance that would cause minor tissue irritation	Any substance that would cause injury or illness

DEFECT	MINOR	MAJOR	CRITICAL
HARMLESS EXTRANEOUS MATERIAL	Paper or plastic <45 cm²; specks of rail dust covering an area <10 mm (GD); or single grass seeds (not associated with inflammation)	Blunt wood>24 mm (GD); paper or plastic >45 cm²; or specks of rail dust covering an area >10 mm (GD); small insect; >5 minor defects that would not seriously affect product use	Large insect; insect associated with unsanitary conditions; any substance that would seriously affect product use
INGESTA			Any amount
OFF CONDITION (sour)			Any amount of off condition meat
PATHOLOGICAL LESIONS		Any lesion which would not have been evident at PM inspection that would not seriously affect product use	Any other lesion(s)
STAINS, DISCOLOURED AREAS	10 - 40 mm (GD)	>40 mm (GD) >5 minor stains *	Stains that would seriously affect product use
OTHER i.e. Freezer burn	Defect(s) that would affect product appearance but not use	Defect(s) that would materially affect product use	Defect(s) that would seriously affect product use
(GD means Greatest Dimension; > means Greater Than; < means Less Than) * Where minor defects are numerous enough to classify as major, do not score as minor also.			

F.1.7 Defect Criteria for Meat From Sheep, Lamb, Goat and Equine

DEFECT	MINOR	MAJOR	CRITICAL
BLOOD CLOTS	40 - 150 mm (GD)	>150 mm (GD); or >5 minor clots *	Any clot(s) that would seriously affect product use
BONE FRAGMENTS	Hard bone <40 mm (GD); bone slivers (from rib) <75 mm x 6 mm	>40 mm (GD); or >5 minor fragments *	Any fragment(s) that would seriously affect product use
BRUISES	25 - 60 mm (GD); or 13 - 25 mm deep	>60 mm (GD); or >25 mm deep; or >5 minor bruises *	Any bruises that would seriously affect product use
DETACHED CARTILAGE LIGAMENTS	>25 mm long and free from muscle tissue	>5 minor defects that would not seriously affect product use	Any cartilage or ligament that would seriously affect product use
FAECAL MATERIAL			Any amount
HAIR, WOOL, HIDE	Hide <10 mm (GD); 5 - 10 strands of hair or wool. The number of minor defects is derived by dividing the number of hairs by 10. Hair cluster in single area	Hide >10 mm (GD); or >25 strands of hair or wool; or >5 clusters of hair provided not affecting product usability *	Hair, hide or wool that seriously affect product use - 100 single strands of hair in one sample unit
HARMFUL EXTRANEOUS MATERIAL		Any substance that would cause minor tissue irritation	Any substance that would cause injury or illness

DEFECT	MINOR	MAJOR	CRITICAL
HARMLESS EXTRANEOUS MATERIAL	Paper or plastic <45 cm²; specks of rail dust covering an area <10 mm (GD); or single grass seeds (not associated with inflammation)	Blunt wood>24 mm (GD); paper or plastic >45 cm²; or specks of rail dust covering an area >10 mm (GD); small insect; >5 minor defects that would not seriously affect product use	Large insect; insect associated with unsanitary conditions; any substance that would seriously affect product use
INGESTA		<10 mm (GD)	>10 mm (GD)
OFF CONDITION (sour)			Any amount of off condition meat
PATHOLOGICAL LESIONS		Any lesion which would not have been evident at PM inspection that would not seriously affect product use	Any other lesion(s)
STAINS, DISCOLOURED AREAS	10 - 40 mm (GD)	>40 mm (GD) >5 minor stains *	Stains that would seriously affect product use
OTHER i.e. Freezer burn	Defect(s) that would affect product appearance but not use	Defect(s) that would materially affect product use	Defect(s) that would seriously affect product use
(GD means Greatest Dimension; > means Greater Than; < means Less Than) * Where minor defects are numerous enough to classify as major, do not score as minor also.			

F.1.8 Defect Criteria for Meat from Swine

DEFECT	MINOR	MAJOR	CRITICAL
BLOOD CLOTS	40 - 150 mm (GD)	>150 mm (GD); or >5 minor clots *	Any clot(s) that would seriously affect product use
BONE FRAGMENTS	Hard bone <40 mm (GD); bone slivers (from rib) <75 mm x 6 mm	>40 mm (GD); or >5 minor fragments *	Any fragment(s) that would seriously affect product use
BRUISES	25 - 60 mm (GD); or 13 - 25 mm deep	>60 mm (GD); or >25 mm deep; or > 5 minor bruises *	Any bruises that would seriously affect product use
DETACHED CARTILAGE LIGAMENTS	>25 mm long and free from muscle tissue	>5 minor defects that would not seriously affect product use	Any cartilage or ligament that would seriously affect product use
FAECAL MATERIAL			Any amount
HARMFUL EXTRANEOUS MATERIAL		Any substance that would cause minor tissue irritation	Any substance that would cause injury or illness
HARMLESS EXTRANEOUS MATERIAL	Paper or plastic <45 cm²; specks of rail dust covering an area <10 mm (GD); or single grass seeds (not associated with inflammation)	Blunt wood >24 mm (GD); paper or plastic >45 cm²; or specks of rail dust covering an area >10 mm (GD); small insect; >5 minor defects that would not seriously affect product use	Large insect; insect associated with unsanitary conditions; any substance that would seriously affect product use
INGESTA		<10 mm (GD)	>10 mm (GD)

DEFECT	MINOR	MAJOR	CRITICAL
LIPS, EAR CANALS, TEETH, KIDNEYS, LIVER		Any amount for each sample unit	
LUNG TISSUE			Any amount
OFF CONDITION (sour)			Any amount of off condition meat
PATHOLOGICAL LESIONS		Any lesion which would not have been evident at PM inspection that would not seriously affect product use	Any other lesion(s)
SKIN (ON SKINLESS CUTS), HAIR, HAIR ROOTS	Skin (on skinless cuts) <10 mm (GD); Skin (on skinless cuts) with hair or visible hair roots <20 cm^2; 1 defect = - If <13 (strands of hair), Total # of hairs ÷ 3 and/or - Total # of hair roots ÷ 1 and/or - Clusters of hairs in single area.	Skin (on skinless cuts) >10 mm (GD); Skin (on skinless cuts) with - hair or visible hair roots >20 cm^2; or - >13 but <100 single strands of hair in one sample unit.	Skinless or skin on cuts: - skin, hair or hair roots seriously affecting product usability - 100 single strands of hair in one sample unit
STAINS, DISCOLOURED AREAS	10 - 40 mm (GD)	>40 mm (GD) >5 minor stains *	Stains that would seriously affect product use
OTHER i.e. Freezer burn	Defect(s) that would affect product appearance but not use	Defect(s) that would materially affect product use	Defect(s) that would seriously affect product use
(GD means Greatest Dimension; > means Greater Than; < means Less Than) * Where minor defects are numerous enough to classify as major, do not score as minor also.			

F.2 Poultry Reinspection Program for Fresh and Frozen Poultry Carcasses and Parts

See Chapter 19.

Annex G

List of Accepted Starter Cultures

Trade name	Manufacturer
Blend PC, PP, 18, M and PC/M Custom Cultures Custom Cultures TM	ABC Research Corp. 5301 Monona Drive Monona, Wi 53716
Lacto-Set L Lacto-Set M Lacto-Set PC	Auro Tech Inc. N92W144224 Anthony Ave. P.O. Box 774 Menomonee Falls Wi 53052-0774
B-2 Baktoferment 61 (frozen) C-P-77 CS CS299 (CS in freeze-dried form) CSL Duploferment 66 (frozen) Duploferment 66 Special Duploferment 77 STM Duploferment 78 P (freeze-dried) F-LC* (SafePro culture) F-RM-7 Fermentang HP LL-1 LHP LP M-EK-72 RM 2000 S-B-61 (freeze-dried) T-D-66 (freeze-dried) T-RM-10	Chr. Hansen Lab. Inc. 9015 West Maple Street Milwaukee, Wi 53214
Texel M72	Danisco A/S Langebrogade 1001 Copenhagen Denmark
Bitec LK-30 Bitec LM-1 Bitec LS-25 Bitec RP-3	Gewürzmüller GmbH Klagenfurter Straße 1-3 D-70469 Stuttgart Germany
Germet Germet GT Germet X	Hermann Laue 950 Denison Street, Unit 22 Markham, Ont. L3R 3K5

Trade name	Manufacturer
Lyoflore	Lacto-Labo 23, rue du Collège 86620 Dangé-St-Romain France
Lactacel 68 Lactacel 95 Red Lactacel 110 Lactacel 331 Lactacel 804 Lactacel Plus SAGA 75 SAGA 115 SAGA 200 SAGA 444 SAGA 448	Quest International Canada Inc. 2610 J.B. Deschamps Blvd. Lachine, Québec H8T 1C9
Roselae A Roselae B Roselae C	Rosell Inst. 8480 St-Laurent Montréal, Québec. H2P 2M6
Roger Cultures SausageMATE Cultures	Systems Bio-Industries, Inc. 620 Progress Avenue P.O. Box 1609 Waukesha, Wisconsin USA
Trumark Formula 100 Trumark Formula 101 Trumark Formula 102 Trumark Formula 103 Trumark Formula 105 Trumark Formula 150 Trumark Formula LT-1 Trumark Formula LT-11	Trumark Inc. 443 East First Ave. Roselle, N.J. 07203
Biobak Classic No. 6860 Biobak Contra 6864 Biobak K 6820 Biobak N 6810 Biobak P 6840 Biobak S 6850 Biobak SAL 6830 Biobak Ultra 6862	Wiberg Export Ges. Adolf-Schemel-Straße P.O. Box 24A-5O33 Salzburg, Austria

