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

Ottawa, Ontario
K1A 0Y9

October 26, 2010

MEAT HYGIENE DIRECTIVE

2010- 64

SUBJECT: Chapter 5 - Section 5.3 and Annex I

Changes to be made:

1. This directive is a housekeeping directive that aligns all *Listeria*-related changes to section 5.3.11 and Annex I of Chapter 5 of the Manual of Procedures (MOP) since its last revision. These sections have been amended to reflect current changes in the *Listeria* control measures which have already been communicated to CFIA inspection staff and industry and have been implemented according to Health Canada's *Listeria* control policy 2004.

2. The remaining part of section 5.3 has been amended according to current Guidelines for the Microbiology Sampling in red meat and poultry, and current references to appropriate chapter in the MOP.

ENGLISH AND FRENCH VERSIONS

Please replace Chapter 5 in your Manual of Procedures with the attached pages.
Please replace Annex I of Chapter 5 in your manual of procedures with the attached pages.

Ottawa (Ontario)
K1A 0Y9

Le 26 octobre 2010

DIRECTIVE DE L'HYGIENE DES VIANDES

2010- 64

OBJET : Chapitre 5 - Section 5.3 et annexe I

Changements à apporter :

1. Cette directive est une directive administrative mineure qui aligne tous les changements liées à *Listeria* dans la section 5.3.11 et l'annexe 1 de chapitre 5 du Manuel des Méthodes (MDM) depuis sa dernière révision. Ces sections ont été modifiées pour refléter les changements actuels des mesures de lutte contre *Listeria* qui ont été communiqués au personnel d'inspection de l'ACIA et à l'industrie et qui ont été déjà mis en œuvre en fonction de la politique de 2004 de Santé Canada sur le contrôle de *Listeria*.

2. Les autres parties de la section 5.3. ont été modifiés selon les Directives pour l'échantillonnage en microbiologie des viandes rouges et des produits de la volaille actuelles, et selon les références actuelles au chapitre approprié du MDM.

VERSIONS ANGLAISE ET FRANÇAISE

Veuillez remplacer le chapitre 5 de votre Manuel des méthodes par les pages ci-jointes.
Veuillez remplacer l'annexe I du chapitre 5 de votre Manuel des méthodes par les pages ci-jointes.

Richard Arsenault
Director
Meat Programs Division

Richard Arsenault
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Att./p.j.

Canada

Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

CHAPTER 5

SAMPLING AND TESTING

Canada

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Suggestions for changes or corrections to this chapter should be directed in writing to:

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5.1 TYPES OF TESTING

Testing is classified into one of three categories, based on its purpose and methods.

5.1.1 Monitoring

Monitoring is performed to identify possible areas of concern, or to provide information about violation rates. Monitoring is normally conducted using statistically based random samples. The sampled lots are usually not held, and are released to consumers before the test results are known.

5.1.2 Directed sampling

Directed sampling is designed to identify suspected problems. Directed samples are taken from animals or products which are suspected to have residues, or from groups of animals or types of product which are at higher risk. Animals or products which are deemed suspect are detained until the results of testing are available.

5.1.3 Compliance

Compliance testing is conducted when a violation has occurred, in order to determine whether a corrective action has been effective.

5.2 CHEMICAL RESIDUES

5.2.1 Introduction

5.2.1.1 Definition

A chemical residue is the presence of a chemical in one or more tissues of the body at some time after administration or exposure, particularly at the time of slaughter. The tissues of importance for the purposes of the chemical residues program are skeletal muscle, liver, kidney, and fat. Techniques and instrumentation used today are sufficiently sophisticated to detect a variety of drugs in small amounts.

5.2.1.2 Concerns

Although microbial contamination of food continues to account for the majority of instances of illness, consumers still have a high level of concern about chemical residues in food. Drugs developed for use by the animal industry in Canada must be thoroughly tested and approved by Health Canada's Health Products and Food Branch, Veterinary Drugs Directorate, prior to being offered for sale in Canada. Veterinary biologics are regulated by the CFIA under the *Health of Animals Act*.

Concerns raised about the possible presence of antibiotics, hormones, or pesticides in meats include the following:

- Allergic reactions are known to occur in sensitized persons. Penicillin causes the most severe adverse reactions and is implicated more frequently than all other antimicrobials combined. Small amounts of penicillin are metabolized in the body to penicilloic acid, which is a potent allergen. Allergy to the sulfa drugs is also common.
- The development of antimicrobial resistance by bacteria has received widespread media attention. The concern has been raised that exposure of humans to low levels of antimicrobials through food could contribute to the development of resistant strains of pathogenic bacteria in the human population.
- Residues could have direct pharmacologic effects if ingested. This is primarily a concern with the β-adrenergics.
- Residues could have direct, acute toxic effects. This effect has been seen as a result of consuming fish and shellfish. The banned antibiotic chloramphenicol is known to cause aplastic anemia in some individuals. Most acutely toxic compounds are unlikely to pose a problem in meats, because levels high enough to affect the consumer will cause severe illness or death in the affected animal.
- It has been postulated that chronic toxicity could occur from exposure to minute amounts of some chemicals over prolonged periods of time. This concern has been directed mainly at carcinogens and at compounds which are known to bio-accumulate.
- Consumer confidence in our food supply may be reduced, even when there is little or no health risk.
- Presence or suspicion of drug residues in a product can jeopardize export markets.

5.2.1.3 Causes

Veterinary drugs and agricultural chemicals used according to label directions should not result in residues at slaughter. Possible reasons for such residues include:

- not following recommended label directions or dosage (extra-label usage);
- not adhering to recommended withdrawal times;
- administering too large a volume at a single injection site, resulting in the formation of a depot;
- use of drug-contaminated equipment, or failure to properly clean equipment used to mix or administer drugs;
- dosing, measuring, or mixing errors;
- allowing animals access to spilled chemicals or medicated feeds;
- animal effects - age, pregnancy, congenital, illness, allergies;
- chemical interactions between drugs;
- variations in water temperature for fish species;
- environmental contamination; and
- improper use of agricultural chemicals such as pesticides.

5.2.1.4 Legal authorities

5.2.1.4.1 *Food and Drugs Act*

Section 4(d) of the *Food and Drugs Act* prohibits the sale of "an article of food that ... is adulterated."

Section 23(1)(d) authorizes an inspector to detain any product which he "believes on reasonable grounds" does not comply.

5.2.1.4.2 *Food and Drug Regulations*

Maximum Residue Limits (MRLs) are set by Health Canada in the *Food and Drug Regulations*. MRLs for meat are set in Division 15, Sections B.15.001 to B.15.003, and the

accompanying Tables. Table I deals with metals, Table II deals with agricultural chemicals and Table III deals with veterinary drugs.

A current version of the *Food and Drug Regulations* can be found on the Justice Canada Web site at:

http://laws-lois.justice.gc.ca/eng/index.html

Section B.15.002 sets a default MRL of 0.1 ppm for any agricultural chemicals not explicitly listed in Table II. Note that there is no equivalent provision for veterinary drugs; the MRL for veterinary drugs is therefore zero unless stated otherwise in Table III.

Section B.01.048 of the *Food and Drug Regulations* prohibits the sale, for food, of animals which have been treated with certain drugs, specifically

a) chloramphenicol and its salts and derivatives;
b) 5-nitrofurans;
c) clenbuterol and its salts and derivatives;
d) 5-nitroimidazole compounds; and
e) diethylstilbestrol and other stilbenes.

Health Canada has set "administrative" MRLs (aMRLs) for some compounds. These and the MRLs may be found on the Health Canada Web site at:

http://www.hc-sc.gc.ca/dhp-mps/vet/mrl-lmr/index-eng.php

Product which contains a residue at a level less than or equal to an MRL in the *Food and Drug Regulations*, or an administrative MRL posted on Health Canada's Web site, is not considered adulterated, and may be released.

5.2.1.4.3 *Meat Inspection Act*

Section 13.(1)(b) authorizes an inspector to inspect and take samples of any meat product or other thing that the inspector believes on reasonable grounds does not comply with this Act or the regulations.

Section 15.(1) authorizes an inspector to seize and detain any meat product or other thing if he believes on reasonable grounds that the product is out of compliance.

5.2.1.4.4 *Meat Inspection Regulations, 1990*

Section 2(1) of the Regulations provides a definition of "adulterated".

Section 20(1) of the Regulations authorizes an inspector to detain an adulterated meat product until it can be brought into compliance, or condemn it if it cannot be brought into compliance.

Section 68(1) requires an operator to comply with an instruction from an official veterinarian to hold and segregate an animal.

Section 131(1) of the Regulations requires an operator or importer to provide any samples requested, free of charge.

5.2.1.4.5 *Health of Animals Act*

The *Health of Animals Act* empowers inspectors to deal with named "toxic substances." However, no toxic substances have been named under the Act. Therefore, powers of inspectors under this Act cannot be invoked. Regulations relating to this section of the Act and a list of substances are under development.

5.2.2 Individual exposure

5.2.2.1 Introduction

Some medications are deliberately administered to animals to treat specific disease conditions, by injection, bolus, or infusion.

In addition, animals may be exposed to agricultural chemicals or environmental contaminants through accidental ingestion or environmental exposure, and then culled because of signs of illness or impaired production.

Treatment or exposure may result in residues in edible portions of the animal.

5.2.2.2 Sample selection

Every animal which an inspector believes on reasonable grounds may have been treated with a medication or exposed to a chemical is a residue suspect, and must be detained until its status can be determined.

"Reasonable grounds" may include (but are not limited to):

- the presence on ante mortem examination of signs of a disease condition for which a medical therapy is available;
- the presence on post mortem examination of pathological changes typical of a disease condition for which a medical therapy is available;
- behavioural changes or clinical signs associated with exposure to or treatment with a particular substance or class of substances (such as dystonia with botulina toxin or pupillary constriction with organophosphates);
- the presence on ante mortem or post mortem examination of anatomical changes associated with exposure to or treatment with a particular substance or class of substances (such as heavy muscling with β-agonists, or development of sexual structures with estrogens or androgens); and
- a history of recent medical treatment, such that the animal may not have reached the withdrawal period, or such that slightly delayed clearance may result in residues still being present.

Additional guidance may be found in the following sections on specific compounds. The Area Program Specialist, Chemical Residues, may also be able to provide advice.

5.2.2.3 Testing

Appropriate testing is dependent on the particular compound. See the following sections on specific compounds for guidance. The Area Program Specialist, Chemical Residues, may also be able to provide advice.

5.2.2.4 Follow-up

Hold the carcass and all its parts until laboratory results are received. Alternatively, the company may elect, with the inspector's permission, to treat the held product as condemned material in accordance with Section 88 of the *Meat Inspection Regulations, 1990*, rather than incur the cost or inconvenience of storing it pending results. However, portions must be disposed of under inspectional control. It is also prudent to keep samples for repeat tests or additional testing. Additional guidance may be found in the following sections on specific compounds.

For most compounds, where only a single animal is involved, disposal of the carcass or portions via inedible rendering is permissible, due to the considerable dilution. This may not apply in the case of known or suspected carcinogens.

5.2.3 Exposure of a lot

5.2.3.1 Introduction

Note: Herdmates of animals which test positive on the Sulfa On Site test are dealt with under that section. See section 5.2.9, sulfonamides.

Section 5.2.2 deals with medications normally administered to individual animals.

Other medications are customarily administered to groups of animals, usually through medicated feed or water, for the purpose of:

- growth promotion or other production enhancement;
- disease prevention; and
- treatment of a disease outbreak.

If an animal is found to have residues of medications normally administered to groups of animals, it is likely that other animals from the same production group (farm, herd, flock, barn, pen, etc.) or herdmates have similar residues.

Detection of a residue of a herd or flock medication in one animal of a lot is sufficient grounds to suspect presence of a residue in the other animals in the same lot presented for slaughter at the same time.

Occasionally, an owner may seek advice on a herd or flock known to have received treatment prior to slaughter, when doubt exists whether the observed withdrawal time was sufficient to clear the medication from tissues. All requests of this type which are submitted to the Veterinarian in Charge must be discussed with the Program Specialist, Chemical Residues. In general, the producer is responsible to ensure that animals he sends for slaughter are free of chemical residues, and the abattoir is required to have controls in place to assure this. If the situation warrants it, and the shipping of pre-test animals is indicated, the producer should send only the number of animals specified by the Program Specialist, usually six. The carcasses and all their parts must be held until the appropriate tissues have been analysed. Other samples may be collected at the time of slaughter of the production lot which the pre-test animals represent.

If a medication was administered extra label by a veterinary practitioner, that veterinarian can contact the Canadian Global Food Animal Residue Avoidance Database (CgFARAD) to obtain a recommended withdrawal time. For some antibiotics, rapid urine test kits are available.

The Veterinarian in Charge will consult the residue specialist to determine what measures are required in each case. The consultation process shall happen before the animals are brought to the plant, to permit preparation for the arrival of animals and avoid a premature or accidental kill of the lot before a decision is made. The CFIA will provide the operator with conditions to be met to allow the animals to be slaughtered. These shall be accepted by the plant operator before the kill actually occurs.

Operators are responsible to accept only animals which are free of harmful chemical residues for the preparation of meat. This should have been addressed by the plant's HACCP plan. If an operator wishes to bring animals of uncertain status into his plant, he should provide all available information to the veterinarian in charge in advance, so that an assessment can be made and to avoid the need to hold large amounts of animals or product.