Annex H

MEAT INSPECTION LEGEND STAMP ORDER FORM / FORMULAIRE DE COMMANDE POUR LES ÉTAMPES PORTANT L'ESTAMPILLE

MANUFACTURER (NAME AND ADDRESS)/ FABRICANT (NOM ET ADRESSE) :

STOCK # / # D'INVENTAIRE	DESCRIPTION	QUANTITY / QUANTITÉ	R = Replacement / Remplacement A = Add / Ajout	Total Inventory Now in Stock/ Inventaire complet présentement disponible
	BRASS LEGEND STAMP 1" / ÉTAMPE DE LAITON - ESTAMPILLE 1"			
	BRASS LEGEND STAMP 1½" / ÉTAMPE DE LAITON - ESTAMPILLE 1½"			
	BRASS LEGEND STAMP 2" / ÉTAMPE DE LAITON - ESTAMPILE 2"			
	NEEDLEPOINT LEGEND STAMP 1½" / ÉTAMPE AIGUILLE - ESTAMPILLE 1½"			
	NEEDLEPOINT LEGEND STAMP 2" / ÉTAMPE AIGUILLE - ESTAMPILLE 2"			
	BRASS FACED "T-EU" STAMP / ÉTAMPE DE LAITON - "T-UE"			
	EQUINO STAMP / ÉTAMPE "EQUINO"			
	OVAL BRASS FACED EXPORT STAMP / ÉTAMPE OVALE DE LAITON - EXPORTATION			
	OVAL NEEDLEPOINT EXPORT STAMP / ÉTAMPE OVALE AIGUILLE - EXPORTATION			
	RUBBER FACED EXPORT STAMP COMPLETE WITH ALL LETTERS AND NUMBERS / ÉTAMPE D'EXPORTATION EN CAOUTCHOUC, COMPLET AVEC LETTRES ET CHIFFRES			
	LETTER SET A-Z / JEU DE LETTRE A-Z			
	NUMBER SET 0-9 / JEU DE CHIFFRE 0-9			
	PLASTIC 14" HANDLE / MANCHE-PLASTIQUE - 14"			
	ALUMINUM 11½" HANDLE ONLY / MANCHE-ALUMINIUM - 11½"			
	BRANDER ONLY (NO HEAD) / FER CHAUFFANT (PAS DE TÊTE)			
	1" ENGRAVED BRASS HEAD / TÊTE DE LAITON - ESTAMPILLE 1"			
	1½" ENGRAVED BRASS HEAD / TÊTE DE LAITON - ESTAMPILLE 1½"			
	2" x 1 " ENGRAVED OVAL BRASS HEAD / TÊTE OVALE DE LAITON 2" x 1¾"			

PERSON ORDERING / PERSONNE PLAÇANT LA COMMANDE :			
Name/Nom :	Title/Titre :		
Signature:	Date :		
Billing address / Facturer à :			

For government use only / Pour usage officiel seulement AUTHORIZED BY INSPECTOR-IN-CHARGE / AUTORISÉ PAR INSPECTEUR-EN-CHEF :			
Name / Nom :			
Signature :	Date :		
Ship to / Expédier à :	Address/Adresse :		
❑ Inspector-in-Charge / Inspecteur-en-chef Est.# / N° d'étab. :			
❑ Regional Supervisor / Surveillant régional			
❑ Regional Office / Bureau régional			

Original → Stamp Manufacturer / Fabricant d'estampilles
Copy 1 / Copie 1 → Regional Office / Bureau régional
Copy 2 / Copie 2 → Inspector-in-Charge / Inspecteur-en-chef

Annex K

Tracking Sheet – Option Used for the Control of *E. coli* O157:H7 in Dry and Semi-dry Fermented Sausage

Instructions:

i. Complete a copy of Part I of this form for each dry or semi-dry meat sausage made at the facility.
ii. *If the formulation/manufacturing processes is being changed as a result of the new requirements, a new label registration will be required*. **In this case, complete a copy of Part II of this form as well; AND**
iii. Attach a copy of the registered label and detailed (stamped copy) formulation/processing information which was provided to the labels section at the time of label registration.

The material must be reviewed by the inspector in charge of the establishment and thereafter sent to the Area Program Specialist, Meat Processing.

PART I - to be completed individually for each dry or semi-dry meat sausage made at the facility

1. Product name:

2. Label Registration Number:

3. Option/process controls currently used for the Control of *E. coli* O157:H7:

Option #:	Details regarding the Option
1	Time x Internal Temperature combination is: ___ °C / ___ °F x __ Minutes
2	Check off the process method which you are using under this option

✓❒	Fermentation chamber temperature		pH at the end of fermentation process	Casing diameter	Subsequent process (dry, hold or cook)
	°F	°C			
❒	70	21	≥ 5.0	≤ 55 mm	HEAT (1hr @ 110°F and 6 hrs @ 125°F)
❒	90	32	≤ 4.6	≤ 55 mm	HOLD @ 90°F for ≥ 6 days
❒	90	32	≤ 4.6	≤ 55 mm	HEAT (1hr @ 110°F then 6 hrs @ 125°F)
❒	90	32	≤ 4.6	56 to 105 mm	HEAT (1hr @ 100°F, 1 hr @110°F, 1hr @ 120°F, then 7hrs @ 125°F)
❒	90	32	≥ 5.0	56 to 105 mm	HEAT (1hr @ 100°F, 1 hr @110°F, 1hr @ 120°F, then 7hrs @ 125°F)
❒	96	36	≤ 5.0	≤ 55 mm	HEAT (128°F internal product temperature x 60 minutes) and DRY (at 55°F and 65% Relative Humidity to a Moisture Protein Ration of ≤ 1.6:1)
❒	110	43	≤ 4.6	≤ 55 mm	HOLD @ 110°F for ≥ 4 days
❒	110	43	≤ 4.6	56 to 105 mm	HOLD @ 110°F for ≥ 4 days
❒	110	43	≥ 5.0	56 to 105 mm	HOLD @ 110°F for ≥ 7 days

Option Used for the Control of E. coli O157:H7 in fermented sausage

3	End Product Testing - ***30*** **samples from each lot of finished product** must be tested for at least *E. coli* O157:H7 and *Salmonella*

What laboratory is being used:

What is the official laboratory method used:

4	Check off the process method which you are using under this option

✓❒	Fermentation chamber temperature		pH at the end of fermentation process	Casing diameter	Subsequent process (dry, hold or cook)
	°F	°C			
❒	70	21	≥ 5.0	56 to 105 mm	HEAT (1hr @ 110°F and 6 hrs @ 125°F)
❒	90	32	≤ 4.6	56 to 105 mm	HOLD @ 90°F for 7 days then dry
❒	90	32	≥ 5.0	56 to 105 mm	HOLD @ 90°F for 7 days then dry
❒	110	43	≥ 5.0	≤ 55 mm	HOLD @ 110°F for 7 days then dry
❒	110	43	≥ 5.0	56 to 105 mm	HEAT (1hr @ 110°F and 6 hrs @ 125°F)

Under this option 15 samples of raw batter must be tested **for each lot**

What laboratory is being used:

What is the official laboratory method used:

5	Outside validation by a 3rd party

When/where was the validation test conducted?

Have the testing results been accepted by the Meat Programs Division and the Food Safety Division?
YES ❒ NO ❒
(Until the results are forwarded and accepted, the operator cannot use them to justify manufacturing product under either Option 2 or 4)

What is the D reduction achieved?

If the reduction is less than 5D, 15 samples of raw batter must be tested *for each lot.*

What laboratory is being used:

What is the official laboratory method used:

Option Used for the Control of E. coli O157:H7 in fermented sausage

PART II - To be completed if a change to the process is being made and the label is being re-submitted in order to register the new process.

1. Product name:

2. Previous Label Registration Number:

Date of label (re)submission:

Which option is being proposed for the control of *E. coli* O157:H7?
(indicate the option on the label submission request as well. Ensure that you also provide the following information for the option which you have selected.)

Option #:	Details regarding the Option
1	Time x Internal Temperature combination is: ___ °C / ___ °F x __ Minutes
2	Check off the process method which you are using under this option;

✓❒	Fermentation chamber temperature		pH at the end of fermentation process	Casing diameter	Subsequent process (dry, hold or cook)
	°F	°C			
❒	70	21	≥5.0	≤ 55 mm	HEAT (1hr @ 110°F and 6 hrs @ 125°F)
❒	90	32	≤4.6	≤ 55 mm	HOLD @ 90°F for ≥ 6 days
❒	90	32	≤4.6	≤ 55 mm	HEAT (1hr @ 110°F then 6 hrs @ 125°F)
❒	90	32	≤4.6	56 to 105 mm	HEAT (1hr @ 100°F, 1hr @110°F, 1hr @ 120°F, then 7 hrs @ 125°F)
❒	90	32	≥5.0	56 to 105 mm	HEAT (1hr @ 100°F, 1hr @110°F, 1hr @ 120°F, then 7 hrs @ 125°F)
❒	96	36	≤5.0	≤ 55 mm	HEAT (128°F internal product temperature x 60 minutes) and DRY (at 55°F and 65% Relative Humidity to a Moisture Protein Ration of ≤ 1.6:1)
❒	110	43	≤4.6	≤ 55 mm	HOLD @ 110°F for ≥ 4 days
❒	110	43	≤4.6	56 to 105 mm	HOLD @ 110°F for ≥ 4 days
❒	110	43	≥5.0	56 to 105 mm	HOLD @ 110°F for ≥ 7 days

3	End Product Testing - ***30* samples from each lot of finished product** must be tested for at least *E. coli* O157:H7 and *Salmonella*

What laboratory is being used:

What is the official laboratory method used:

Option Used for the Control of E. coli O157:H7 in fermented sausage

4			Check off the process method which you are using under this option		
✓❒	Fermentation chamber temperature		pH at the end of fermentation process	Casing diameter	Subsequent process (dry, hold or cook)
	°F	°C			
❒	70	21	≥5.0	56 to 105 mm	HEAT (1hr @ 110°F and 6 hrs @ 125°F)
❒	90	32	≤4.6	56 to 105 mm	HOLD @ 90°F for 7 days then dry
❒	90	32	≥5.0	56 to 105 mm	HOLD @ 90°F for 7 days then dry
❒	110	43	≥5.0	≤ 55 mm	HOLD @ 110°F for 7 days then dry
❒	110	43	≥5.0	56 to 105 mm	HEAT (1hr @ 110°F and 6 hrs @ 125°F
❒	96	36	≤5.0	≤ 55 mm	HEAT (128°F internal product temperature x 60 minutes) and DRY (at 55°F and 65% Relative Humidity to a Moisture Protein Ration of ≤ 1.6:1)

5	Outside validation

When/where was the validation test conducted?

Have the testing results been accepted by the Meat Programs Division and the Food Safety Division?
YES ❒ NO ❒
(Until the results are forwarded and accepted, the operator cannot use them to justify manufacturing product under either Option 2 or 4)

What is the D reduction achieved?

If the reduction is less than 5D, 15 samples of raw batter must be tested *for each lot.*

What laboratory is being used:

What is the official laboratory method used:

Option Used for the Control of E. coli O157:H7 in fermented sausage

Annex O

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

O.1 Effective date

This policy is effective on the date of publication.

O.2 Purpose

This policy is being updated for the following reasons:

- to provide clear guidance to industry and inspection staff on the measures required to control *E. coli* O157:H7 in raw beef products, and maintain equivalence with corresponding US policy; and
- to reflect the risk-based approach taken by the CFIA to address the risk posed by this pathogen.

All operators of registered establishments handling raw beef are required to proceed as follows:

- Reassess their HACCP system (prerequisite programs and CCPs) to ensure that it meets this policy's requirements. Please note that, if applicable, pertinent process controls must also be reassessed. Refer to sections O.4 and O.5 of this policy for further details.
- For abattoirs: validate the pathogen reduction step(s) as per section O.8 of this policy.

O.3 Definitions

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

O.3.1 Accredited laboratory

An accredited laboratory, for the purposes of food testing to meet regulatory requirements, is one that is recognized by the Standards Council of Canada (SCC) as conforming to its Program for the Accreditation of Laboratories/Canada (PALCAN) requirements including the requirements of the Agriculture and Food Products Program Speciality Area.

O.3.2 Confirmed Positive for *E. coli* O157:H7

A biochemically-identified *Escherichia coli* isolate that is serologically or genetically determined to be "O157" that meets at least one of the following criteria:

1) positive for Shiga toxin (ST) production; and/or
2) positive for Shiga toxin gene(s) (*stx*); and/or
3) genetically determined to be "H7".

O.3.3 D value

A unit which expresses the lethality of a process. One "D" equals the destruction of 90% of the target organisms that may be present in the product. Hence, a process that achieves a 5 D reduction for *E. coli* O157:H7 is capable of destroying 10^5 of these organisms in the product, or achieving a 99.999% reduction in the number of any organisms potentially present.

O.3.4 *E. coli* O157:H7

E. coli O157:H7 is an enterohaemorrhagic, shiga toxin producing strain of *E. coli*. For the purpose of this policy, this pathogen is defined as follows:

- gives a positive test for detection of *E. coli* serotype O157 from an enrichment broth, and
- a pure isolate from the enrichment broth is confirmed with biochemical and serological tests as *E. coli* O157. Further, an accredited laboratory must confirm the pathogenicity of the isolate by a positive result on either of the following tests:
  - the production of Shiga toxin(s)
  - presence of one or more of the Shiga toxin genes
  - serological and/or molecular test confirming the presence of the H7 antigen.

Note: All the results from the above listed options to confirm the pathogen must be found negative in order to report a **negative** final assessment report.

O.3.5 Full lethality treatment as applicable to beef products

In the context of this policy, a beef product is considered to have received a full lethality treatment when the manufacturing process has been scientifically validated to achieve a 5 D reduction of *E. coli* O157:H7.

O.3.6 Lot

When testing raw beef as per this policy's requirements, a lot is defined as comprising all cartons, packages or containers of raw beef either:

- packed on a given packing line and based on Sanitation Standard Operating Procedures; or
- determined by the operator when implementing a statistically based sampling program (robust testing or alternate sampling protocol accepted by the CFIA).

A lot may be defined either in time or space but cannot exceed a single day’s production.

O.3.7 Presumptive Positive for *E. coli* O157:H7

A sample that causes a positive reaction with a CFIA recognized screening test (see Appendix 2 at the end of this policy).

O.3.8 Raw beef

For the purpose of this policy, the term raw beef includes beef, veal as well as their hearts, head meat, cheek meat, oesophagus, etc. (i.e., striated muscle). Raw beef includes 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.

O.3.8.1 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, trimmings removed from the aforementioned parts, head meat, cheek meat, diaphragm, and intercostal muscle.

O.3.8.2 Non-intact raw beef:

Non intact raw beef is beef that has been either:

- tenderized;
- injected;
- submitted to a process that incorporates a solution (e.g.: massaging, tumbling); or
- diced.

Comminuted beef:

This includes ground/comminuted beef, finely textured beef and mechanically separated beef.

O.3.9 Robust testing of beef trim or raw beef material that is used in the production of ground beef

A minimum of 60 samples must be examined per lot.

A lot cannot exceed 5 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., one pallet of boxes of product = 1 combo), provided the number of units and weight do not exceed 5 and approximately 4,500 kg respectively.

All combos/units must be sampled. A minimum of 12 individual pieces shall be taken from each combo/unit.

A minimum of 325 g of material from each lot shall be collected and submitted for testing and at least 65 g of material shall come from each of the combo/units making up the lot. This means that each sampled piece should weigh approximately 5-6 g. The material sampled for testing must represent the outside surface of the cut (e.g., carcass surface, exposed surfaces of the heart muscle, external aspect of the diaphragm muscle, etc.), i.e. it must not be taken from inner meat tissue.

Notes:

- In the N-60 sampling procedure, 60 represent the minimum number of sub-samples required, regardless of the size of the lot. That is to say, whether the lot comprises one, two, three, four, or five combos, 60 sub-samples must be collected from the lot. As well, a total of 60 sub-samples must be collected from the lot regardless of its weight.

- Alternate parameters may be used to define robust testing provided they have been evaluated by CFIA (the Meat Programs Division and Food Safety Division) and provide an equivalent or increased level of confidence.

O.4 Risk posed by *E. coli* O157:H7

Operators are required to maintain their HACCP system up-to date so all applicable regulatory and policy requirements are met. In light of the up-dating of policy requirements, operators of *all* establishments that produce or receive raw beef products are required to **reassess their HACCP system** to ensure that it meets this policy's requirements. For the purpose of this policy, the term HACCP system encompasses all process controls that need to be used by the operator to control *E. coli* O157:H7.

It is clear, based on available information, that ***E. coli* O157:H7 contamination of raw beef is a health hazard likely to occur** and that control measures need to be implemented. It should be kept in mind that *E. coli* O157:H7 is an unacceptable contaminant in beef and that contaminated products are subject to recall.

As part of the reassessment, the following information must be included in the HACCP system:

- FSEP forms (or equivalent) on **product identification** and **intended use** are to be reviewed for **completeness** and **accuracy** with regards to the *E. coli* O157:H7 hazard and controls;

- the *E. coli* O157:H7 hazard shall be clearly identified on the FSEP form # 5 (or equivalent). This hazard must be passed through the decision tree (FSEP form # 8 or equivalent);

- the operator has to determine how the hazard will be addressed:
  - through CCP(s) at the establishment during production;
  - when receiving raw beef products or
  - through other validated measures that will prevent distribution of potentially contaminated products.

For abattoirs, particular attention must be paid to airflow, as well as employee movement between the clean and the relatively less clean areas of the processing areas as these factors have recently been strongly associated with the microbiological contamination levels of the carcasses. Segregation of incompatible activities, product flow, equipment sanitation as well as employee training (GMPs, hygienic handling, dressing procedures etc.) should also be evaluated. Finally, as adequate refrigeration plays an important role in preventing the multiplication of *E. coli* O157:H7, operators should confirm that they have sufficient cooling capacity to handle their volume of production while meeting the carcass cooling guidelines found in the Meat Hygiene Manual of Procedures, Chapter 4.

The operator must ensure that all pertinent aspects of his HACCP system have been updated as required.