In cases in which the shipping of pre-test animals is not practical, such as poultry flocks, the producer may euthanize, or have euthanized, a number of animals and send them for residue testing in advance of the anticipated slaughter date. All testing of live animals or animals euthanized for the purpose of demonstrating freedom from residues will be done at the producer's expense. Samples should be selected by a competent, objective, independent third party, such as a private veterinary practitioner, and submitted to an accredited private

laboratory. A list of available Standards Council of Canada (SCC)/CFIA accredited labs providing testing for such samples is available at:

http://palcan.scc.ca/SpecsSearch/SpecsSearchAction.do

The producer or veterinary practitioner should contact the accredited lab to schedule the testing and to confirm sampling, packaging and shipping requirements.

If the Veterinarian in Charge is not satisfied that the animals have been demonstrated to be residue-free, he still has the discretion to hold the carcasses and all their parts and submit samples for testing, in consultation with the Area Program Specialist, Chemical Residues.

5.2.3.2 Sample selection

Where a herd or flock is known to have received treatment prior to slaughter and doubt exists whether the observed withdrawal time was sufficient to clear the medication from tissues, several animals from that lot should be tested for the substance suspected. Animals selected for sampling should be the poorest of the lot, as these are the ones most likely to have a residue. Codex Alimentarius document CAC/GL 16, titled "Codex Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods", section 6.4.1, Sampling suspect lots, states:

"A minimum of 6 to a maximum of 30 primary samples should be collected from a suspect lot. When the suspected adulteration is expected to occur throughout the lot or is readily identifiable within the lot, the smaller number of samples is sufficient."

Consult with your Area Program Specialist, Chemical Residues, to determine the appropriate sample size.

Medications are sometimes used "extra label", in other words not in accordance with the label instructions. This may include exceeding the label dose, or using the product in a species other than that for which the label provides directions. Withdrawal times can vary dramatically between species, even closely related ones.

Guidance on withdrawal times for extra label use can be obtained from the Canadian offices of the Global Food Animal Residue Avoidance Database (CgFARAD). They can be contacted at:

Telephone: 1-866-C-GFARAD (1-866-243-2723)

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If gFARAD provides a written opinion regarding an appropriate withdrawal time for an extra label use, and the affected animals have met that withdrawal time, then they are deemed not to be residue suspects, and should not be detained. However, it may be appropriate, in consultation with the program specialist, to collect a check sample to validate our confidence in the advice.

5.2.3.3 Testing

For red meat species, if the residue suspected is an antibiotic, it may be possible to use the STOP test to screen six carcasses from the suspect lot. If the STOP is negative, then the suspect herd can be released. This is only applicable if the STOP is known to be sensitive for the antibiotic suspected. Discuss this option with the Area program specialist, chemical residues, before proceeding. The STOP test is not valid for use in poultry. See section 5.2.7, Antibiotics.

Unscheduled samples must not be submitted without prior arrangement. Contact your Area Program Specialist to make the arrangements, and to determine what samples are required. As a general rule, unscheduled samples should go to a CFIA laboratory, and the cost of the analysis shall be charged to the operator. It will sometimes be necessary to use a private laboratory if the test is of a type not available "in house".

When analysing multiple tissues from a suspect herd, the CFIA will stop the analysis once a violation is demonstrated. Any further testing is the responsibility of the operator.

5.2.3.4 Follow-up

5.2.3.4.1 Herdmates alive

As a rule, no animal suspected of harbouring harmful residues should be brought to a registered establishment, so this should be a rare occurrence.

If the remaining herdmates are alive, they should be withheld from slaughter until they have had time to clear the residue from their system. Another six "pre-test" animals from the group should then be slaughtered and tested.

The suspect group may be held in the company's live receiving area. If so, precautions must be taken to ensure that the animals are not inadvertently slaughtered and their identity lost. Care must also be taken that the animals do not become a source of contamination for other animals in adjacent pens.

Alternatively, the suspect lot may be removed from the registered premises back to their farm of origin, or to any other suitable place, with the written permission of the veterinarian, to await clearance of the residue. In this case, the animals must be properly identified or otherwise controlled to ensure that they are not slaughtered elsewhere in the interim.

If the animals must be slaughtered, for humane or operational reasons, then they should be segregated during slaughter and handled in accordance with section 5.2.3.4.2, "Herdmates slaughtered."

5.2.3.4.2 Herdmates slaughtered

If a herd problem is suspected during slaughter, then all carcasses and offal from that herd should be held pending test results. This is much easier than attempting to locate the carcasses of herdmates following a violative result.

If a group of animals is not determined to be suspect until after they have been slaughtered, then every effort should be made to locate and detain the affected carcasses and offal.

Samples of appropriate tissues from six animals should be selected at random and submitted for analysis to determine whether there are likely to be violative residues in the lot.

Where a flock or herd is deemed suspect, and has been sampled, the lot shall be deemed unacceptable if one animal or carcass exceeds the tolerance limit.

If the product has become mixed with other production and cannot be identified, then all product which might include the affected portions must be held.

If some or all of the carcasses or offal of herdmates has left the plant, a determination must be made whether a product recall is warranted. This decision will be made by the Area Program Specialist in consultation with the National Manager, Chemical Evaluation. The decision will be based on the tissues affected, the level of residue suspected, and the degree of hazard associated with exposure to the compound.

5.2.4 In-plant exposure

5.2.4.1 Introduction

Product in registered establishments is sometimes exposed to chemical contamination as a result of an accident in the plant, such as a fire, ammonia leak, or burst hydraulic line. In most cases, such exposure only affects the surface of exposed product. However, potentially contaminated product should be detained until its status can be determined.

Request the plant management to provide a detailed **written description** of the incident that led to the contamination, signed by the operator, to avoid any dispute at a later time as to what actually happened. The veterinarian or inspector in charge should add a statement that, to the best of his knowledge, the operator's statement is correct.

If the operator wishes to attempt to salvage any of the exposed product, he should also make a written **request for risk assessment**, including what use the operator wishes to make of the product for the purpose of this assessment.

Contact your Area Program Specialist, Chemical Residues, for guidance.

5.2.4.2 Sample selection

If the contaminant is a volatile agent, such as ammonia or chlorine, the operator should ventilate the area and allow time for the agent to dissipate.

In addition to the hazards of ingestion of residues, the possibility of product adulteration (off flavours or odours) must be considered. For some substances, organoleptic testing (smell and taste) is more sensitive than any laboratory assay.

Depending on the nature of the exposure, product may not have been uniformly exposed. If product is to be submitted for laboratory evaluation, collect a minimum of six samples, from various locations throughout the affected product.

5.2.4.3 Testing

Organoleptic testing should be conducted in the following order:

- odour test of exposed product at room temperature;
- odour test of exposed product after heating in a sealed plastic bag; and
- taste test of cooked product.

Laboratory assays may not be available for the compounds of interest. Consult with your Area Program Specialist, Chemical Residues, for guidance. Where exposure involves a mixture of compounds (such as smoke exposure from a fire), it may be possible to test for an indicator substance, or a compound of particular concern (for example benzo-a-pyrene).

5.2.4.4 Follow-up

Any product which has been visibly affected (such as by smoke discolouration) must be trimmed or condemned.

Any product which has been detectably adulterated, as determined by the presence of off flavours or odours on organoleptic testing, must be condemned.

Any product which contains a chemical in excess of the maximum residue limit, as determined by laboratory analysis, must be condemned.

See Chapter 6 for guidance on disposal of condemned material containing chemical residues.

If the contaminant is volatile and could plausibly dissipate from the product surface, the company may, at its discretion, hold the product for a period of time and then submit further samples at its own expense. However, the product may not be restacked or mixed, in such a way that surfaces which were exposed to contamination become buried in the interior. The product may not be held in such a manner that it poses a contamination hazard to unaffected product.

5.2.5 National Chemical Residue Monitoring Program - Domestic

5.2.5.1 Introduction

The National Chemical Residue Monitoring Program is the CFIA's main program for monitoring various species to determine the prevalence of residues of various compounds of concern. The program consists of a statistical random sampling designed to detect a 1% incidence of violations at a confidence level of 95%. Sampling plans are prepared at headquarters, and distributed in the form of a sampling plan booklet, with one sample per page. One sample may consist of several tissues.

The National Chemical Residue Monitoring Program uses the Multiple Analysis Submission System (MASS), which permits the performance of several analytical operations on a single sample, in an attempt to keep sampling time and associated shipping costs to a minimum. Each sample is uniquely identified on the basis of a sample number by affixing the sample number to the bag using a CFIA/ACIA 1461, in such a fashion that it will not become detached in transit, and will remain legible. This number tells the laboratory which analyses to perform. The need for the inspector to list the desired tests is thus eliminated.

If a new establishment opens, or an existing establishment closes, or changes the main species it slaughters, it may be necessary to reallocate samples before the end of the fiscal year, in order to ensure that the samples continue to be representative of the entire slaughter population. In the event of an operational change, the Area Program Specialist, Chemical Residues, may assign additional samples to your establishment part way through the year.

5.2.5.2 Sample selection

Only normal (not suspect), domestic animals are to be sampled.

To ensure random sampling, the sampling plan specifies not only the day but also the hour of sampling to avoid bias or duplicate sampling from the same owner if more than one sample is required on the same day.

If an establishment is not slaughtering the applicable species on the day specified in the sampling plan, or for some reason a sample cannot be taken, the sample may be taken at random from one of the next day's production, or the next day on which the applicable species is available. However, do not carry scheduled samples over from one fiscal year to the next, in other words past March 31.

If your plant no longer slaughters the indicated species, notify your Area Program Specialist, Chemical Residues, and return **copies** of the applicable pages from your sample plan booklet, so that the samples can be reallocated. The original pages should be retained in the sampling plan booklet, and annotated to indicate that this has been done.

The owner's name and address and (where applicable) the national livestock identification number must be recorded in the space at the bottom of each page in the sampling plan. Also include any other identifying information, such as sale or auction backtags, Heath of Animals eartags, brands or tattoos, and the breed and sex of the animal. If residues are found on analysis, you will need to be able to provide this information to permit follow-up. At the end of each fiscal year, the booklet should be filed in the inspection office as a permanent record. Booklets must be retained for three years from the end of each fiscal year.

It is important to collect a sufficient weight of the correct tissues, as indicated in the sample plan booklet.

Where a sampling plan calls for samples of muscle, the requirement is for skeletal muscle. To the extent possible, the sample should be taken from low-value portions of the carcass, such as diaphragm or neck. Avoid sampling injection sites, or tissue which may have been subjected to post mortem contamination.

5.2.5.3 Testing

Only the laboratory which is scheduled to receive the sample will have all the necessary information to complete the testing. It is therefore absolutely essential to submit the sample to the correct laboratory. The name and address of the correct lab is provided on every sheet in the sampling plan booklet. The sampling plans for one establishment may make use of several different labs, so check each sheet carefully and ensure that the sample goes to the correct lab.

Since product is not held for monitoring programs, these samples will be processed as a low priority by the lab. Samples may be accumulated by the lab for several weeks or months, then processed as a batch, to make the most efficient use of lab resources.

To reduce shipping costs, several samples may be shipped together as a single package. However, do not hold samples at the plant for longer than one week. Samples held too long in storage may deteriorate, or be lost or forgotten.

After shipping the sample, record the date and waybill number on the page in the sampling plan booklet, as proof that the sample was submitted, and to permit tracing in the event that the sample is not received at the lab.

See section 5.7.3 for direction on sample submission.

5.2.5.4 Follow-up

Since product is not held for monitoring tests, product disposition will not normally be affected by any violative result. Otherwise, samples which are found to be violative under the National Chemical Residue Monitoring Program will be followed up in the same manner as any other violative test. The presence of a violative residue will trigger a farm visit, similar to that for antibiotics (see section 5.2.7.5). Based on the results of that inspection, the producer may be subjected to compliance testing.

5.2.6 National Chemical Residue Monitoring Program - Imports

5.2.6.1 Introduction

Like the domestic program, the imports program attempts to conduct statistically based sampling for residues in the population of interest. Because the arrival of shipments cannot

be predicted in advance, it is not possible to produce a plan with specific sampling dates like that used in the domestic program. Instead, sampling frequencies are specified.

5.2.6.2 Sample selection

Sample selection is based on the country of origin and the type of product. Details are found in Annex M of Chapter 10. The main table specifies the country of origin, the frequency of sampling, and the amount of product to be sampled.

When Chapter 10, Annex M refers to sampling of "muscle", this means skeletal muscle only.

5.2.6.3 Testing

Annex M of Chapter 10 also specifies to which laboratory the samples are to be sent. Note that, in most cases, the laboratory is determined by the Area in which the product is received and reinspected, but that a few sampling programs are exceptions. Read the Annex very carefully before shipping the sample.

Whether the sample goes to a private lab or a CFIA lab, it should be accompanied by a form CFIA/ACIA 5164 "Food product sampling submission form", generated by the Sample Submission Form application.

Because private laboratories do not use LSTS, forms for submissions to private labs cannot be submitted or filled out electronically. Instead, click on the "Issue blank form" button to print a hard copy, and fill it out manually.

The sampling plan number is the fiscal year, followed by an underscore and "M8IMP", for example "2009_M8IMP". Use the "import control number" as the laboratory sample number.

Please ensure that the Food Product Sampling form is completed in sufficient detail to permit a rapid and efficient identification of the production lot sampled. For imported products the Import Inspection Report number **must** also be entered in the "identification code" field.

In the case of an unsatisfactory laboratory result, the submission form must provide all necessary product information to initiate a recall or follow up investigation and in the case of imported products, to advise the foreign country.