O.5 Control measures/interventions

Operators shall ensure that their HACCP system has been validated and is effective, such that the level of *E. coli* O157:H7 in raw beef products distributed outside of federally registered establishments is below detectable level (i.e., no *E. coli* O157:H7 detected in a sample when tested with one of the approved methodologies [please refer to Appendix 2 at the end of this policy for the relevant information]. In all cases, control measures must be in place at the establishment to prevent growth of, or contamination with, *E. coli* O157:H7.

The following **control measures** are to be implemented:

O.5.1 Abattoirs

Cattle are the primary source of *E. coli* O157:H7 that infects humans. The shedding of *E. coli* O157:H7 in cattle feces is intermittent and increases during summer and fall season. Contamination of beef carcasses with *E. coli* O157:H7 occurs during slaughtering and dressing procedures, especially during the de-hiding process.

Subsequent use of any meat components derived from a contaminated carcass may find its way into raw ground beef, which is considered the greatest risk in causing human illnesses. In the case of a slaughter establishment, as a result of the reassessment of the operator's HACCP system, the operator is expected to:

O.5.1.1 All abattoirs

- Use one or more intervention(s), such as steam pasteurizer, organic acid sprays, etc., validated according to this policy (please refer to section O.8), at the time of slaughter to reduce the *E. coli* O157:H7 contamination to below detectable level; cover this (these) intervention(s) with a CCP.

- Control air contamination, airflow (positive pressure) and employee movements between clean and relatively less clean areas of the processing areas.
- The storage and transportation prerequisite program must indicate that conditions under which the carcasses were kept were satisfactory. This includes, but is not limited to, storage temperature.
- Implement a verification step to ensure the effectiveness of the interventions covered by the CCP. This procedure must include either:
  - testing of the carcasses for the pathogen, or a surrogate organism, as described in section O.9 of this policy; OR
  - integrated use of test results for downstream *E. coli* O157:H7 tests performed by affiliated establishments that receive carcasses from the establishment: the operator of the abattoir must first present the integrated plan to the CFIA, and the CFIA must accept the plan as equivalent to carcass testing in order for this option to be allowed. Contact the area program network specialist for details.

O.5.1.2 Abattoirs with boning/cutting operations

For abattoirs which also have boning/cutting operations, **in addition to the requirements stated under section O.5.1.1 above,** the following requirements apply to carcasses being processed as well as to product obtained after the cutting/boning operations:

- Carcasses must have been subject to the pathogen reduction intervention(s) (validated CCP as per O.5.1.1) used at the establishment; pertinent HACCP records must indicate that the CCP was under control;
- The storage prerequisite program must indicate that conditions under which the carcasses were kept until being boned/cut were satisfactory. This includes, but is not limited to, storage temperature as well as cross-contamination potential;
- Conditions under which the carcasses were further processed (cutting/boning) were satisfactory and met the HACCP system specifications;
- If any of the raw beef products obtained from the boning/cutting processes tests positive for *E. coli* O157:H7 (whether the test is performed at the establishment or when product is received by a customer), the investigation must also include the evaluation of all the parameters of the slaughter process that have an impact on the presence of *E. coli* O157:H7.

O.5.2 Receiving establishment

After the reassessment of their HACCP system, the operator receiving raw beef must choose either one of the following options:

- Implement purchase specifications (please refer to section O.6 of this policy) and determine that the control provided by either the Receiving CCP or the Transportation, Receiving & Storage Prerequisite Program (B2.1.3) receiving step is adequate to ensure that these purchase specifications are met. These purchase specifications must require that all suppliers have one or more validated CCPs in their production of raw beef shipped to the receiving establishment and that their controls are effective and ensure that *E. coli* O157:H7 is below detectable level;
- Determine that validated CCP(s) is (are) already in place at the establishment or will be added to control the hazard associated with *E. coli* O157:H7 (e.g., all raw beef received is used in the production of fully cooked product or subjected to another accepted full lethality treatment).

O.5.3 Mandated testing of beef trim and other raw beef components that are used for the production of ground beef

Trim as well as other raw beef components, such as chucks, head meat, cheek meat, weasand meat, hearts, etc. may be used for the production of ground beef. Operators must determine, for each of these products, whether or not part of their production may be used in

the manufacture of ground beef. If so, that product must be tested at the frequency indicated below. This testing frequency has been determined according to the volume of production which has a direct impact on the level of risk as it in linked to consumer exposure. The tests used must satisfy the conditions set out in Appendix 2 at the end of this policy document.

Operators must therefore establish their yearly production volume (in kg) for the trim, as well as for any of the raw beef components they produce that may be used in the production of ground beef. When only part of the production of a given product will be used for the production of ground beef, operators only need to test the product that will be used in the production of ground beef. This must be adequately documented in the operator's HACCP plan. For instance, records indicate that 30% of the hearts produced yearly are used for the production of ground beef. This means that the hearts making up that 30% must be tested at the applicable frequency (section O.5.3.1 will apply when the weight of the hearts used for ground beef production is 25,000 kg or less, and section O.5.3.2 will apply when this weight is greater than 25,000 kg).

When the use of the product can not 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 ground beef and **must** be included in the production that falls under the testing requirement.

Operators must keep this information current and accurate. For instance, any increase in the production must be evaluated to determine if it impacts the testing frequency of a given product.

When receiving raw materials used in the manufacture of raw ground beef, the operator has verified that the raw materials have all been tested as required under this section.

O.5.3.1 Production of 25,000 kg or less per year of a given product

Considering the small volume of product this represents, operators need to test this product three (3) times per year as per the N=60 sampling procedure.

O.5.3.2 Production of over 25,000 kg per year of a given product

These operators must implement a robust testing protocol, as defined in this policy, for any product that falls under this category.

O.5.4 Raw beef used to manufacture fully cooked products or used in a process that includes an accepted full lethality treatment

As a result of the reassessment of its HACCP system, the operator may determine that the hazard related to *E. coli* O157:H7 is likely to occur, but that no new CCP(s) is/are required in the establishment because all products are subjected on site to a full lethality process (e.g., cooked to achieve a 5D reduction) or shipped directly to another federally registered establishment where similar steps are taken to control the hazard.

Where this occurs, the operator must provide details on the control measures in place to ensure that the product receives the full lethality process and that it is not diverted elsewhere (i.e., how inventory is managed, if boxes have special markings [e.g., "For Cooking"/"For Full Lethality Treatment"]). The measures need to be incorporated and evaluated for compliance and effectiveness within the operator's HACCP system.

In the case of product sent for a lethality treatment after it has been tested and found positive for *E. coli* O157:H7, or that the operator has chosen to treat as positive for the pathogen based on screening results, refer to section O.13.1.1 of the present text.

O.5.5 Production of non-intact raw beef products

For products which will be subjected to **dicing, massaging/tumbling, mechanical tenderization, needling** or **injection,** the equipment used may translocate bacteria from the surface of a contaminated cut of meat to its interior, as well as cross contaminate subsequent portions processed by the same machine.

Operators utilizing these types of process are therefore required to review the effectiveness of their **sanitation procedures** in regards to the tenderizing equipment, as well as the effectiveness of their purchasing specifications and receiving controls for incoming raw beef. Operators manufacturing non-intact products should assess their activities against published industry best practices, for example the Beef Industry Food Safety Council "Condensed Non-intact Processing Best Practices" (http://www.bifsco.org/BestPractices.aspx) – in cases where products manufactured at the facility are found to be associated with a positive *E. coli* O157:H7 sample of trim meat, they must be able to justify any deviation from these practices.

O.5.6 Raw intact primal and sub-primal cuts

It should be noted that intact primal and sub-primal cuts used as such by the consumers do not pose the same level of risk as ground beef. In contrast to ground beef, the interior of these intact raw beef products is considered free of pathogens. Consequently, customary cooking of these products will destroy any *E. coli* O157:H7 that might be present on surfaces.

Trim generated during the manufacture of primal and sub-primal cuts must be subjected to controls to ensure that the end product into which they will be used do not contain detectable levels of *E. coli* O157:H7. In the case they will be used for the production of ground beef, they must be tested at the frequency prescribed under section O.5.3 of this policy. The other option is to use the trim for the production of a product that will be cooked or subjected to a full lethality treatment in a federally registered establishment and under a HACCP system that addresses the potential *E. coli* O157:H7 contamination hazard.

Like all establishment s producing raw beef products, an establishment processing primal and sub-primal cuts is required to reassess its HACCP system for this product in light of relevant data on *E. coli* O157:H7 to determine whether its HACCP system appropriately addresses this hazard. An establishment producing and distributing pre-packaged intact steaks may conclude it does not need to change its HACCP system for these products.

O.6 Purchase specifications

The following **purchase specifications** must be recognized and filed accordingly by receiving operators in their HACCP system:

O.6.1 Letter of guarantee

A letter of guarantee from supplying companies must be on file identifying the validated intervention(s) (CCP) as well as other measures used to reduce, prevent or eliminate the hazard associated with *E. coli* O157:H7. The letter must be dated and signed by the operator, or a designated person, of the supplying establishment. The letter must include a statement to the effect that when the supplier obtains an unsatisfactory result, the operator(s) of the establishment(s) which have received implicated product will be notified as well as the supplier's local CFIA inspection staff. Once notified, the operator(s) of the receiving establishment(s) must in their turn inform their respective CFIA Inspector in Charge.