The specific tests which will be performed are based on the country of origin and the type of product. The laboratory will have this information.

5.2.6.4 Follow-up

Product sampled under this program is not detained, unless there are other problems with the shipment. All violative laboratory results from monitoring samples of imported meat are followed by intensified inspection. This means that the next 15 shipments, of a weight at least equal to that of the shipment found in violation, will be held and tested for the compound. Rather than wait for the test result, the exporting establishment has the option to have the product pre-tested, in an accredited private laboratory, and have the certificate accompany the shipment.

5.2.7 Antibiotics

5.2.7.1 Introduction

Antibiotics may be administered for growth promotion, for disease prevention, or for the treatment of infections. They may be administered via feed or water, by injection, or via timed-release boluses.

5.2.7.2 Sample selection

The Veterinarian in Charge will determine whether an animal is considered a suspect or not and whether to initiate testing for the possible presence of antibiotic residues. Practitioner certification that an animal has not been given antibiotics does not override this authority or this responsibility.

Antibiotic use should be suspected in any animal in which an injection site is found, and any animal affected with a septic condition, which might have been treated with antibiotics. The following is a partial list of pathologies and conditions that warrant retention and testing of carcasses.

- Mastitis – carcasses with inflammatory ventral edema in the perineal area resulting from mastitis. Hemorrhages and yellow serous infiltrate, located ventrally, are typically present.

- Metritis – carcasses with acute metritis. Associated pathology includes enlargement of the uterine body, distension of the uterine horns with a fetid brown, red brown, or black fluid; thinning of the uterine wall; and lack of evidence of normal uterine involution (no lines of contracture in the myometrium).

- Peritonitis and surgery – carcasses with active peritoneal inflammation associated with fibrinous exudate or fetid ascitic fluid, no matter how limited the extent of the lesions, or with ventral abdominal cellulitis secondary to percutaneous abomasal surgery. Findings of surgical devices (suture, toggles, fistula devices, etc.) are only significant if they are associated with active peritoneal inflammation (the presence of fibrin as opposed to chronic peritonitis with fibrous adhesions).

- Injection sites – carcasses with lesions associated with injections. Injection sites are likely to be found in a variety of locations including the neck, shoulder, thorax, axilla, ventral abdomen (along the subcutaneous abdominal vein), flank, hindquarter, pelvic area (perirectal) and tail. Also, look for cellulitis that is away from pressure points (e.g., tuber ischii, hip joint, stifle joint). These are generally found in the semimembranosus and semitendinosus muscles.

- Pneumonia – carcasses with acute, subacute, or chronic active pneumonia; with pleural cellulitis resulting from reticuloperitonitis complex; or with embolic pneumonia.

- Pericarditis – carcasses with fibrinous or fibrinosuppurative pericarditis.

- Endocarditis – carcasses with endocarditis and acute pulmonary, renal or other embolic lesions. Also, test carcasses that are condemned due to septicemia, toxemia, or other reasons.

- Abomasal or intestinal disease – carcasses with abomasal displacement, abomasal torsion, intussusception, mesenteric torsion, or cecal torsion.

- Nephritis or cystitis.

- Septicemia and toxemia – carcasses that are being condemned for septicemia, toxemia, or other inflammatory/infectious conditions.

- Diamond skin or other skin conditions associated with generalized or systemic infection.

- Animals identified during ante mortem inspection that were determined to be suspect for residues.

- Animals identified during ante mortem inspection showing signs of generalized infection (such as depression, a body temperature above or below the normal range, hyperemic skin, congested mucous membranes, dehydration or poor body condition), in association with an injury or inflammatory condition.

- Carcasses with acute cellulitis or other acute inflammations associated with a fibrinous or fibrinosuppurative exudate in any location on the carcass or viscera.

Animals which were non-ambulatory prior to loading would also be suspects, but transportation of this class of animal is not permitted under the *Health of Animals Regulations*.

Even if the animal is condemned because of the pathology, a STOP test should still be conducted, so that residue violations may be detected and traced back.

Antibiotic use may also be reported by the producer.

Any animal suspected of having been treated with an antibiotic, especially if there is a suspicion that the withdrawal time was not observed, should be held for testing. It should be noted that some antibiotics have withdrawal times of up to 30 days.

Testing should also be done on a proportion of normal animals, both to maintain proficiency in plants which receive few suspects, and to use up old kit supplies before they expire. In an establishment where suspect animals are rarely available for testing, having each inspector perform the test at least once a week on a normal animal should be sufficient to maintain this proficiency.

5.2.7.3 Testing

Initial screening of animals suspected of having antibiotic residues is conducted using the Swab Test On Premises (STOP). STOP kits are normally supplied twice a year, Spring and Fall.

The STOP test is performed in accordance with the procedure described in the self-instructional guide, "Performing the Swab Test On Premises (STOP) for antibiotic residues", dated May 2002. **This procedure must be followed exactly.** Variations in the technique have not been tested for reliability, so could result in false test results, and could be challenged in court or by foreign auditors.

Keep the STOP report (CFIA/ACIA 1479) on file at the establishment. These reports should be reviewed regularly by the Regional Veterinary Officer. Send a copy to your Area Program Specialist, Chemical Residues. If a laboratory result is pending for a held carcass, wait for the lab report before sending the completed CFIA/ACIA 1479.

If an animal is suspected of having antibiotic residues, all costs for the initial screening test (STOP) will be charged to the establishment according to the regulations, regardless of whether the result is positive or negative. The fees are specified in the Canadian Food Inspection Agency Fees Notice, Part 10. Random tests on normal animals are not cost recovered.

If the sample is collected from an establishment operating under a federal-provincial agreement, one copy of the STOP report (CFIA/ACIA 1479) must be forwarded to the responsible Regional Office for cost recovery to the applicable province.

NOTE: If it is discovered that a substantial amount of offal or viscera from animals with residues has been sent for rendering, the Veterinarian in Charge will immediately notify the Office of Food Safety and Recall; and the Feed Section, Animal Health and Production Division. It is important to note that raw material delivered to a rendering plant can be rendered into feed and reach farms within 24 hours.

5.2.7.4 Confirmation

The STOP test is only a presumptive test for the presence of microbial inhibitors, and must be confirmed by laboratory testing before a disposition can be made.

If the initial screening result is negative, the carcass is released. If the result is positive, the carcass remains under detention. The company may elect to discard the offal.

The company has the option to accept or decline laboratory confirmation. Explain to the company that, should the laboratory confirmation fail to detect violative residues, no further charges will be levied. If violative residue levels are detected in skeletal muscle, then the costs of the laboratory work will be charged. The charges can vary, depending on the amount of work that needs to be done. In addition, the carcass will be condemned should the muscle sample contain violative levels. The company should indicate its choice by completing the "Submission Form - Cost Recovered Antibiotic Confirmation" (See Annex A).

Statistics on the results of screening and confirmatory testing must be kept at all establishments so that the program results can be reviewed periodically and to aid future decision-making.

The sampling plan number is the fiscal year, followed by an underscore and "M8STP", for example 2009_M78STP.

5.2.7.4.1 Company agrees to confirmation

Submit 500 g of skeletal muscle. Samples of muscle should be selected from a location well away from any suspected injection site, such as the diaphragm. For carcass disposition, skeletal muscle must be used, as smooth and cardiac muscle are metabolically different, and levels detected there cannot be extrapolated to the carcass.

Do not submit the injection site from a STOP positive carcass. Because injection sites often contain high levels of the antibiotic, the residue can contaminate the equipment and the laboratory environment. The laboratory will not analyse these samples.

See section 5.8.4, Samples for antibiotic confirmation.

When the Report of Analysis is received from the laboratory, the Veterinarian in Charge should review it to determine which analyses were performed, then consult the Canadian Food Inspection Agency Fees Notice, Part 10, to determine the cost of the testing. If it is a federally registered establishment, the Veterinarian in Charge will invoice the abattoir by the methods currently in use. In the case of establishments under inspection under federal-provincial agreements, a copy of the submission form (Annex A) should be sent to the Regional Office so that the appropriate provincial government can be invoiced.

5.2.7.4.2 Company declines confirmation

If the operator refuses to accept these conditions, then the operator must make a request in writing to treat the held carcass as condemned (section 88 of the *Meat Inspection Regulations, 1990*). The carcass should be discarded and recorded as screening test positive but not laboratory confirmed. **No condemnation certificate shall be issued** since it was the choice of the company to take this course of action.

In the event that the carcass is condemned at the operator's request, a kidney should be submitted to the Centre for Veterinary Drug Residues, Saskatoon, regardless. This will serve to identify the compound which resulted in the positive test, both to validate the STOP result and to determine whether a residue concern exists. Because the carcass is not held in this case, the lab will treat the sample as low priority.

5.2.7.5 Follow-up

Carcasses and organs may not be released until laboratory reports are received. The dressed carcass and all organs derived from the carcass shall be condemned if the skeletal muscle from that carcass gives a violative result. When a liver or kidney or both are found violative (in excess of the MRL) but the skeletal muscle is negative or non-violative, then only the organs shall be condemned.

See Chapter 6 for guidance on disposal of condemned material containing chemical residues.

Where a violative result is confirmed in kidney or muscle, the Program Specialist will arrange for an inspection of the farm of origin, in accordance with the Animal Health manual on Chemical Residues. Based on the results of that inspection, the producer may be subjected to compliance testing.

Compliance testing is conducted on the basis that, because of the previous violation, any animal from the same producer is deemed suspect until demonstrated otherwise. Subsequent shipments from the same producer will be held for STOP testing until the Program Specialist deems that residue-free status of the herd of origin has been established.

5.2.7.6 Disposal of STOP kit components

5.2.7.6.1 Introduction

The STOP kit uses a culture of *Bacillus subtilis*. This organism is widespread in the environment, and the strain used in our test kits is susceptible to a wide range of antimicrobial agents. It is not considered to be a human pathogen. However, although this kit has been in use for over 20 years, and no problems have been documented from its use, cases of infection with *B. subtilis* have been documented in individuals with impaired immune systems.

Discarding used plates, swabs, etc. into the normal dry waste stream is not considered good laboratory practice. The standards are set out in the Laboratory Biosafety Guidelines 3rd Edition 2004.

5.2.7.6.2 Disposal options

The following are acceptable options for disposal of kit components (culture plates, spore suspensions, used swabs), in descending order of preference.

5.2.7.6.2.1 Plant hazardous waste stream

If the establishment operates a microbiology laboratory of its own, the components may be discarded in the establishment's laboratory waste stream in accordance with their laboratory protocols.

5.2.7.6.2.2 Disinfection – Sodium Hypochlorite

Plates and swabs may be disinfected by flooding the plate with a 0.5% solution of sodium hypochlorite. This is prepared by mixing 1 part household bleach (5.25%) with 9 parts water. Bottles of spore suspension may be disinfected by adding 3 mL of the bleach solution to the bottle, recapping, and shaking. In both cases, materials should be allowed to sit in contact with the disinfectant for 30 minutes before discarding.

The lids should be secured to the plates with celluloid tape or other suitable means prior to discarding.

Containers and bags must be adequate to prevent leakage of disinfectant.

Note: Most commercial disinfectants are ineffective against bacterial spores.

5.2.7.6.2.3 Disinfection – Virkon™

Virkon™ (Antek International) is a general purpose bactericide and virucide. Although it is not registered as a sporicidal or chemosterilant agent, the manufacturer considers it sporicidal with sufficiently long exposure times. Because its ingredients have low environmental toxicity, it may have some appeal for sterilizing the STOP plates.

Plates and swabs may be disinfected by flooding the plate with a 1% solution of Virkon™. This is the concentration obtained by mixing the product according to the manufacturer's directions. Bottles of spore suspension may be disinfected by adding 3 mL of Virkon™ to the bottle, recapping, and shaking. In both cases, materials should be allowed to sit in contact with the disinfectant for **at least eight hours** before discarding.

Virkon™ is sold as a powder, and is not stable once dissolved. Therefore, a fresh supply must be made up each time it is needed.

5.2.7.6.2.4 Autoclave

Autoclave at 121°C for 30 minutes. Plates should be packaged in standard "biohazard" bags with indicator markings prior to autoclaving.

The autoclave should go through a load test to verify that the time and temperature are adequate, in accordance with the manufacturer's instructions, the first time the autoclave is used, and then regularly thereafter depending on use.

5.2.7.6.3 Other details

Kidneys and other readily degradable material may be disposed of in the establishment's inedible waste. Plastic plates and glass bottles would contaminate the rendering process, and may not be discarded by this means.

5.2.8 Tetracyclines

5.2.8.1 Introduction

Tetracyclines (tetracycline, oxytetracycline, chlortetracycline) may be used for either prevention or treatment of bacterial infections. Oxytetracycline and chlortetracycline may be added to feed in accordance with Medicating Ingredient Brochures, alone or in combination with other antimicrobials.

Oxytetracycline is also available for administration by injection. Oxytetracycline and tetracycline may be administered via drinking water. Tetracycline is available as a bolus.

The tetracyclines form insoluble complexes with calcium. Animals treated with tetracyclines therefore acquire permanent deposits of tetracycline in the bones, which are visible as a yellow discolouration which fluoresces under ultraviolet light.

A yellow discolouration in the bones of market hogs is probably due to tetracycline; however, other compounds can cause this.

5.2.8.2 Testing

The presence of the discolouration in bones is not an indicator of tetracycline residues in muscle. Because the deposits are essentially permanent, the medication may have long since been cleared from other tissues. Meat from hogs with yellow bones does not appear to be at an increased risk of having unacceptable tetracycline residues, and residue testing is not warranted unless there are other indications of recent treatment.

5.2.8.3 Follow-up

Tetracycline deposits in bones can be released under acidic conditions. Therefore, the discoloured bones should be removed from the carcasses and considered not suitable for human consumption unless the company can prove that they are not a chemical residue hazard.

5.2.9 Sulfonamides

5.2.9.1 Introduction

Sulfonamides are used primarily in the prophylaxis and therapy of bacterial diseases. In combination with antibiotics, notably of the tetracycline and penicillin group, they are widely employed as medicated feeds to increase the rate of weight gain in livestock.

In hogs, these compounds serve as an aid in maintaining growth rate and feed efficiency in the presence of atrophic rhinitis, and in the prevention of bacterial enteritis, including *Salmonella choleraesuis* and swine dysentery.

In beef cattle, sulfonamides are used to maintain weight gain and feed efficiency during periods of stress due to weaning, shipping or handling.

In poultry, sulfonamides form a valuable aid in preventing or in reducing mortality due to coccidiosis, fowl typhoid and acute fowl cholera.

Injectable and bolus sulfonamides may be administered alone or formulated in combination with a synergist such as trimethoprim. Such products may contain more than one sulfa.

Sulfonamides may therefore be administered to a single animal, or as a mass medication. Only sulfamethazine is licensed for use as a medicated feed ingredient. Sulfaquinoxaline may be administered to poultry via water.

The rationale for testing dressed carcasses and organs for sulfonamide residues is largely analogous to that of antibiotics.

5.2.9.2 Sample selection

Sampling quotas for the Sulfa On Site test are set nationally by the National Manager, Chemical Evaluation, and allocated to the Areas. The Area Program Specialists, Chemical Residues, further allocate these quotas to the swine slaughter plants in their areas based on proportions of kill volumes, and on previous compliance.

Unless the sampling quota is very low, plant inspection staff should conduct tests in groups of six, in order to make the most efficient use of the test plates. If samples are not being taken every day, avoid falling into a pattern, such as testing only on certain days of the week, or every second day. Also avoid taking samples only at certain times of the day. This is to prevent producers from evading testing by predicting when it will occur.

One animal should be selected from each truckload or sale lot. There is no point in testing more than one animal from a single barn.

5.2.9.3 Testing

The presence of sulfamethazine residues in swine is monitored by the use of the Sulfa On Site (SOS) rapid in-plant test.

The SOS test is performed in accordance with the procedure described in the self-instructional guide, "Performing the Sulfa On Site Test", issued October 1997. **This procedure must be followed exactly.** Variations on the technique have not been tested for

reliability, so could result in false test results, and could be challenged in court or by foreign auditors.

All costs associated with sulfonamide testing are to be charged to the establishment, both in-plant screening and confirmatory testing. Fees are to be calculated according to Part 10 of the Meat Products Inspection Section, Canadian Food Inspection Agency Fees Notice.

5.2.9.4 Follow-up procedures on positive SOS urine test

5.2.9.4.1 Introduction

Because sulfamethazine is normally administered to hogs as a feed additive, if the hog selected for testing has violative residues, it is likely that its herdmates also contain violative levels.

See section 5.2.3, Herd or flock exposure, for further guidance.

Laboratory confirmation of presumptive positives is mandatory. One 500g sample of skeletal muscle and 500g of liver must be frozen and shipped to the Centre for Veterinary Drug Residues, Saskatoon accompanied by a completed form CFIA/ACIA 5258 (Meat Inspection Sample Submission Form). See section 5.8.3, Samples for chemical residue analysis.

The sample plan number is the fiscal year, followed by an underscore and "M8SOS", for example "2009_M8SOS".

5.2.9.4.2 Test animal and herdmates slaughtered

A positive SOS test reading, with a band brighter than the low standard, as defined in steps 93-94 of the manual Performing The Sulfa On Site Test, requires that the tested animal and **all** its herdmates be held pending confirmation of the result by the laboratory.

The carcass, viscera, and offal from the test animal, as well as from slaughtered herdmates, must either be held pending laboratory confirmation or treated by the operator as condemned. Such material may not be rendered and must be disposed of in a manner that meets the requirements of the *Meat Inspection Regulations, 1990* section 54 and local environmental requirements. See Chapter 6 for guidance on disposal of condemned material containing chemical residues.

5.2.9.4.3 Herdmates alive

If the remaining herdmates are alive, the operator may choose one of the following options:

- The suspect group may be held in the company's live receiving area to await clearance of the residue. A minimum period of ten days must have expired from the date of the violation before pre-test hogs can be presented for slaughter, in order to allow time for these animals to clear the drug. If the suspects are allowed to remain on the premises, precautions must be taken to ensure that they are not inadvertently slaughtered and their identity lost.

- The suspect lot may be licensed out of the registered premises back to their farm of origin, or to any other suitable place, pending lab confirmation, in accordance with Section 43(1) of the *Meat Inspection Regulations, 1990*. This is accomplished by issuing a CFIA/ACIA 1509 License for removal of animals or things. Again, a minimum period of 10 days must have expired from the date of the violation before pre-test hogs can be presented for slaughter, in order to allow time for these animals to clear the drug. In this case, the animals must be properly identified or otherwise controlled in a manner suitable to the CFIA, to ensure that they are not slaughtered elsewhere in the interim.

- If the animals must be slaughtered, for humane or operational reasons, then they **must** be segregated during slaughter and their products handled in accordance with above section 5.2.9.4.2 (Test animal and herdmates slaughtered). If the operator or the producer wishes to test some or all of the herdmates to demonstrate that the result of a test performed on a hog is not representative of the status of the herdmates, such testing will be at the operator's or producer's expense. The tests must be conducted in a private, CFIA-accredited laboratory and must be agreed on beforehand.

5.2.9.5 Follow-up procedures on notification of confirmatory lab results

5.2.9.5.1 Test animal and herdmates slaughtered

Upon notification of confirmatory lab results, the following action shall be taken on the tested animal and its herdmates:

Case #	LIVER	MUSCLE	IMMEDIATE ACTION	FUTURE SHIPMENTS:
1	≤ 0.1 ppm	≤ 0.1 ppm	pass carcass, viscera and offal	no restriction
2	> 0.1 ppm	≤ 0.1 ppm	pass carcass, condemn* viscera and offal	pre-testing
3	> 0.1 ppm	> 0.1 ppm	condemn* carcass, including viscera and offal	pre-testing
4**	≤ 0.1 ppm	> 0.1 ppm	condemn* carcass, including viscera and offal	pre-testing

*Except for pre-test animals, such material may not be rendered and must be disposed of in a manner that meets the requirements of the *Meat Inspection Regulations, 1990* section 54 and local environmental requirements.

**Case 4 is a rare occurrence that warrants further investigation at the discretion of the National Manager, Chemical Evaluation.

5.2.9.5.2 Herdmates alive

If the confirmatory lab tests are positive, the operator may choose one of the options under 5.2.9.4.3 for the remaining live herdmates.

5.2.9.5.3 Pre-testing

Producers who supply animals found to be in violation of the Maximum Residue Limit for sulfonamides will be subject to pretesting.

Pre-testing consists of sampling six hogs sent in advance of the next production lot. These animals will be screened by SOS, and if negative the carcasses will be released. The rest of the herd can proceed to slaughter. Any positive test is handled in the same manner as described in section 5.2.9.4 above.

Viscera from pre-test animals can be sent for inedible rendering, regardless of the presence of residues.

Marketing Boards will advise inspection personnel and management of the establishment when pre-test animals are being shipped. A minimum period of ten days must have expired from the date of the violation before pre-test hogs can be presented for slaughter, in order to allow time for the animals on farm to clear the drug.

Violative results obtained while on pretest will require a submission of a further set of pre-test hogs upon the expiration of a minimum of ten days following the date of the previous submission.

5.2.9.5.4 On-farm inspection

In all cases of animals found in violation, an on-farm inspection is conducted by animal health or feeds inspectors.

5.2.9.6 Company testing

Some companies perform considerable Sulfa On Site testing in order to meet customer requirements. In such cases, these tests may be included in our testing program, instead of requiring our inspectors to perform additional tests. However, for this to take place, a written contract must be in place, signed by the company management and by the Veterinarian in Charge, specifying the details of the testing. The agreement will be specific to each establishment, but should, as a minimum, contain the following:

1. The CFIA reserves the right to audit sampling and testing of carcasses for sulfa.

2. The CFIA has access to all sulfa testing results.

3. The CFIA will perform confirmatory positive testing, (laboratory confirmation of SOS positive results), just as it would for our own positive results, and this will be cost recovered in the usual manner.

4. The CFIA may include the company in proficiency testing for SOS, as we do for our own inspectors.

5. When an SOS test result is brighter than the low standard band, the company agrees that it will follow CFIA policy for handling positive carcasses and the carcasses of herd mates, and follow-up testing.

6. This contract is null and void if either party violates the agreement.

A copy of the contract must be sent to the National Manager, Chemical Evaluation, for approval prior to signing.

5.2.10 Steroid hormones

5.2.10.1 Introduction

5.2.10.1.1 Use of hormonal substances

- as anabolic agents (to increase feed efficiency, accelerate attainment of market weight and improve carcass quality);
- as estrus regulators; and
- for the treatment of specific disorders.

5.2.10.1.2 Steroidal growth promotants

There are various endogenous hormone preparations and two exogenous hormone preparations (zeranol and trenbolone) which are licensed for use as implanted pellets for growth promotion in calves, heifers and steers. In all cases, the recommended implant site is the ear.

The following are approved in Canada.

Registered Trade Name	Ingredient	Species	Dose
Component E-C (Elanco)	100 mg progesterone 10 mg estradiol benzoate	Suckling beef calves up to 185 kg. Should not be used in veal calves intended for slaughter. Do not use in calves under 45 days of age or more than 185 kg body weight.	1 implant (4 pellets)
Component E-C with Tylan (Elanco)	100 mg progesterone 10 mg estradiol benzoate 29 mg tylosin	Suckling beef calves up to 185 kg. Should not be used in veal calves intended for slaughter. Do not use in calves under 45 days of age or more than 185 kg body weight.	1 implant (5 pellets)
Component E-H (Elanco)	200 mg testosterone 20 mg estradiol benzoate	Heifers 185 to 365 kg	1 implant (8 pellets)
Component E-H with Tylan (Elanco)	200 mg testosterone 20 mg estradiol 29 mg tylosin	Heifers 185 to 365 kg	1 implant (9 pellets)
Component E-S (Elanco)	200 mg progesterone 20 mg estradiol benzoate	Steers 185 to 365 kg	1 implant (8 pellets)
Component E-S with Tylan (Elanco)	200 mg testosterone 20 mg estradiol 29 mg tylosin	Steers 185 to 365 kg	1 implant (9 pellets)
Component TE-H (Elanco)	140 mg trenbolone acetate 14 mg estradiol	Feedlot heifers 300-450 kg	1 implant (7 pellets)
Component TE-H with Tylan (Elanco)	140 mg trenbolone acetate 14 mg estradiol 29 mg tylosin	Feedlot heifers 300-450 kg	1 implant (8 pellets)
Component TE-S (Elanco)	120 mg trenbolone acetate 24 mg estradiol	Feedlot steers 250-450 kg	1 implant (6 pellets)
Component TE-S with Tylan (Elanco)	120 mg trenbolone acetate 24 mg estradiol 29 mg tylosin	Feedlot steers 250-450 kg	1 implant (7 pellets)
Compudose	Estradiol	- Suckling and growing steers greater than 80 kg - Heifers and steers over 260 kg	1 implant (24 mg)
Ralgo	36 mg Zeranol	Suckling, weaned and growing beef cattle, feedlot steers and heifers	1 implant (3x12 mg pellets)
Ralgo Magnum	72 mg Zeranol	Feedlot steers	1 implant (6x12 mg pellets)
Revalor 200	200 mg trenbolone acetate 20 mg estradiol	Feedlot steers and heifers	1 implant (10 pellets)
Revalor - G	40 mg trenbolone acetate 84 mg estradiol	Pasture steers 195-320 kg	1 implant (2 yellow pellets)
Revalor - H	140 mg trenbolone acetate 14 mg estradiol	Feedlot heifers 300-450 kg	1 implant (7 pellets)

Registered Trade Name	Ingredient	Species	Dose
Revalor - S	120 mg trenbolone acetate 24 mg estradiol	Feedlot steers	1 implant (6 pellets)
Synovex - C	10 mg estradiol benzoate 100 mg progesterone	Calves. Synovex - C implants should not be used in veal calves intended for slaughter. Do not use in calves under 45 days of age or more than 185 kg body weight.	1 implant (4 pellets)
Synovex Choice	100 mg trenbolone acetate 14 mg estradiol benzoate	Feedlot steers	1 implant (8 pellets)
Synovex - H	20 mg estradiol benzoate 200 mg testosterone propionate	Heifers 180-400 kg	1 implant (8 pellets)
Synovex - S	20 mg estradiol benzoate 200 mg progesterone	Steers 180-450 kg	1 implant (8 pellets)
Synovex Plus	28 mg estradiol benzoate 200 mg trenbolone acetate	Feedlot steers and heifers	1 implant (8 pellets)

Note that none of these products is approved for use in calves intended for veal production. The presence of any hormonal growth promotant (implant) in a calf presented for slaughter constitutes adulteration. Carcasses of such animals shall be condemned. No testing is required.