Note: A certificate of analysis, although providing an increased level of confidence, cannot be used in lieu of a letter of guarantee. A letter of guarantee provides confirmation that the process under which the product was manufactured is under control and that the purchase specifications are met. A certificate of analysis provides additional information about testing results for a specific lot.

O.6.2 Verification step for the receiving CCP or PP (B.2.1.3)

As a **verification step for the receiving CCP or PP (B.2.1.3),** the receiving operator must verify that the supplier is applying effective measures for the control of *E. coli* O157:H7 in **raw beef trim and other raw beef components used in the manufacture of ground beef, and are doing all testing required by section O.5.3 of this policy**.

The receiving operator may achieve this by specifying the following requirements within purchase specifications for each of their suppliers:

O.6.2.1 For suppliers producing more than 25,000 kg per year of raw beef trim and ground meat components (per category):

- the supplier performs robust testing on each production lot of raw beef trim and ground meat components as per section O.5.3 of the CFIA "Policy on the Control of E. coli O157:H7 Contamination in Raw Beef Products"
- the supplier provides a certificate of analysis (COA) for each lot of raw beef trim and ground meat components sent to the receiving establishment. The COA must indicate results of testing for the specific lot being sent. The result of the test must be negative (*E. coli* O157:H7 not detected);
  - the supplier does routine *E. coli* O157:H7 verification testing of raw beef trim and ground meat components, with the frequency adjusted for low and high prevalence seasons (e.g., increasing from May to September); and
  - the supplier is subjected to third-party audits and can demonstrate through the audit reports that the above requirements are all being implemented in a suitable manner.

Notes: (For suppliers producing more than 25,000 kg per year**)**

- The third-party audits must be conducted by a firm, organization or individual who has a proven track record in performing this type of review. On an exceptional basis and with the agreement of the supplying establishment, an audit may be conducted by an employee of the receiving establishment. The CFIA reserves the right to reject an auditor who fails to suitably demonstrate that they meet the above criteria or who refuses to provide reports to the CFIA upon request.
- If all of the above requirements are met, the receiving establishment would not need to perform verification testing of received lots of raw beef trim or ground beef components.
- Where all of the above requirements are met for all incoming raw material, the operator would be eligible to develop and, subject to CFIA approval, implement a protocol to subdivide ground beef production into separate lots based on timed end product testing.

O.6.2.2 For suppliers producing 25 000 kg or less per year of raw beef trim and ground meat components (per category):

A letter to that effect is provided by the supplier and kept on file by the purchaser. The supplier also confirms on a yearly basis that the requested tests have been performed.

The following requirements apply when testing product at reception:

- Product tested must be from a single supplier.
- The supplier must be informed that the product shipped will be tested when received.
- No co-mingling of lots can be done (each lot must be sampled on its own)

- There must be an agreement as to whether or not presumptive positives will be confirmed.
- The disposition of the product must be agreed to when the laboratory result is not satisfactory.

When a presumptive positive result obtained by the receiving operator impacts on another establishment (for instance, product tested at the receiving step was a presumptive positive), the operator performing the test must have a prior agreement with the supplier whether a presumptive positive is accepted as a positive result. (see section O.13 of this policy)

O.7 Cross-contamination potential

In the case of operator handling both raw beef products considered to be below detectable level for *E. coli* O157:H7 and beef products potentially contaminated with *E. coli* O157:H7, the operator must develop and implement a written segregation protocol to ensure that raw beef products received for cooking or other full lethality process are not used in the production of finished raw beef products and that cross-contamination is prevented.

The appropriate information must be reflected 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. For example, a letter of guarantee regarding *E. coli* O157:H7 is required only for products received for raw beef product manufacturing and not for those received for further cooking or other full lethality process. For audit purposes, these segregation procedures would be audited under the appropriate Prerequisite Program.

O.8 Validation of pathogen reduction step(s) - Abattoirs

Validation of in-plant pathogen reduction steps (CCPs) must be performed as per the FSEP approach. FSEP defines "validation" as: obtaining confirmation that the elements of the HACCP system are **complete** and **effective** in controlling biological, chemical and physical hazards. This may include ingredient sampling, end product sampling, etc. In this case, this means more specifically doing all of these 3 steps:

Step 1
Gather published scientific information on the experimental reduction effect of the chosen pathogen reduction intervention and all relevant critical factors (for example, intervention “Y” should result in a 2.0 log reduction considering parameters defined under experimental conditions such as pressure, temperature, time, chemical concentration, etc.);

Step 2
Demonstrate the effectiveness in reducing a suitable surrogate level by “X” logs under in-plant operational conditions (e.g., generic *E. coli* or *Enterobacteriaceae* as indicators are reduced by “X” logs by intervention “Y”) for each of the interventions that the operator has chosen to implement. An appropriate surrogate is an organism that has a heat resistance, growth range, pH range, ability to grow on selective media, etc. that is similar to *E. coli* O157:H7. This is normally done by comparing surrogate levels in a sample taken **before and after** the intervention. The operator shall choose a statistically significant sample size over a period of **4 months** to demonstrate that on-site intervention is achieving the log reduction targeted. ***E. coli* O157:H7 must not be introduced for experimental purpose in registered establishments.** Please see Appendix 1 for guidance on sample size, **required number** of samples (Table 1) and statistical analysis, and refer to Annex T of the United States section of Chapter 11 of the Meat Hygiene Manual of Procedures for the complete information about the testing procedure.

Step 3
The sum of the log reductions from all interventions (CCPs) must result in a final product that is below detectable level for *E. coli* O157:H7. The demonstration should be based on a

statistically significant number of finished product samples i.e., provide a 95% level of confidence that *E. coli* O157:H7 is below detectable level. Because of the expected variability of *E. coli* O157:H7, this validation sampling should be done by randomly taking the required number of samples **over one month** of production as reflected in Table 1, Appendix 1. Based on the current prevalence of *E. coli* O157:H7 in raw beef products, sampling plans used for validation of controls must use a 0.1% expected prevalence. Sampling of carcasses should be conducted in accordance with Annex T of the United States section of Chapter 11 of the Meat Hygiene Manual of Procedures for the complete information about the testing procedure.

Notes

- If the lot size (i.e., number of animals slaughtered) falls between two values appearing in columns 1 for Tables 1 and 2, 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 when testing for validation or verification purposes. In all cases, laboratories MUST use a Health Canada official method (see Appendix 2). Laboratory results (laboratory tests certificates) shall indicate which method has been used to analyze the samples.

Validation is to be completed initially to demonstrate that the interventions put in place by the operator are effective in producing meat products that are below detection level for *E. coli* O157:H7. Validation has to be conducted again when the operations have changed substantively and/or pathogen intervention(s) has (have) been added or modified in a novel manner. The plant management and VIC/IIC may consult with the area program specialist regarding the need to revalidate a pathogen reduction intervention.

O.9 Verification activities and testing

O.9.1 Abattoirs (with or without boning/cutting operations)

Pathogen reduction steps are expected to become part of a CCP when passed through the decision tree (FSEP form # 8). Verification must therefore be performed as per the FSEP Program. In this case, this means more specifically that:

- Records are reviewed.
- On-site reviews are conducted to ensure that the written program is implemented as planned.
- The appropriate level of random product testing is done on a routine basis for *E. coli* O157:H7 or a surrogate organism. For the purpose of this testing, a lot may be defined as one carcass that is randomly selected for testing. The carcass, as well as one carcass preceding and following the tested carcass, should be held pending the receipt of results. In the event that the result for the tested carcass is positive, all three carcasses are considered as contaminated by the pathogen and must be subjected to a full lethality treatment or denatured and condemned.

When operators decide to test for a surrogate organism, they will have to meet the following conditions:

- Justify the choice of the surrogate organism used for that purpose.
- Indicate what level of that organism will be considered as a non-compliance (critical limits) and provide the rationale for that decision.
- Include in the HACCP system the corrective actions that will be implemented when the concentration of the surrogate organism is above the critical limit.

- This option may be used after the CFIA has reviewed and accepted the operator's proposal for the use of this surrogate organism.

Please refer to Annex T of the United States section of Chapter 11 of the Meat Hygiene Manual of Procedures for the complete information about the testing procedure. Acceptable laboratory methodologies are listed under Appendix 2 of this policy. The following minimum testing frequencies, based on the average production volume per month, have been established:

Establishment's category	Average production volume per month	Frequency of sampling*
High volume	More than 5000 heads	One carcass every month
Medium volume	500 to 5000 heads	One carcass every other month
Small volume	Less than 500 heads	One carcass every three months

* It is the operator's responsibility to implement these activities at a frequency which will ensure that finished product will meet applicable requirements.

Note: Abattoirs operators that can provide test results from downstream *E. coli* O157:H7 testing performed by affiliated operators receiving their carcasses may be exempted from carcass testing as indicated under section O.5.1.1 of this policy.

O.9.2 Receiving establishments

Operators receiving raw beef products ensure that the products received meet their purchase specifications either by a Receiving CCP or the Transportation, Receiving & Storage Prerequisite Program (B2.1.3). Verification must therefore be performed as per the FSEP Program. In this case, this means more specifically that:

- records are reviewed;
- on-site reviews are conducted to ensure that the written program is implemented as planned;
- in the case of raw materials used in the manufacture of raw ground beef, the operator has verified that the raw materials have all been tested as required under section O.5.3 and O.6.2 of this policy;
- auditing of suppliers (Optional) may also be performed as a verification activity.