If an implant is detected in a calf on ante mortem, the operator may elect to return it to an off-site facility for grow-out to a full weight beef animal. Note that prior to the removal of any animal from the facility, written permission from the veterinarian in charge is required, in accordance with Section 43(1) of the *Meat Inspection Regulations, 1990*. The CCIA identification tag number should be recorded, and measures taken to ensure that the animal will not be simply transported to a different slaughter facility.

Steers and heifers slaughtered at an unusually early age must be considered as suspect for the presence of an implant because some are approved for use on beef calves. If a steer or a heifer of a beef breed is presented at such an early age that the carcass will likely show the maturity characteristics of a veal calf described in Chapter 17, care must be taken to verify that no implant was used, as described above. The meat from an implanted steer or heifer slaughtered at an unusually early age cannot be marketed as veal if the use of a hormonal implant is suspected. If it can be demonstrated through veterinary certification, examination, and inspection that an implant was used according to the label, the meat will be allowed on the market as ungraded beef.

Only one steroidal growth promotant, melengestrol acetate (MGA) is approved as a feed additive. It has a withdrawal time of 48 hours, and must not be fed to heifers implanted with or being fed other hormone drugs. See Medicating Ingredient Brochure 46.

5.2.10.1.3 Other steroidal drugs

Several steroidal hormones or their analogs are available for use by veterinarians. These fall into three major categories.

Estrus Regulators:

- Regumate (altrenogest)
- Veramix (medroxyprogesterone)

Anti-inflammatories:

- Azium (dexamethasone)
- Betasone (betamethasone)
- Flucort (flumethasone)

Anabolics:

- Equipoise (boldenone)
- Winstrol-V (stanozolol)

5.2.10.1.4 DES

The use of the synthetic stilbene derivative diethylstilbestrol (DES) has been prohibited in Canadian food producing animals since 1974. Use of this compound in other countries has been reported.

5.2.10.2 Sample selection

5.2.10.2.1 Implants

According to Health Canada, "the use of an implantation site other than what is recommended would unlikely be sufficient proof of adulteration under the *Food and Drugs Act*. While acknowledging the probable absence of harmful residue, the Drugs Directorate recommended that liver and kidney of animals implanted with these drugs in areas other than the ear not be permitted for sale as food. As well, all the area of implantation and any adjacent areas showing evidence of inflammation are to be completely destroyed." Should implanted pellets of any description be found in any area other than the ear, the above policy is in effect.

Should an inspector have any reason to believe that implanted pellets may be other than those licensed for use in Canada, then the carcass and offal should be detained. Collect the implant site into a plastic bag, freeze, and submit to the Centre for Veterinary Drug Residues in Saskatoon for analysis.

Because the ears are removed along with the hide, animals must be inspected for the presence of implants prior to hide removal.

During ante mortem screening, the operator must segregate all calves which have a missing ear, an ear with an incision indicating recent surgery, or a mutilated ear. The producer or operator must provide an acceptable written explanation for this anomaly. If the veterinary inspector is unable to determine that an implant was not present, the carcass and all its parts shall be condemned, on the basis that there are reasonable grounds to believe that the derived meat products are adulterated from the use of hormonal growth promotants.

5.2.10.2.2 DES

Since illegal use of DES in Canada could be attempted, inspectors in calf slaughter establishments should check for precocious sexual development in veal calves on ante and post mortem inspection. Special attention should be paid to the mammary gland and teat development in males and females, uterine and ovarian enlargement in females, and testicular and prostatic enlargement in males.

The following samples should be taken from suspected carcasses and submitted for laboratory testing.

- 500 g of liver that is immediately frozen and sent to the laboratory as per section 5.7.3.

- The sexual organs of the pelvic cavity, specifically prostate or Bartholin glands, as well as mammary glands or teats are required for histological examination. Sexual organs are to be immersed in 10% formalin. Care should be taken to avoid large pieces of tissue, as formalin will only penetrate a quarter of an inch of tissue. Samples should be sent to the laboratory as per instructions in section 5.8.10.

The prostate in calves is located in the pelvic portion of the penis at the junction of the ureter, seminal vesicles, and corpus peni and the end of the urethral muscle. It straddles the dorsal side of the ureter in the form of a horseshoe the size of a large pea. The Bartholin glands are found on the caudo-ventral side of the vagina, on each side of the end of the ureter and clitoris. As a sample, the caudo-ventral portion of the vagina should be taken.

5.2.10.3 Testing

Do not submit unscheduled samples to the lab without prior authorization. The assay that you require may not be available at all labs. Private labs which process samples for the National Chemical Residue Monitoring Program (Section 5.2.5, 5.2.6) can only perform the tests, and the number of samples, for which they have a contract.

Contact your Program Specialist, Chemical Residues, to determine where the sample must be submitted, and to obtain a sample submission number.

5.2.10.4 Follow-up

Carcasses and organs are to be held until laboratory reports are received. The laboratory result will determine the disposition of the carcass or offal, based on the applicable MRL in the *Food and Drug Regulations*. The dressed carcass and all organs derived from the carcass shall be condemned if the skeletal muscle from that carcass is violative. When a liver or kidney or both are found to be violative but the level in the skeletal muscle is below the applicable MRL, then only the organs shall be condemned. Contact your Program Specialist, Chemical Residues, for guidance.

Because the use of DES is prohibited in food producing animals, the presence of a residue of DES in any tissue constitutes adulteration. The carcass and all its parts will be condemned.

See Chapter 6 for guidance on disposal of condemned material containing chemical residues.

The presence of a violative residue will trigger a farm visit, similar to that for antibiotics (see section 5.2.7.5). Based on the results of that inspection, subsequent animals sent to slaughter by that producer may be subjected to compliance testing.

Compliance testing requires that, because of the previous violation, any animal from the same producer is deemed suspect until demonstrated otherwise. The Program Specialist, Chemical Residues, will determine whether a check sample (carcass not held), a compliance sample (carcass held), or a series of compliance samples is warranted; and, in the last case, how many times the producer's animals will be sampled.

5.2.10.5 Surveillance program for hormones in veal

5.2.10.5.1 Introduction

Since January 5, 2005, producers of veal calves have stopped the extra-label use of hormonal implants approved for growth promotion in market cattle. Since then, a few cases have been found in which hormones were administered by injection in calves intended to be sold as veal.

Suspect veal fall into three categories, depending on whether the lot or individual animals are suspect or not. The conformation of the animals and the history of the producer are the criteria used to establish suspicion.

In all cases, pay close attention to the following points:

1. When a large quantity of product must be placed under detention, contact your Program Specialist, Chemical Residues, or your Regional Veterinary Officer to confirm that this approach is appropriate to the situation. **The Agency must, among other things, decide whether samples should be collected for possible legal proceedings** and adapt the method of collection accordingly.

2. The offal and blood of held carcasses must also be held.

3. Product suspected of containing residues of hormones is to be detained on the grounds that it is an adulterated food under the *Food and Drug Regulations*, or meat product under the *Meat Inspection Regulations, 1990*. The condemnation of product found in violation will be done under the authority of sections 20(1) and 54 of the *Meat Inspection Regulations, 1990*.

5.2.10.5.2 Entire lot is suspect

A lot is suspect if:

- the calves originate from a producer who has previously presented calves with injection sites containing hormone residues **AND**
- the lot has a conformation suggesting the use of hormones (very pronounced muscular development, changes in the genital organs) **AND**
- multiple carcasses have injection sites in a location where it is unusual to find signs of injection of common products such as vitamins or antibiotics.

In the event of a suspect **lot**,

1. Seize and detain **the entire lot**, including offal.

2. Consult your Program Specialist, Chemical Residues, or your Regional Veterinary Officer to determine the number of samples needed for laboratory confirmation and whether samples must be taken according to the protocol for legal samples. Usually, six samples are required to evaluate a lot, regardless of the size of the lot.

3. Sample the injection sites and normal muscle (250 g of diaphragm from the same animal) from each sample carcass.

If hormones are detected in a sample at a level which cannot be explained by the natural variation in the level of a hormone, the entire lot will be condemned.

5.2.10.5.3 Suspect carcass

Carcasses are in this category if:

- the calves originate from a producer who has previously presented calves with injection sites containing residues of hormones **AND**
- some carcasses carrying marks suggestive of an injection at a location where it is uncommon to find traces of injections for common products such as vitamins or antibiotics.

In this case:

1. Seize and detain **individual carcasses** with marks suggestive of injections, including offal.

2. Consult your Program Specialist, Chemical Residues, if more than six carcasses are affected.

3. If six or fewer carcasses are affected, sample the injection sites and normal muscle (250g of diaphragm from the same animal) from each held carcass.

If hormones are detected at a level which cannot be explained by normal variation in hormone levels, the carcasses will be condemned.

If several carcasses are placed under detention, the CFIA laboratory may decide to stop the analyses when the first violative sample is found.

5.2.10.5.4 Other situations

Carcasses are in this category if:

- the carcasses have a normal appearance (normal muscling);
- there are marks suggestive of a possible injection site in a location where it is unusual to find traces of injections; and
- the calves originate from a producer which has never presented calves bearing injection sites which contain hormone residues

In these situations, in which there is a need to verify a possible injection site:

1. Sample the lesion. It is critical to follow the protocol for legal samples. If you have not been trained in this, contact your RVO or Program Specialist for guidance.

2. The CFIA will not routinely hold these products because the suspicion is not strong enough to justify it, but the operator may decide not to distribute the product pending the results of the analysis.

3. Notify the operator that the tissues are being submitted to be tested for hormones, and that if hormones are detected at a level which cannot be explained by natural variation in the level of the hormones, the CFIA may use the results to initiate legal action.

5.2.11 Prostaglandins

5.2.11.1 Introduction

Prostaglandins are hormones derived from fatty acids, which regulate reproduction and inflammation. Prostaglandins approved for veterinary use include:

- Estrumate™, Planate™ (cloprostenol)
- Lutalyse™ (prostaglandin F2α)

5.2.11.2 Sample selection

Although these products carry a 48-hour label withdrawal time, their tissue half-life is on the order of minutes, and they should not cause a residue concern. If in doubt, contact your Area Program Specialist, Chemical Residues, for guidance.

5.2.12 Somatotropin

5.2.12.1 Introduction

Somatotropins are large molecular weight proteins which regulate growth and maturation in normal animals. They have been manufactured commercially through recombinant DNA technology.

Bovine somatotropin has been approved in the United States for the enhancement of milk production in dairy cattle, under the trade name Posilac™. Research is underway for the development of porcine somatotropin as a growth promotant in market hogs.

5.2.12.2 Sample selection

Bovine and porcine somatotropin are not pharmacologically active in primates. Treated animals do not have circulating somatotropin levels outside the range of physiological variation. Somatotropins are ineffective if administered orally. These compounds are not a residue concern.

5.2.13 Beta agonists

5.2.13.1 Introduction

The β-agonists (β-adrenergics) are synthetic analogues of adrenalin. Members of this family of medications include clenbuterol, salbutamol, and terbutaline. β-agonists may be used illegally as growth promotants or repartitioning agents, particularly in veal.

Clenbuterol is a β-agonist approved by Health Canada for use in horses only. Specifically, clenbuterol is approved for use as a bronchial dilator in horses that are not to be slaughtered for food (Ventipulmin™, Boeringer). It is an extremely potent β-agonist with preferential affinity for bronchial and uterine smooth muscle. Veterinarians have been known to prescribe this drug, in an off label manner, as an agent for the delaying of parturition. The *Food and Drug Regulations*, Section B.01.048, prohibits the sale of any animal intended for consumption as food, which has been treated with clenbuterol.

Clenbuterol is illegally distributed in many countries as a growth promotant. This is an unapproved usage and has severe adverse health consequences. Outbreaks of poisoning have been reported in other countries, and at high enough concentrations (parts per billion), death can occur. Manifestations of poisoning include heart palpitations, tachycardia, dizziness, headaches, and tremors.

One β-agonist (ractopamine) is licensed for use as a repartitioning agent in hogs in Canada (Paylean™, Elanco). See Medicating Ingredient Brochure #82.

5.2.13.2 Sample selection

Veal calves showing heavy muscling should be deemed suspect. Collect eyes, liver, and muscle.

5.2.13.3 Testing

Detain the carcass and offal of suspect animals. β-agonists have an affinity for neural tissue, and residues will persist in the retina after they have been cleared from other tissues. Contact your Program Specialist, Chemical Residues, to determine where the sample must be submitted, and to obtain a sample submission number. Ship the eyes and 500 g each of liver and skeletal muscle, frozen, to the Centre for Veterinary Drug Residues, Saskatoon. Ensure that you collect as much identifying information as possible, such as live weight, eartag or backtag numbers, sale lot numbers, breed, and National Livestock Identification Number.

5.2.13.4 Follow-up

If an animal tests positive (retina test), the carcass and offal shall be condemned.

See Chapter 6 for guidance on disposal of condemned material containing chemical residues.

The Area Program Specialist will notify the producer, in writing, that clenbuterol residues have been detected in the retina of one of his lot, and that this constitutes an adulteration under the *Meat Inspection Act* and *Regulations* and the *Food and Drugs Act* and *Regulations* (see Annex B for Letter of Notification).

Prior to presenting his next lot for slaughter, and each time after, until five (5) consecutive lots test negative, the producer must notify the Canadian Food Inspection Agency's (CFIA) area office by telephone, of the date and place of the next intended slaughter. This applies whether the slaughter establishment is in the home province of the producer or another province.

If the producer sells his animals to an intermediary or a commercial agent or at auction he must inform the buyer that they must contact the CFIA's regional office and provide the date and place of the intended slaughter.