It is the operator's responsibility to implement these activities at a frequency which will ensure that finished product will meet applicable requirements.

O.10 Lot considerations

The following guidelines should be used to define a lot for the purpose of sampling carcasses, trimmings, manufacturing beef or ground beef for *E. coli* O157:H7.

Before taking a sample for *E. coli* O157:H7 testing, the operator must isolate and clearly identify the lot to the satisfaction of the CFIA inspector. It is strongly recommended that the lot, and any raw product manufactured from the lot, be detained 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.

- For trimmings, as well as other raw beef material that may be used in the production of ground beef, CFIA would recognize the operator's definition of the sampled lot, provided the operator has implemented a robust sampling plan as per section O.5.3 of this policy.

- For the purpose of carcass testing, it has been accepted by both Health Canada and the CFIA that the tested carcass represents a lot on its own. However, to address cross-contamination potential when a carcass is found positive for *E. coli* O157:H7, the tested carcass as well as the one carcass preceding and following the tested one will be considered as positive product.

For other raw beef products, if no satisfactory scientific basis is provided by the operator for lot definition, **the default lot considered** by the CFIA will be from clean-up and sanitation to the next clean-up and sanitation.

It should be noted that if an operator has a validated HACCP system and regularly tests specific lots of product and are found negative for *E. coli* O157:H7, this information could possibly be a basis for determining whether one *E. coli* O157:H7-positive lot will implicate other lots produced on the same day.

O.11 Transit of raw product within the federal system

When an establishment receiving raw beef is in turn supplying raw beef products to another establishment, the following guidelines apply:

- Both operators must have purchase specifications to prevent *E. coli* O157:H7 from entering their facilities, which could be based on those described in section O.6.2 of this policy, as part of their verification activities. In this case, the letter of guarantee provided by the establishment that receives and ships raw beef should state that the operator has a control in place to address the risk associated with *E. coli* O157:H7 at receiving (CCP or pre-requisite program), and has letters of guarantee from all of their own suppliers on file.
- In addition to purchase specifications addressing *E. coli* O157:H7 referred in O.5.2, receiving establishments must ensure that measures are in place to prevent *E. coli* O157:H7 growth or contamination after product is received.

  For additional information on letters of guarantee, please refer to section O.6.1.

O.12 Shipping of tested product pending receipt of results

O.12.1 Product shipped to a storage

When tested product is shipped to a storage facility pending reception of results, the following conditions apply:

- The **shipping** establishment must:
  - Maintain complete records identifying the type of product, as well as quantity, being shipped
  - Identify the product in an appropriate way
  - Control product while it is in transit. The use of company seals is mandatory.
  - 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.)

- The **receiving** establishment must:
  - Maintain complete and accurate records of all product received under these conditions. This information must be captured in their HACCP files.
  - Keep the product segregated until the laboratory results are obtained.

O.12.2 Product shipped to a customer

Operators who elect to ship tested product to a customer prior to being informed of the laboratory results must inform their clients that the product cannot be used before they are notified that the results were satisfactory. The CFIA strongly advises against this procedure.

When a product has been distributed prior to its testing results being known and the test results indicate a potential or confirmed *E. coli* O157:H7 result, the CFIA must be immediately notified and the incident treated as a potential recall situation.

O.13 Positive results for *E. coli* O157:H7

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 (for instance, product tested at the receiving step was a presumptive positive), the operator performing the test must have a prior agreement with the supplier whether a presumptive positive is accepted as a positive result, or a complete laboratory confirmation will be performed to determine either a positive or negative result (please refer to Appendix 2 of this policy). All registered establishments who purchase raw beef must document prior agreements in their HACCP systems. This ensures that product disposition and follow-up for both the supplier establishment and purchasing establishment can proceed expediently when a presumptive positive result is obtained.

When obtaining positive results for *E. coli* O157:H7, whether confirmed or considered as positive, the operator must:

- dispose appropriately of the positive product, as per section O.13.1 of this policy; and
- take immediate action, as per section O.13.2 of this policy.

O.13.1 Product disposition

The options for product disposition, which must be conducted under the CFIA's authorization and supervision, are as follows:

- Process the product into a fully cooked finished product within the federally registered sector. If done in a different establishment, it must be transferred under company seal and the adulterated product must be sent directly to an establishment that provides the heat treatment to the product; appropriate records must be kept by all involved operators to ensure complete control over the product until the risk has been addressed.

- Denature and condemn the product under direct CFIA's supervision. OR

- 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 options described above.

Whichever option is selected, the traceability component must be covered in detail in the operator's HACCP system.

Note: Operators may ask the CFIA to store positive product prior to submitting it to the lethality treatment (cooking). Any such request must be presented to the Area Program Specialist for evaluation. If accepted, the HACCP systems of both the shipping establishment and the storage establishment must address this situation. Appropriate controls must be in place and monitored (including but not limited to product inventory, segregation procedures, seals used for transit etc.).

O.13.1.1 Product salvage - Cooking

In all cases where product is salvaged, as per the above first option, the following requirements apply:

- The cooking process must be approved by the area Program Specialist (meat processing) before being used;
- The operator must maintain a complete and up to date inventory of all product being salvaged because it was found positive for *E. coli* O157:H7 or because the Operator has chosen to treat it as positive for *E. coli* O157:H7. The inventory shall include the following information: initial lot numbers and test results, type of product, weights, time/date of cooking, lot numbers of finished products, weights, and finished product test results.
- All lots of cooked products made from components that come from a lot with a ***presumptive or confirmed*** *E. coli* O157:H7 positive product must be tested and found negative for the pathogen prior to being released for sale (one sample of 5 x 65 g must be analyzed for each such cooked lot of product made from raw beef that did not have a satisfactory laboratory result).

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

- The **shipping** establishment must:
  - Maintain complete records identifying the type of product, as well as quantity, being shipped for cooking.
  - 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:H7 test results are known, the product can be labelled at the storage facility, with the consent of the CFIA inspector.
  - Control product while it is in transit. The use of company seals is mandatory.
  - 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.)

- The **receiving** establishment must:
  - Confirm the reception of positive product with the shipping establishment.
  - Maintain complete and accurate records of all positive product received for cooking process.
  - Meet the three requirements applicable to this procedure (approved cooking process, testing end product for the pathogen and inventory of product).

O.13.2 Follow-up actions - Operators

Any raw beef product that is positive or presumptive positive (positive screening test result) for *E. coli* O157:H7 is considered adulterated by the CFIA. That is why the operator must inform the CFIA of this situation whenever it arises. For auditing purposes, the information must be presented to the CFIA in the written form.

O.13.2.1 Positive results obtained from products produced at the establishment

Operators using a robust testing protocol as a process control will very likely get more positive results than operators who test only for verification purposes. The CFIA still expects these operators to comply with sections O.13.1 and O.13.2.1 of this policy. However, the impact of any positive result must be part of the trend analysis done on all laboratory results. Any potential link between positive results must be evaluated. When the number of positives exceeds what is expected (based on the prevalence of the pathogen and the level of testing

applied), the operator should conclude that the **measures to control** the risk posed by *E. coli* O157:H7 must be increased (better or additional pathogen reduction steps).

The operator must take those results as evidence that their HACCP system has been ineffective in producing a product that is below detectable levels. Consequently, the operator must immediately notify the responsible inspector/veterinarian in charge of the establishment, who will in turn notify their Inspection Manager and the Area Program Specialist. The operator must also take the following steps:

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

   Notes:
   - This also includes beef **slaughter** activities, whether these take place on site or at another registered establishment.
   - 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 current circumstances, taking into account such factors as the frequency and number of positives being found (trend analysis), and the type(s) of product(s) affected.
3. Apply a corrective action to eliminate the deviation cause.
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 preventative measures to prevent recurrence of the deviations. Serious consideration should be given to increase the lethality 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 substantively modified to increase its efficacy, the intervention must be re-validated by taking the required number of samples over a complete month of production (i.e., Step 3 of the validation, see section O.8 of this policy. Validation of pathogen reduction step(s)). The plant management and VIC/IIC 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 includes the date, time recorded, and is signed or initialled by the establishment employee making the entry.
9. Provide the inspector with the operator's risk management plan with regards to the adulterated product explaining how the product will be handled, controlled, brought back into compliance or disposed of (denatured and condemned).

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

- documents reviewed;
- procedure used to review;
- dates reviewed;
- evaluation of the impact of this positive result on their own testing results for this type of product; and
- appropriate signatures of reviewer(s).

***In all cases*: The inspector evaluates the investigation done by the operator in collaboration with the designated area Program Specialist, Complex Supervisor and Regional Veterinary Officer. When the investigation's conclusion or the corrective actions taken are judged inadequate, a Corrective Action Request (CAR) is issued.**

O.13.2.2 Positive results obtained as a result of verification testing done on products received from a supplier

In the case where a positive result (or presumptive positive, if applicable) is obtained as a result of verification testing done on products **received from a supplier**, the following requirements apply:

- The operator having performed the test must immediately notify the supplying establishment of the unsatisfactory results. The supplying operator will then inform the inspector/veterinarian in charge at their establishment of the unsatisfactory result. The inspector/veterinarian in charge of the supplying establishment will inform their own Inspection Manager and Area Program Specialist of the situation.
- The receiving operator must dispose of affected product as per one of the three options presented under section O.13.1 of this policy.
- The supplying establishment must treat this notification as evidence that their HACCP system may have been ineffective in producing a product with *E. coli* O157:H7 below detectable level and must investigate the situation accordingly and take immediate follow-up actions as per section O.13.2.1 above.