These animals will undergo the normal ante mortem and post mortem examination and will then be placed under detention. One (1) out of six (6) of the lot will be sampled and tested (skeletal muscle, liver and retina).

- If the retina is negative, the lot will be released.
- If the retina is positive, the corresponding carcass will be condemned. The producer will then have the option of proving, at his cost, that the retinas from each of the other carcasses are negative, or they will be condemned.

The National Chemical Residue Monitoring Program will continue to randomly select animals for retina sampling and testing. All positive findings will be subject to the aforementioned procedure.

5.2.14 Other therapeutic agents

5.2.14.1 Introduction

Therapeutic agents not covered previously in this chapter form a heterogeneous group of chemical substances. The persistence of residues varies accordingly and very few statements can be made that would have general applicability.

This group includes medicating feed ingredients as well as veterinary drugs for direct administration. Medicating feed ingredients include anti-microbial and antiprotozoan agents, coccidiostats, hypotensives, and anthelmintics. Some of these can be administered without veterinary prescription. For more details, consult the Compendium of Medicating Ingredient Brochures (MIB), accessible on the Web at:

http://www.inspection.gc.ca/english/anima/feebet/mib/cmibe.shtml

Some compounds are typically administered to individual animals with specific medical conditions. Others are typically administered as mass medications through feed or water, and may require use of the herdmates policy (See section 5.2.3). CFIA veterinarians may be able to make this determination through knowledge of the specific medications or by reference to the Compendium of Veterinary Products. If you require assistance, contact your Area Program Specialist, Chemical Residues.

5.2.14.2 Sample selection

You may detain any product which you believe, on reasonable grounds, may contain residues. This may be based on the presence of a disease condition or a physical or physiological change; or a report or allegation by a producer, transporter, or other source.

Ensure that you hold all organs and byproducts, as well as the carcass and its parts.

The selection of tissues for analysis depends on the suspected substance. Contact your Area Program Specialist, Chemical Residues, for guidance.

The presence of a recent injection site in an animal which is negative on the STOP test may indicate the use of a therapeutic agent other than an anti-microbial, such as an anti-

inflammatory. In these cases, submit a sample of the injection site. Ensure that it is clearly labelled, and that the submission form clearly indicates the reason for submission.

5.2.14.3 Testing

Do not submit unscheduled sample to the lab without prior authorization. The assay that you require may not be available at all labs. Private labs which process samples for the National Chemical Residues Monitoring Program (Section 5.2.5, 5.2.6) can only perform the tests, and the number of samples, for which they have a contract.

Contact your Area Program Specialist, Chemical Residues, to determine where the sample must be submitted, and to obtain a sample submission number.

5.2.14.4 Follow-up

Carcasses and organs are to be held until laboratory reports are received. The laboratory result will determine the disposition of the carcass or offal, based on the applicable MRL in the *Food and Drug Regulations*. The dressed carcass and all offal derived from the carcass shall be condemned if the skeletal muscle from that carcass is violative. When a liver or kidney or both are found to be violative but the level in the skeletal muscle is below the applicable MRL, then only the offal shall be condemned. Contact your Program Specialist, Chemical Residues, for guidance.

See Chapter 6 for guidance on disposal of condemned material containing chemical residues.

The presence of a violative residue will trigger a farm visit, similar to that for antibiotics (see section 5.2.7.5). Based on the results of that inspection, the producer may be subjected to compliance testing.

Compliance testing requires that, because of the previous violation, any animal from the same producer is deemed suspect until demonstrated otherwise. The Area Program Specialist, Chemical Residues, will determine whether a check sample (carcass not held), a compliance sample (carcass held), or a series of compliance samples is warranted; and, in the last case, how many times the producer's animals will be sampled.

5.2.15 Insecticides

5.2.15.1 Introduction

Insecticides are widely used in agriculture, both to protect crops from insect predation and to treat animals affected with insect pests or ectoparasites. Most insecticides are compounds which have a much higher acute toxicity for insects than for mammals. Residues may result from accidental environmental exposure (overspray, improperly stored containers, improper disposal), or from improper use of insecticides to treat animals (extra label use, failure to observe withdrawal).

Insecticides may be classed according to their chemical composition:

- Organohalogens (Halogenated Hydrocarbons)
- Organophosphates
- Organosulfur Compounds
- Organonitrogen Compounds
- Pyrethrins and Analogues

5.2.15.1.1 Organohalogens

Organohalogens are organic chemicals containing one or more halogen substituents. In the majority of cases, these substituents are chlorine atoms (organochlorine pesticides), with bromine and fluorine substituted chemicals (organobromine and organofluorine pesticides)

comprising the balance. Typical representatives of this group of compounds are aldrin, dieldrin, benzene hexachloride (BHC), lindane, chlordane, DDT and its metabolites, dicofol, heptachlor and its epoxide, methoxychlor and toxaphene.

Organohalogen insecticides are relatively stable compounds, broken down under normal environmental conditions at a very slow rate with half-lives ranging from a few months to well over a hundred years. They are practically insoluble in water, but soluble in fat and organic solvents. Because of their solubility in fat, intermittent or continued exposure to relatively low concentrations can result in residue accumulation in adipose (fatty) tissues. As a result, these compounds reach higher levels in older animals, and become more concentrated as they migrate upwards in the trophic food chain. Pharmacological effects on mammalian species, including man, are usually chronic in nature, although delayed semi-acute symptoms can appear if stress or disease causes an animal to rapidly mobilize its lipid reserves.

5.2.15.1.2 Organophosphates

Organophosphates are organic chemicals containing a central phosphorus atom (normally pentavalent), linked to aliphatic or aromatic side chains by oxygen or sulphur bridges. Typical representatives of this group are dimethoate (Cygon™, American Cyanamid), chlorpyrifos (Dursban™, DowElanco), diazinon, ethion, fenthion (Spotton®, Bayer), malathion and parathion. Halogenated compounds for direct application to livestock and facilities include coumaphos (Co-Ral™, Bayer), tetrachlorvinphos (Gardona™, American Cyanamid), trichlorfon (Dipterex™, Dylox™, Bayer) and dichlorvos (Vapona™, Shell).

The organophosphates are water soluble, quickly broken down in the environment, and rapidly metabolized in the body. Oxidative reactions in metabolism are usually detoxification mechanisms, but with organophosphates, oxidation can form a metabolite which is more toxic than the original pesticide. Certain hydrolytic metabolic processes, known to destroy the actual or potential activity of the chemical, continue under post mortem conditions. As these are temperature dependent processes, it is of utmost importance to have a sample for analysis frozen immediately and have it arrive at the laboratory in a frozen state.

Organophosphates are acutely toxic, inducing typical symptoms of acetylcholinesterase inhibition (e.g. salivation, lacrimation, diarrhea, nervous twitching and trembling). Because they are water-soluble, these compounds are not normally bio-accumulated. Notable exceptions are, however, a few representatives of this group used as systemic pesticides, which contain halogen-substituted side chains and exhibit some of the characteristics of the organohalogen group.

5.2.15.1.3 Organosulfur compounds

Organosulfur compounds are organic chemicals containing one or more sulphur atoms bound to oxygen to form a sulfoxide or sulphone. Typical examples are phenylsulphone and technical sulfoxide. Since the majority of pesticides in this group are also halogenated (e.g. endosulfan), they have the characteristics of the halogenated hydrocarbons, and are normally listed as representatives of that group.

Sulphur compounds of the classical sulphate and polysulphide type find little application in modern agricultural practice.

5.2.15.1.4 Organonitrogen compounds

Organonitrogen compounds are organic chemicals containing one or more nitrogen atoms in characteristic locations within the aliphatic or aromatic part of the molecule. The site and configuration of the nitrogen permits a broad subdivision into two groups, aliphatic and aromatic.

5.2.15.1.4.1 Aliphatic compounds

Carbamates, carbonates, carboxylates and substituted ureas are generally water soluble and characterized by a low persistence in the environment and animal body. Typical representatives of this group of insecticides are propoxur (Baygon™, Bayer), carbaryl, dimetilan, and methomyl. All of these are permitted for use on animal facilities, and carbaryl is also used in topical applications to livestock, but the primary use is for crop protection.

The insecticidal efficacy of these compounds parallels mammalian toxicity and, in the case of carbamates, acute symptoms due to a moderate acetylcholinesterase inhibition have been observed. Terminal residues in meat products are rarely seen due to the rapid in vivo metabolization and continued chemical and enzymatic breakdown in post mortem tissues.

5.2.15.1.4.2 Aromatic compounds

These include pyridine and diazine (pyrimidines and uracils) derivatives. Both sub-groups are usually characterized by the simultaneous presence of phosphorus (e.g. chlorpyrifos - Dursban™, diazinon) or halogen, permitting their classification with those groups.

5.2.15.1.5 Pyrethrins and their analogues

Pyrethrins are derivatives of chrysanthemumic acid, the oldest and best known representative being a natural pyrethrum extract, which due to cost consideration has met with a large competition from synthetic pyrethrin analogues. Typical representatives of this group are permethrin, allethrin and technical pyrethrin.

Together with piperonyl butoxide (which acts as a synergist), pyrethrins have been licensed for use as an insecticide in feed and food establishments, as well as for systemic and topical application to livestock. Pyrethrins are insoluble in water and easily destroyed by the application of heat. Their insecticidal properties are attributable to their action on the respiratory system (contact insecticide). The mammalian toxicity is generally low and absorption by normal pathways minimal.

Terminal residue formation has been reported as being negligible.

5.2.15.2 Sample selection

The above considerations are important for deciding on sample selection for testing and checking for clinical signs in suspected animals. If insecticides are not used carefully and in accordance with label directions, accidental contamination of feeds or direct exposure of livestock is possible. In certain cases, animals may be suspected of heavy exposure to a particular insecticide, either from reports of owners or other people connected with the livestock industry, or from observation on ante mortem and post mortem inspection. Such indications of exposure must be followed up. All available information, including ante and post mortem signs, should be reported to your Area Program Specialist, Chemical Residues, who will decide whether further investigation and sample submission will be necessary. It is important to identify the suspected chemical at least by group. Any reasonable suspicion should be checked out by laboratory tests, but it should be borne in mind that analyses are costly and laboratory facilities are limited.

The tissue of choice for regular halogenated hydrocarbons residue analyses is perirenal fat. In cases where a topical dorsal application may be suspected, the subcutaneous fat from that region is more suitable.

The tissues of choice for most organophosphate residue assays are liver and kidney, but perirenal or dorsal fat should be included if the application of a systemic compound is suspected. To keep the residue from being broken down by enzymes before testing, it is of utmost importance to have a sample for analysis frozen immediately and have it arrive at the laboratory in a frozen state.

For aliphatic organonitrogen compounds, liver tissue is considered the best choice for sampling purposes because the liver is one of the transient target organs.

5.2.15.3 Testing

If samples are submitted for laboratory analysis, then the carcass and all parts of the index animal and any herdmates suspected of being exposed must be detained pending the results of analysis.

Do not submit unscheduled samples to the lab without prior authorization. The assay that you require may not be available at all labs. Private labs which process samples for the National Chemical Residue Monitoring Plan (Section 5.2.5, 5.2.6) can only perform the tests, and the number of samples, for which they have a contract.

Contact your Program Specialist, Chemical Residues, to determine where the sample must be submitted, and to obtain a sample submission number.

Monitoring for organochlorine pesticides insecticides is carried out to assess their prevalence in the major slaughter populations, as part of the National Chemical Residue Monitoring Plan (See sections 5.2.5, 5.2.6).

5.2.15.4 Follow-up

Insecticide exposure should be dealt with as for any other herd or flock exposure. (See section 5.2.3)

5.2.16 Other pesticides

5.2.16.1 Introduction

Pesticides form a class of agricultural chemicals which, if applied correctly, serve to increase the efficiency of food production through the control of pests affecting both plant and animal life. Besides the insecticides, the general class of pesticidal chemicals thus includes: attractants, defoliants, fungicides, herbicides, molluscicides, nematocides, ovicides, plant bactericides, plant growth regulators, repellents, rodenticides, sterilants, and others. An extremely wide scope of chemicals is needed to fulfil this multiplicity of functions. For analytical purposes, it is therefore convenient to divide pesticides according to their general chemical structure:

- Triazines
- Phenoxyacid derivatives
- Organometallic compounds
- Other inorganic and organic compounds

5.2.16.1.1 Triazines

Triazines find widespread application as herbicides. While practically insoluble in water, triazine herbicides exhibit a relatively low mammalian toxicity. Accumulation in the trophic food chain has not been observed to any appreciable degree.

5.2.16.1.2 Phenoxyacid derivatives

Phenoxyacid derivatives are very efficacious herbicides and are frequently applied as such. Typical examples of this group of compounds are 2,4-dichlorophenoxyacetic acid (2,4-D), 2,4,5-trichlorophenoxyacetic acid (2,4,5-T), 4-chloro-2-methylphenoxyacetic acid (MCPA), and 4-(4-chloro-o-tolyloxy)butyric acid (MCPB).

They are generally water soluble and quickly metabolized. Their mammalian toxicity is relatively low. Of primary interest are, however, residual constituents and metabolic end products of the polychlorinated aromatic type, such as chlorinated dibenzo-p-dioxins (CDD)

and chlorinated dibenzofurans (CDF). See the section on polyhalogenated hydrocarbons (5.2.18).

5.2.16.1.3 Organometallic compounds

This group of compounds includes organomercurials and arsenicals. Organomercurials find application as fungicides for seed treatment, while arsenicals are used as medicating feed ingredients for poultry and swine in the control of coccidiosis, hexamitiasis, blackhead and to improve pigmentation and weight gain. Copper chromated arsenate (CCA) was widely used as a preservative on pressure-treated lumber, but is being phased out in favour of less toxic compounds.

Any hazard with these compounds is associated with the metal (mercury or arsenic) component. See section 5.2.19.

5.2.16.1.4 Other inorganic and organic compounds

Several pesticidal substances, notably rodenticides and special purpose formulations, do not fit any of the above categories and are equally unsuited to multiple residue approaches. Residues of this nature can only be analysed for on special request using compound specific techniques.

5.2.16.2 Sample selection

Where an animal is suspected of exposure to a pesticide, collect 250 g each of liver, kidney, and fat. Samples should be immediately frozen to stop the break-down of compounds by enzyme activity.

5.2.16.3 Testing

The above considerations are important for deciding on sample selection for testing and checking for clinical symptoms on suspected animals. If pesticides are not used carefully and in accordance with label directions, accidental contamination of feeds or direct exposure of livestock is possible. In certain cases, animals may be suspected of heavy exposure to a particular pesticide, either from reports of owners or other people connected with the livestock industry, or from observation on ante mortem and post mortem inspection. Such indications of exposure must be followed up. All available information, including ante and post mortem signs, should be reported to your Area Program Specialist, Chemical Residues, who will decide whether further investigation and sample submission will be necessary. It is important to identify the suspected chemical at least by group. Any reasonable suspicion should be checked out by laboratory tests, but it should be borne in mind that analyses are costly and laboratory facilities are limited.

Do not submit unscheduled samples to the lab without prior authorization. The assay that you require may not be available at all labs. Private labs which process samples for the National Chemical Residue Monitoring Plan (Section 5.2.5, 5.2.6) can only perform the tests, and the number of samples, for which they have a contract.

Contact your Program Specialist, Chemical Residues, to determine where the sample must be submitted, and to obtain a sample submission number.

Monitoring for polyhalogenated hydrocarbons (PCBs, dioxins) is carried out to assess their prevalence in the major slaughter populations, as part of the National Chemical Residue Monitoring Plan (See sections 5.2.5, 5.2.6).

5.2.16.4 Follow-up

Pesticide exposure should be dealt with as for any other herd or flock exposure.
(See section 5.2.3)

5.2.17 Chlorine

5.2.17.1 Introduction

Chlorine compounds are used in registered establishments as antimicrobial agents in the plant environment, on product contact surfaces, and on carcasses via either spray or immersion. These compounds may include dissolved chlorine gas (Cl_2), chlorine dioxide (ClO_2), and sodium hypochlorite (NaClO). The antimicrobial action is exerted through the strong oxidizing ability of free chlorine.

In contact with organic matter, chlorine will react to form various organochlorine compounds. Those of greatest health concern in drinking water are the chloramines (monochloroamine, NH_2Cl; dichloramine, $NHCl_2$; and trichloramine, NCl_3) and the chloromethanes (methyl chloride, CH_3Cl; methylene chloride, CH_2Cl_2; chloroform, $CHCl_3$; and carbon tetrachloride, CCl_4). Chloroform is a carcinogen, dichloromethane is a mutagen, and several of these compounds can cause liver or kidney damage.

Chloramines and chloromethanes are volatile, so will not leave persistent residues in the finished product. However, higher molecular weight organochlorine compounds with carcinogenic potential may be formed. See section 5.2.18, polyhalogenated hydrocarbons.

Health Canada has issued a letter of no objection to the use of chlorine at levels **up to 50 ppm in poultry, and up to 20 ppm in red meat**. In the case of red meat, a rinse with potable water is always required after such use. Operators who wish an exemption from the potable water rinse must request it in writing from Health Canada.

5.2.17.2 Sample selection and testing

As specific compounds of concern have not been identified, laboratory analysis is not practical.

5.2.17.3 Follow-up

All product exposed, or potentially exposed, to chlorine in excess of the Health Canada limits should be detained until its status can be determined. Notify your inspection manager, and your Area Program Specialist, Chemical Residues.

If chlorine levels are not monitored continuously, such as by an automated in-line sensor with an alarm, then all product exposed since the last acceptable test is deemed suspect.

Companies using chlorine as an antimicrobial product treatment, either by spray or by immersion, must have measures in place to prevent exceeding the approved limit. On the first occurrence of exposure in excess of the limit, affected product may have the contact surfaces removed. Alternatively, the producer may chose to dispose of any suspect product to inedible rendering or landfill. The company must produce an action plan to prevent recurrence.

On the second occurrence of exposure in excess of the limit, the corrective action plan should be reviewed to determine why it failed, and a letter of advice issued to the company. Product may again be either reworked or discarded.

In the event of any subsequent exposures, the product shall be condemned. In addition, a third occurrence constitutes failure of the HACCP plan, and must be addressed accordingly.

5.2.18 Polyhalogenated hydrocarbons

5.2.18.1 Introduction

Polyhalogenated hydrocarbons comprise several families of compounds, of varying toxicity. Groups of interest include:

- Pentachlorophenol (PCP)

- Polychlorinated Biphenyls (PCB)
- Chlorinated Dibenzo-p-dioxins (CDD)
- Chlorinated Dibenzofurans (CDF)

PCBs, dioxins, and dibenzofurans are homologous series of derivatives varying in the degree of halogen substitution, which together with isomers, form an entire spectrum of individual compounds. Members of each family vary from highly toxic to relatively non-toxic, so doses and maximum residue levels are normally expressed as "toxic equivalents" (TEQ) of the most toxic compound.

5.2.18.1.1 Pentachlorophenol (PCP)

PCP is widely used as a fungicide and wood preservative. PCP in higher concentration is toxic. The compound is to an extent lipophilic and accumulates in fat. The use of wood treated with PCP in barns or wood shavings as litter has caused concern in two areas:

- PCP present in chicken litter is converted through bacterial action into chlorinated anisoles, which impart a musty odour and taste to chicken meat.

- Commercial PCP may be contaminated with chlorinated dibenzodioxins (CDD) and chlorinated dibenzofurans (CDF). See section 5.2.18.1.3. CDD and CDF have higher chemical stability than PCP and may persist in tissues after PCP is metabolized.

5.2.18.1.2 Polychlorinated biphenyls (PCBs)

Polychlorinated biphenyls were developed as heat exchangers in electrical transformers, and were widely used in plastics and paper manufacturing. Their high chemical stability, which was a desirable property in their industrial applications, also made them an environmental contaminant. Trace levels of PCBs are found universally in nearly every species of land and aquatic animals tested. PCBs were never manufactured in Canada, and their manufacture in the United States was terminated voluntarily in 1977, but they may still be found in older equipment. Accidental spills have resulted in serious contamination of feed in isolated areas. PCBs have similar chemical characteristics to those of organochlorine pesticides. (See section 5.2.15.1.1) They are lipid soluble and accumulate in the fat of animals.

5.2.18.1.3 Dioxins

Polychlorinated dibenzo-p-dioxins (PCDDs) and dibenzofurans (PCDFs) are often referred to simply as "dioxins". They are very stable and fat-soluble, and therefore accumulate in the food chain. They may be present as contaminants or by-products in the manufacture of other halogenated compounds. They are also found in fly ash from incinerators, and produced naturally in forest fires. As a result, they are a ubiquitous environmental contaminant, found at very low levels in all living organisms.

Depending on the degree of chlorination (1-8 chlorine atoms) and the substitution pattern, one can distinguish between 75 PCDDs and 135 PCDFs, called "congeners". The toxicity of dioxins varies considerably. Of the 210 congeners, only 17 are of toxicological concern. Exposure levels or residues are expressed in toxic equivalents (TEQ) of the most toxic congener, 2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD).

Exposure to a concentrated source, or to an unusually contaminated environment, may result in measured dioxin levels significantly above the background level.
These compounds produce a syndrome characterized by a delayed onset and involving widespread degenerative changes in several organs, in particular liver, thymus, and skin. CDD and CDF are formed during manufacture of chlorinated hydrocarbons and are also present in PCBs, organochlorine pesticides and phenoxyacid herbicides.

5.2.18.2 Sample selection

If any reasonable suspicion exists about the possible presence of residues due to industrial accidents or localized environmental contamination, the matter should be brought to the attention of the Area Program Specialist, Chemical Residues, for further action.

Monitoring for PCP and dioxins is conducted as part of the National Chemical Residue Monitoring Program. (See sections 5.2.5, 5.2.6)

A sample submission shall consist of fat and liver. In the case of birds, the sample can be pooled from several birds of the same flock.

PCBs are detected by the same analytical method as the organochlorine pesticides, and monitoring for PCBs is conducted within the program for pesticides.

5.2.18.3 Testing

Do not submit an unscheduled sample to the lab without prior authorization. The assay that you require may not be available at all labs. Private labs which process samples for the National Chemical Residue Monitoring Program (Section 5.2.5, 5.2.6) can only perform the tests, and the number of samples, for which they have a contract.

Contact your Area Program Specialist, Chemical Residues, to determine where the sample must be submitted, and to obtain a sample submission number.

5.2.18.4 Follow-up

The Area Program Specialist, Chemical Residues, will likely request a check sample from the same producer, to determine whether the residue was transient or represents an on-farm problem. A visit to the farm of origin may be conducted to attempt to determine the route of exposure.

5.2.19 Heavy metals

5.2.19.1 Introduction

Contamination with heavy metal residues has occurred from seeds treated with fungicides or disinfectants containing mercury or arsenic, and subsequent use in feedstuffs. Contamination has also occurred as a result of accidents in formulations of feeds with arsenicals or from environmental contamination by lead, cadmium, or mercury.

Arsenic poisoning is no longer common, because most farm chemicals and veterinary medications containing arsenic are no longer in use. Arsanilic acid is still employed at low levels as a medicating feed ingredient for pork and poultry. (See Medicating Ingredient Brochure 4.) Main sources for environmental access are discarded cans of arsenicals, areas of industrial pollution (smelters), and ashes from the burning of treated fence posts. Animals will develop a tolerance to arsenic if it is fed at sublethal doses over a period of time.

Cadmium is present in areas of high industrialization as an environmental pollutant and finds widespread use as a plating metal. It is also present as a natural soil component in some areas. It accumulates in liver and kidney as a function of age, while muscle tissue levels remain constant. Kidney levels are generally somewhat higher than corresponding liver levels. Horses are particularly prone to concentrating cadmium in their organs; for this reason, horse kidneys and livers are not considered edible.
Copper is an ubiquitously distributed element essential to the animal at trace mineral levels. It is normally poorly absorbed, and not all copper circulating in the blood is available to the animal. Deficiency is a greater problem than excessive dosage. The distribution of copper in the liver is very uneven, the caudate lobe having higher concentrations than those found in the dorsal or ventral lobes.

Lead levels in ditchbank vegetation due to automobile exhaust have dropped significantly with the introduction of lead-free gasoline. Current sources of access to livestock include industrial pollution, waste engine oil, putty, roofing tiles, old lead-based paint, and lead batteries. So-called lead-free paint may contain up to 1% of lead.

Mercury as a general environmental pollutant is strictly controlled by legislation, making high level occurrences less frequent. Distribution of mercury in the body depends on the form in which it is ingested. Organic mercurials lead to high blood and brain levels with equal amounts in liver and kidney, while inorganic mercury tends to exhibit higher levels in the kidneys. Organic mercurials are more toxic than inorganic mercury.

Selenium, aside from extremely localized areas of industrial pollution, is introduced primarily with the feed. Bound forms of selenium, such as selenomethionine, are available in the majority of vegetable diets. Deficiency is a greater problem than excessive dosage. Absorption and utilisation is extremely variable and highly dependent on the type of diet and antagonistic effect of other trace elements. Even animals with clinical signs due to selenium toxicity do not usually demonstrate tissue selenium levels above the normal range.

Zinc finds widespread application as a plating and galvanizing metal and can be found in high concentration in areas of industrial pollution (smelters). Toxicity is uncommon, young animals being more susceptible than older ones. Zinc is an essential trace element and deficiency represents a problem. Infectious diseases are known to lower liver and serum levels while increasing corresponding kidney levels.

5.2.19.2 Sample selection

For metals, skeletal muscle, liver, and kidney are sampled. Metals are monitored for under the National Chemical Residue Monitoring Program (see sections 5.2.5, 5.2.6). Animals originating from sources with suspected or known access to heavy metals, if not condemned on ante mortem inspection for clearly visible symptoms, shall be held and sampled, and samples submitted to the laboratory. Contact your Area Program Specialist, Chemical Residues, for guidance.

5.2.19.3 Testing

Do not submit unscheduled sample to the lab without prior authorization. The assay that you require may not be available at all labs. Private labs which process samples for the National Chemical Residue Monitoring Program (Section 5.2.5, 5.2.6) can only perform the tests, and the number of samples, for which they have a contract.

Contact your Area Program Specialist, Chemical Residues, to determine where the sample must be submitted, and to obtain a sample submission number.

5.2.19.4 Follow-up

Animals found with elevated levels will be traced to the farm of origin. An inspection may be conducted by a feed inspector to determine the source of elevated levels. Subsequent shipments from the producer should be checked.

The accompanying sample submission form should, if at all possible, state the specific heavy metal suspected. The additional remark "special request" will avoid confusion with regular monitoring and assure the priority status for the sample submitted.