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

O.13.3 Follow-up actions – CFIA

Any raw beef product that is positive or presumptive positive (positive screening test result) for *E. coli* O157:H7 is considered adulterated by the CFIA. That is why the operator must inform the CFIA of this situation whenever it arises. For auditing purposes, the information must be presented to the CFIA in the written form.

As per section 20(2) of the *Meat Inspection Regulations, 1990* (MIR), the inspector will hold (held tag CFIA/ACIA 0093) the product until it is made to conform to those standards by the operator. The inspector will keep on file the appropriate information as per the Meat Hygiene Manual of Procedures section on the use of held tags (CFIA/ACIA 0093) under control mechanisms.

The inspector must also indicate at the back of the held tag CFIA/ACIA 0093 the sections under which the detention is taken, which are section 20.(2), and section 130 of the MIR for the necessity to obtain from the inspector the authorization to remove an official tag or to handle or use this meat product.

The inspector must be provided with the operator's risk management plan with regards to the adulterated product. Files must be kept with all the needed information: product involved, quantity, lot identification, link to the laboratory result etc.

If adulterated product is sent to another federally registered establishment for cooking, the HACCP plan of this (these) other establishment (s) must also address the needed controls. In such cases, the CFIA inspector of the other establishment must be notified on each occasion.

As per section 130 of the MIR, the inspector must either remove the held tag in person or authorize its removal. This must also be documented as it pertains to this specific issue in both the operator's HACCP plan and the inspector's files.

Notes:

- If the product was imported, the Area Program Specialist will immediately notify in writing the National specialist, Import Programs, Meat Programs Division, in Ottawa. The National specialist, Import Programs will notify the authorities of the exporting country for a follow-up investigation.
- If any product affected by the unsatisfactory result is in distribution, the Food Recall and Emergency Response office must be informed.

O.14 Systematic review of reassessment of HACCP system

The CFIA will conduct a systematic review of operators' reassessment to evaluate the acceptability and effectiveness of the measures taken to comply with this policy. As part of the process, the CFIA responsible inspector/veterinarian in charge of the plant will complete task # 7102 and confirm that the information supplied by the Operator (e.g., HACCP Coordinator) is complete and reflects in-plant conditions. The completed task and copies of the relevant control measures will be sent to the Area Program Specialist, who will review the entire package, in consultation with the FSEP Specialist.

The information collected will also be used when the CFIA updates sampling plans M-201 for the analysis of ground beef, and M-218 for the analysis of trim and raw beef components that may be used for the production of ground beef.

Appendix 1: Validation Procedure – Pathogen Reduction Step for Abattoirs

Sampling Protocol

The sampling should encompass a **4 month period**. It is recommended to sample during the seasons having the highest prevalence level.

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 (e.g. 5th carcass following a carcass purposely selected). Side A (right or left) should be sampled for EB evaluation before the intervention of interest. Side B (left or right) of the same carcass should be sampled after the intervention. For the next carcass identified in the sampling plan, side B should be sampled first (before) and then side A (after). 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 EB evaluation before the intervention of interest.

Statistical Evaluation

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

Table 1: Number (n) of beef carcasses to select for the validation of microbiological reduction - Interventions based on Indicator counts (STEP 2)

N	Group 1	Group 2	Group 3
	n for each Group		
100000	15	133	237
50000	15	133	236
25000	15	133	235
10000	15	132	231
5000	15	130	226
1000	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 EB log counts with 95% confidence Level
n =	Number of samples to be taken over a 4-month period according to the 4-month production volume (N)
N =	Production volume over 4 months
Group 1 =	Standardized intervention i.e. fully automated commercial equipment with monitoring devices e.g. steam pasteurizers
Group 2 =	Intervention that is not fully automated i.e., equipment involving some manual intervention or not having monitoring devices for all parameters e.g., steam vacuum, organic acid sprays, etc.
Group 3 =	New interventions and all other interventions not in group 1 or 2

Table 2: Sample size to obtain a 95% confidence level that the product will be below 0.1% of *E. coli* O157:H7 during a one-month period (STEP 3)

Lot size (No. slaughtered per month)	Sample size (0.1% threshold)	Lot size (No. slaughtered per month)	Sample size (0.1% threshold)
10 - 69	All	1900	1507
70	All	2000	1552
80	All	2100	1595
90	All	2200	1636
100	All	2300	1674
110	All	2400	1711
120	All	2500	1745
130	All	2600	1778
140	All	2700	1809
150	All	2800	1839
160	All	2900	1867
170	All	3000	1894
180	All	3200	1945
190	All	3500	2012
200	All	3800	2072
300	All	4200	2141
400	All	4600	2201
500	499	5100	2265
600	596	5700	2329
700	690	5800	2339
800	781	6700	2415
900	868	7900	2492
1000	950	9700	2576

Lot size (No. slaughtered per month)	Sample size (0.1% threshold)	Lot size (No. slaughtered per month)	Sample size (0.1% threshold)
1100	1028	12 400	2660
1200	1101	17 200	2748
1300	1170	28 200	2841
1400	1235	77 300	2937
1500	1296	100 000	2950
1600	1354	125 000	2959
1700	1408	Over 125 000	3000
1800	1459		

Appendix 2: Testing Considerations for *E. coli* O157:H7

(As pertains to "raw ground beef", raw ground beef patties, trim used in the production of ground beef, other components used to manufacture ground beef and carcass surface meat used to produce this trim)

A. SAMPLE PICK-UP

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

B. SCREENING METHODOLOGY (optional - the lab may proceed directly to confirmation)

- Testing with screening methodology must be performed either:
  - in a lab accredited by the Standards Council of Canada (SCC) 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; OR
  - in a non-accredited laboratory that CFIA may audit if deemed necessary, to determine if the laboratory is proficient with the methods used and that there is an established quality system in place.

- A potential positive result will be considered definitive, i.e., to correspond to a confirmed positive test result for *E. coli* O157:H7 **unless** the sample proceeds to the confirmation method as described in section C (Confirmation Methodology Requirements).

- An approved sampling methodology must be used and appropriately followed as directed by the CFIA Meat Program.

- For ground beef/patties, trim or trim components, 5 sub-samples of 65 g each must be tested, representing a total of 325 grams of meat product (for industry testing, this may be tested as one composite of 325 grams, with one test result).

- The following additional requirements apply to establishments that are eligible to export to the US:
  - The method used must include an enrichment in a selective broth medium
  - The test method should be able to detect 0.23 colony forming units (cfu)/g in a 25 g sample of 75/25 (lean/fat) ground beef.

- Other federally registered establishments: any of the following screening methods ***or equivalent*** (see * below) are acceptable:

Assurance GDS:	MFLP-16
Bax:	MFLP-30
VIP:	MFLP-87
Warnex:	MFLP-12
DuPont LFD:	MFLP-19
Assurance EHEC EIA:	MFLP-81
Merck Singlepath:	MFLP-82
Tecra Visual Immunoassay:	MFLP-91
Polymyxin ELISA:	MFLP-92
20 hour Reveal:	MFLP-95

C. CONFIRMATION METHODOLOGY REQUIREMENTS

- The confirmation test must be done in an accredited laboratory (as described in section B, Screening Methodology).

- If the initial screening was done in a non-accredited laboratory: product must be shipped to an accredited laboratory according to the *Transportation of Dangerous Goods Regulations* – the sending laboratory must have the facilities and training required by the *Transportation of Dangerous Goods Regulations*.

- The potential positive enriched broth must be kept between 2 and 8°C and arrive in the accredited lab within 24 hours of obtaining the potential positive result. The accredited lab must start the confirmation procedure within 24 hours of the initial potential positive result.

- The confirmation test must be done from the same broth that was tested potentially positive by the screening test.

- The confirmation method used must be approved and include an Immuno-Magnetic Separation step.

- The following method ***or equivalent*** (see * below) is acceptable:

  - **MFLP-80 (Health Canada Compendium of Analytical Methods)**

- **When performing confirmation testing of samples submitted by a federally registered establishment listed as eligible to export to the US, MFLP-80 will be modified as described below:**

  - If the cultural method confirms the presence of typical, non-sorbitol fermenting *E. coli* O157 the following steps are **required** in addition to the requirements outlined in MFLP-80.

  - It is mandatory to perform either the serological test for H7 or to confirm the presence or absence of the toxin with acceptable methodology (e.g., MFLP-83, MFLP-93, ***or equivalent*** [see * below]).

  - If the test performed (either H7 or the toxin test) is negative, it is required that both of these tests be performed.

  - If the test performed (either H7 or the toxin test) is positive, it will be concluded that the isolate is a confirmed verotoxin producing *E. coli* O157 positive and no further confirmatory testing is required.

  - If the tests performed (H7 and the toxin test) are both negative, proceed as follows.

    NOTE - the following PCR tests for the presence of toxin genes and/or H7 genes will be done in CFIA laboratories or in private accredited laboratories using methodology approved by the CFIA.

    If the tests for the toxin and H7 are negative, a test for the presence of the toxin genes (*stx*1 and/or *stx*2) with an acceptable PCR method will be performed. If the toxin genes are confirmed positive, then the sample is considered confirmed positive for *E. coli* O157:H7.

If the test for the toxin genes is negative, a PCR test for the presence of the H7 gene (*fliC*) will be performed. If the test for the H7 gene is confirmed positive, then the sample is considered confirmed positive for *E. coli* O157:H7.

- If the H7 gene is not confirmed (assuming toxin and toxin gene, as well as H7 serology tests were negative), then the sample is considered to be negative for *E. coli* O157:H7.

Footnote

* "***or equivalent***" - contact the CFIA, National Laboratory Operations, Executive Director, for CFIA requirements to demonstrate equivalency of methodology not listed as acceptable in this document.

Annex P

CFIA Protocol for Evaluating Bulk Container Freezing Processes for Meat Products

P.1 Introduction

This protocol sets out the steps operators are to follow when developing a method for freezing meat products (e.g. carcasses, carcass portions and offal) in bulk containers (hereinafter "**bulk container freezing**"). In order to validate their HACCP (Hazard Analysis Critical Control Point) systems, operators must show that their processes reduce the core temperature of these products to -18°C within a time frame allowing for the preservation of organoleptic and microbiological qualities.

P.2 Scope

The following processes must be evaluated in accordance with the present protocol:

- Pallets (without spacers) of boxes of meat products that were pre-cooled (4°C) with a view to subsequent freezing.
- Combo bins of meat products that were pre-cooled (4°C) with a view to subsequent freezing.

Additional conditions may apply if freezing is intended to prepare products for subsequent treatment (e.g., to destroy *trichinosis* or *cysticercosis* parasite).

The present protocol does not cover situations in which products that have not reached a core temperature of 4°C are placed in bulk containers for freezing purposes. Processes that involve this approach (i.e. placing products that have not yet reached this temperature in bulk containers) are subject to the requirements set out in the "Alternative cooling processes" section 4.4.3 of Chapter 4, Meat Hygiene Manual of Procedures.

P.3 Prerequisites for freezing meat products in bulk containers

- HACCP system

  Establishments may freeze products in bulk containers, provided that the validity of their methods has been proven through tests. HACCP controls are required in order to conduct the tests, and the establishment's HACCP system must be adjusted to encompass data collection. The results of tests conducted in this manner are used to validate the HACCP system itself.

- Establishments that produce meat to be frozen in bulk containers must have determined and validated the shelf life of all of these meat products in order to confirm that a given product will have reached the freezing temperature during its specified shelf life. This will ensure that frozen meat products in bulk containers have the requisite microbiological quality upon thawing.

- Specify the products targeted, the packaging method (including palletization method) and the freezing method. This must be determined jointly by the establishment producing and packaging the meat products and by the establishment freezing the meat products, as appropriate.

  Once a method has been selected, the test results **cannot be used** to validate another process. Here are examples of bulk container freezing that an operator might want to validate:

  - Pork hams weighing between X and Y kg (market weight animals) are received at a temperature not exceeding 4°C in a cardboard combo with a sealed PVC lining. The maximum quantity per combo bin is 800 kg. Combo bins are stored in a warehouse

at -18°C for five days; they are stacked five high on racks with spacing of at least ..... between each combo level and row. Air velocity .... Estimated time to reach -18°C: 48 hours.

- Cuts of beef (the largest being an outside round weighing x kg), vacuum-packed and received at a temperature not exceeding 4°C, are stored five per box. The boxes are stacked five high, with x boxes per row, and stretch-wrapped. They are kept in a freezer at -25°C with spacing of at least .... between pallets. The air velocity is .... Estimated time to reach -10°C: 48 hours. Once the temperature is reached, the boxes are palletized without spacers and stored for 10 days.

- Have labelled containers.

  The inspector will determine whether the proposed method enables him/her to identify containers that undergo testing.

- Determine a method for taking temperature readings that accurately reflects the process to be tested.

  Temperature readings taken during testing will be used to demonstrate that the freezing method, when properly applied, guarantees that the temperatures required in order to control unacceptable bacterial growth are reached within a given time frame. The operator must prove that the data collected during testing represent the worst-case scenario.

- Determine the temperature profile of the freezer rooms.

  If the temperature of the freezer room is uniform throughout the room, the test may be conducted anywhere in the room. If the temperature is not uniform, the data must be collected in the warmest part of the room to reflect the worst-case scenario.

- Identify and analyse hazards specific to the process that is the subject of the request.

  The capacity to systematically cool meat products to a specific temperature within a given time frame depends on how precisely the process under evaluation is applied. When the cooling process is not rigorously implemented, bacteria may have the opportunity to grow, resulting in an unacceptable risk.

  For each parameter of the **bulk container freezing** process that is the subject of the request, the operator must identify the hazards that could arise in the event that the process is not strictly followed.

  To continue with the examples above, the following hazards could pose an unacceptable risk and need to be assessed:

  - *Presence of pathogens because the product is delivered in a state that makes it unsuitable for freezing in a bulk container.*
  - *Bacterial growth that occurs between the time the product is received and the time it reaches a temperature at which bacteria are no longer able to grow.*
  - *Bacterial growth resulting from failure to maintain the ambient temperature required for the process.*
  - *Bacterial growth resulting from a slowdown in freezing caused by packaging that does not comply with the specifications of the process being evaluated.*
  - *Etc*.

  Incorporate each new hazard into the HACCP plan (i.e., apply the decision tree and determine whether the hazard is controlled by prerequisite programs or whether a CCP needs to be established).

P.4 Submitting the request for in-plant testing to the inspector

Before a **bulk container freezing** process can be adopted, testing needs to be done to identify potential shortcomings. The management of the establishment must submit the following documents before testing can be authorized.

Item No. 1. A letter from management containing:

- a brief description of the proposed process;
- a statement explaining that the hazard analysis of the process complied with HACCP principles and that the HACCP system was modified in order to monitor the hazards during testing;
- a statement explaining that, for testing purposes, the company agrees to submit only those analysis results obtained using recognized laboratory methods; and
- a statement explaining that quality control officials have been instructed to stop the test if they feel it is not being carried out in the manner agreed upon with the CFIA.

Item No. 2. The dated test protocol specifying:

- The name of the official to be contacted in the event of problems during the test;
- The duration of the test (start and end date);
- The number of lots proposed for testing before the process can be implemented in normal production operations;
- The method for taking temperature readings of products and in cooling rooms that will be used during testing, including:
  - Who will take the temperature readings - How - How often - Number of samples - What products - etc.;
- Data on the microbiological quality of meat products at the start of the bulk container freezing process. Microbiological data generated for the validation of the product's shelf life may be used;
- When applicable, the microbiological method that will be used during testing, including:
  - Who will take the samples - How - How often - Number of samples - Type of analysis to be conducted - etc.:
- A model of the table to be used to record temperatures from the time the product is received to the time the product reaches a temperature at which bacteria are no longer able to grow. This must include the temperature range from 4°C to -5°C; and
- The date on which management is expected to submit its test report to the CFIA following data collection and analysis.

Note: When responsibility for ensuring the microbiological quality of **frozen products in bulk containers** is to be shared between two or more establishments, the cover letter and the test protocol must be signed by the management of all the establishments concerned.

P.5 CFIA decision on whether the testing may be authorized

The inspector who receives the request determines whether it includes all of the information required. With the assistance of the program specialist, the inspector determines whether the request appears to be compatible with sound hygiene practices and whether any changes need to be made to the protocol before the testing can be conducted. Together with the program specialist, the inspector gives the go-ahead for the testing when he/she is satisfied that the test protocol is complete and acceptable.

P.6 Conducting the test

The operator must conduct the test in compliance with the approved test protocol. The operator must inform the inspector in writing if it becomes necessary to modify the protocol before, during or after the test. The inspector may temporarily halt the test to discuss protocol

changes with the program specialist. The inspector may also require that the test be stopped if changes are made to the protocol without his/her knowledge.

P.7 Test report: analysing and submitting collected data

The operator is responsible for collecting and analysing data gathered during testing and submitting them to the inspector within the agreed time frame. To this end, the operator will submit a report to the inspector. The report must be prepared in such a manner that anyone who reviews the report (e.g., foreign auditor) has all of the necessary information. Therefore, the test report must include the following:

- An **introduction** summarizing (in a few lines) the purpose of the test and providing an accurate description of the process tested.
- A **methodology** section summarizing (in a few lines) how the test was conducted. The test protocol may be appended to the report to avoid the need to write a methodology section.
- A **results section** summarizing the main observations made during testing.
- If needed, a **discussion section** clarifying results that may raise questions.
- A **conclusion** outlining whether the company will be applying the new process on a regular basis.
- An **appendix**, including at least the following:
  - The data is set out in a table.
  - Cooling curves based on the data collected. The curves must show that the cooling is continuous.
  - Instead of data tables and curves, it is encouraged that sensors attached to a thermograph be used to automatically record temperatures.
  - The results of microbiological analyses conducted during testing.

P.8 CFIA approval

The inspector will review the report submitted by the operator to ensure that it is complete and to assess its content. This involves determining whether the conditions described in the report clearly reflect what he/she knows to be true about the conditions in which the test was conducted and whether the operator satisfactorily explained all of the results that raised questions, in the “discussion” section. If the report is incomplete, the inspector will ask the operator to review the sections in question. When the report is deemed complete, the inspector will forward it to the program specialist with his/her comments on the report’s content. The program specialist will then determine whether the proposed process is acceptable and recommend that the inspector authorize or reject the **bulk container freezing process for meat products.**