5.2.20 Hydraulic fluid

5.2.20.1 Introduction

Hydraulic fluids may be used in various places in registered establishments, such as adjustable stands, restrainers, and forklift trucks. Because the presence of hydraulic fluids in the establishment can be a source of incidental, undetected contamination of edible product,

such as by contact with hands or clothing, these fluids must be of an approved type listed in the Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products. (See Chapter 3, Section 3.6.3.5) These fluids are usually long-chain hydrocarbons.

However, extensive exposure such as from a burst hydraulic line poses a greater risk. Over time, hydraulic fluids, even though approved, may become heavily contaminated with heavy metals or other chemicals from the equipment. In areas where there is exposed product, pneumatic equipment, which uses compressed air instead of liquid is preferable.

5.2.20.2 Assessment

As described under "In plant exposure" (Section 5.2.4), exposed product must be either condemned for adulteration or detained pending assessment and appropriate corrective action. It may be difficult to see the extent of contaminated meat that needs to be removed, and also difficult to demonstrate by means of a meaningful sample that the method of decontamination, for example trimming, has effectively eliminated all contamination.

If the company wishes to attempt to salvage exposed product, contact your Program Specialist, Chemical Residues, who will request a risk assessment from the National Manager, Chemical Evaluation. In order to conduct the assessment, the following information will be required.

Provide a short description of the events that occurred just before, during, and immediately after the discovery of the spill, to allow understanding of the situation. As precisely as possible, answer each of the following questions:

- How was the spill detected? For example, during routine inspection, equipment held, after a fire, etc.
- What was the brand of oil or fluid? If the Material Safety Data Sheet is available, this should be included.
- What amount of fluid escaped?
- Was the fluid under pressure?
- For fluids under pressure, at what temperature and pressure is the fluid normally maintained when the equipment is operating?
- How often is the fluid normally replaced in the equipment, and when was it last changed?
- How much time passed between the start of the spill and the time it was detected? It may be necessary to estimate the time. State "unknown" if it is possible that the spill continued for some time before being discovered.
- What products were exposed to the fluid? A description of all the exposed products is required.
- How did the fluid come into contact with the product? For example, "by dripping", "vaporised under pressure", "smoke produced when fluid burned", etc.
- Was the product that the operator wants evaluated packaged? If yes, describe the packaging. (Plastic or paper? Sealed or not? What thickness?)
- Was the product fresh or frozen at the time of exposure?
- How was the product stored, stacked, etc.

And, concerning the control of the contaminated product:

- **Have actions been taken** to reduce the risks? (For example, visible contamination trimmed immediately)
- Is the product currently under detention and segregated?
- What has the company proposed for reducing the risk? (For example, remove the skin then rinse; discard one hour's production)
- What has the company proposed for testing the product? (For example number of samples, which laboratory, which method)

- Has the company requested the advice of the CFIA about methods of reducing the risk and of testing the product?

5.2.20.3 Follow-up

Appropriate corrective actions will be determined based on the risk assessment. Affected product may need to be condemned or reworked under inspectional control.

5.3 BACTERIA

5.3.1 Introduction

Meat has traditionally been implicated as a major source of bacterial foodborne diseases. The food-producing animals themselves are often contaminated with pathogenic organisms, such as *Campylobacter coli* and *Campylobacter jejuni*, *Clostridium perfringens*, *Escherichia coli*, *Listeria monocytogenes*, *Salmonella* spp., *Staphylococcus aureus*, or *Yersinia enterocolitica*. During slaughter and cutting, surfaces of red meat and poultry may become contaminated with bacteria, finding the available amino acids an ideal nutrient to support growth and propagation.

Ready-to-eat meats are frequently identified as being responsible for outbreaks of foodborne disease, which is primarily caused by recontamination from raw or undercooked products during handling in processing and catering establishments, and in the home kitchen. Direct responsibility of the CFIA is, of course, limited to the first category. Temperature abuse and prolonged exposure of cooked products to moderate or room temperature prior to consumption can lead to a proliferation of bacteria. Risks associated with roast beef and ham are relatively high, while sausage products and cold cuts form a variable hazard. Ground beef, meat loaves and pies, corned beef and beef jerky are occasionally implicated, some supporting *Clostridium botulinum*. While properly cooked poultry is quite safe, risks of cross-contamination from raw chicken are extremely high.

Quality control is the responsibility of the operator, who must put in place all the required critical control points or the equivalent control procedures to ensure that the product is safe. The inspector of an establishment must assure that quality control measures in the establishment are performed satisfactorily. Deviations in processing methods that may result in unsatisfactory product, such as possible contamination of the processing line or raw materials, insufficient heat exposure during cooking or smoking, improper cooling procedures, or extended storage, should be evaluated by qualified plant personnel.

5.3.2 Ready-to-eat products (M200, M203)

5.3.2.1 Introduction

Ready-to-eat (RTE) products are monitored under two sampling programs, which are M200 (Domestic RTE Meat Products) and M203 (Imported RTE Meat Products).

RTE products generally receive adequate heat treatment to destroy all pathogens with the exception of their spores, and to reduce saprophytic bacteria. Dry cured products, such as salamis and some hams, which do not receive any heat treatment, are required to be free of pathogens except for unavoidable low loads of *Staphylococcus aureus*. Raw and semi-prepared products are heat treated prior to consumption and profiles simply reflect sanitary handling, temperature abuse and product age.

5.3.2.2 Sample selection

Samples are frequently selected from new product formulations and from lots identified by inspectors in order to verify that processing methods produce a safe product. The types of pathogens analyzed each year depend on risk-based priorities and completeness of the data base.

Since bacteria are unevenly distributed in meat products, five subsamples of the same production lot are analyzed. For each sample, aseptically collect five subsamples of 200 g each, or five intact units weighing at least a total of 1000 g.

5.3.2.3 Testing

Samples are submitted to the Ottawa (Carling) laboratory. See section 5.8.6, Samples for Microbiological Analysis. Indicate whether the product is fermented. The following analyses will be performed: Aerobic colony count (ACC) (except fermented products), *E. coli, S. aureus, Salmonella* spp. The *E. coli* O157:H7 analysis will be performed only on fermented and dry cured products containing beef.

5.3.2.4 Follow-up

For interpretation of test results, see the sections on the specific organisms. Results are assessed as satisfactory, investigative, or unsatisfactory.

Investigative indicates that organisms are present at a higher level than is considered normal for the type of product. The plant management should be notified of the result, and should undertake a review of their process and sanitation. This may include conducting additional sampling and testing at their own expense. An action plan should be submitted to the Inspector in Charge within 10 days, unless otherwise specified.

Unsatisfactory indicates that the product is out of compliance. It should be placed under detention until it can be brought into compliance, such as by adequate thermal processing. A health risk assessment will be conducted to determine whether a product recall is warranted.

When unsatisfactory or investigative results are encountered, the Inspector-In-Charge or the complex supervisor can contact an Area Program Specialist for guidance with regard to the corrective or follow-up action to be taken.

5.3.3 Domestic raw ground beef and raw ground veal (M201)

5.3.3.1 Introduction

Ground beef has been implicated in a number of food-borne disease outbreaks. In the process of grinding, bacteria present on the surface can be distributed throughout the product. If the product is not cooked for an adequate time at a high enough temperature, bacteria in the centre may not be killed.

Ground beef is monitored for generic *E. coli* as a marker for contamination, and for *E. coli* O157:H7 because this organism has been implicated in disease outbreaks. (See section 5.3.8)

5.3.3.2 Sample selection

Collect samples in accordance with the Guidelines for the Microbiology Sampling in Red Meat and Poultry Products distributed at the start of each fiscal year.

The sample consists of five sample units of 200 g each, collected from five different locations. Do not composite sample units; send five individual sample units to the laboratory.

Inspectors in Charge must ensure that the lot size is not less than one hour's production from the ground beef or veal production line. Whole combos should be used for a lot of ground beef or veal sampled under this plan.

5.3.3.3 Testing

Sample units may be composited for *E. coli* count. Sample units **are not composited** but analysed separately for *E. coli* O157:H7.

5.3.3.4 Follow-up

Test results are assessed as follows.

Analysis	Standard/guideline				Assessment	
	n	c	m	M	Investigative	Unsatisfactory
E. coli (generic)	5	n/d	n/d	10^2	$>10^2$	n/a
E. coli O157:H7	5	0	0	-	n/a	present in 65 g

Follow the guidelines for the Microbiology Sampling in Red Meat and Poultry Products.

5.3.4 Aerobic colony count (ACC)

5.3.4.1 Description

This test, being the most general in nature of all microbiological assays, constitutes an economical way to detect foods that have been held under conditions that permit microbial growth. Comparative counts at different incubation temperatures are particularly useful in monitoring food processing by revealing sources of contamination and prior temperature histories of chilled and frozen products. The test also serves an important role as a sanitation indicator.

The test is performed on special request on a case-by-case basis.

5.3.4.2 Follow-up

See the Meat Microbiology Analysis Assessment Criteria distributed each fiscal year with the Guidelines for the Microbiology Sampling in Red Meat and Poultry Products.

ACC is an indicator of proper handling, and does not demonstrate the presence of pathogens. When levels of indicators are elevated, the information is transmitted to the company for follow-up and corrective actions if required. The limit shown in the table is a guideline, not a standard. Therefore, there is no need for inspection staff to resample the product.

5.3.5 *Campylobacter coli* and *Campylobacter jejuni*

5.3.5.1 Description

Campylobacter coli and *C. jejuni* are slender, non-spore forming, spirally curved, rod-shaped organisms, that are gram-negative, have a minimum growth temperature of 28°C and are resistant to freezing.

5.3.5.2 Occurrence

Campylobacter jejuni, recognized in 1980 as a foodborne pathogen, and more recently *C. coli*, are emerging as important public health concerns. The organisms are relatively ubiquitous in the environment, commonly found in untreated water and in the intestines of poultry, cattle, swine, rodents, wild birds. Poultry products, beef and liver are most commonly implicated in disease outbreaks, primarily due to consumption of raw meats or inadequate cooking. Meat products should reach an internal temperature of at least to 69°C to eliminate the risk of infection.

5.3.5.3 Concern

The minimum infective dose appears to be quite low and toxicological manifestations include headache, fever and muscle pain, followed by self-limiting enterocolitis with severe abdominal pain, anorexia, malaise, and vomiting primarily in young adults. Occasionally, other complications such as septicemia, short-term arthritis, Guillain-Barré syndrome or meningitis have been reported. Symptoms of campylobacteriosis occur within 2 to 10 days after ingesting contaminated food and recovery may take from a few days to a few weeks.

5.3.5.4 Program

Sampling programs are implemented on a rotating basis in the form of surveys or targeted monitoring.

5.3.5.5 Sampling

Sampling is normally limited to ready-to-eat products and testing is conducted to discern the absence or presence of the organism. Specific instructions accompany the call for sampling.

5.3.6 *Clostridium perfringens*

5.3.6.1 Description

Clostridium perfringens is an obligate anaerobic spore-forming bacterium that may grow from 4 to 60 ^{o}C. The optimum temperature for growth is 43 to 47^{o}C and the generation time 10 to 12 minutes. Minimum water activity and pH for growth are 0.95 and 5.0, respectively. Very few new spores are produced in cooked foods. Its enterotoxin, produced in the intestinal tract, is a protein with a molecular weight of approximately 36,000 daltons.

5.3.6.2 Occurrence

The organism is commonly found in most raw agri-food commodities, particularly those of the high-protein or high-starch types, and its spores may survive cooking. These spores are heat activated to germinate when a suitable temperature is reached. Long slow cooling and room temperature storage encourage the multiplication of bacteria. Foods involved in disease outbreaks include cooked meats, poultry, gravy, sauces and soups. Contributing factors are storage of foods at room temperature and holding foods warm for prolonged periods of time.

5.3.6.3 Concern

Clostridium perfringens is recognized as ranking among the top-most important cases of food poisoning in North America and Europe. The commonly observed symptoms of the disease are headaches, gassy diarrhea and abdominal pain occurring approximately 8 to 22 hours (on the average 10 hours) after the ingestion of contaminated food. The symptoms may last for one or two days. Counts of *C. perfringens* vegetative cells usually exceed 10^{6}/g in food causing poisoning. The enterotoxin is responsible for food poisoning. Disease prevention depends entirely on the suppression of bacteria growth in foods after cooking, while cooling must be relatively rapid and refrigerated storage maintained. Testing is of special importance in ready-to-eat meat products.

5.3.6.4 Program

Sampling programs consist of incidence-related surveillance and compliance activities and are performed in connection with plant sanitation.

5.3.6.5 Sampling

Sampling is normally limited to ready-to-eat products and testing is conducted to discern the absence or presence of the organism.

5.3.7 Generic *E. coli*

5.3.7.1 Introduction

While of little significance in raw commodities, the presence of these non-hazardous organisms in processed products serves as a useful indicator that contamination may have occurred. As an index for sanitation, they permit monitoring of plant hygiene for a wide range of processed foods and are therefore indispensable to HACCP approaches. This is also the case for the broader categories of coliforms and fecal coliforms.

5.3.7.2 Testing

E. coli counts are routinely performed on multiple analysis submissions (MASS) of ready-to-eat meat products including fermented commodities.

5.3.7.3 Follow-up

Test results are interpreted based on the specific commodity, as follows:

Product	Standard/guideline				Assessment	
	n	c	m	M	Investigative	Unsatisfactory
Non-fermented RTE products	5	1	10^2	10^3	>60/g on composite	>10^3/g or >10^2/g in more than 2 units
Heat treated fermented RTE sausage	5	1	10	10^3	10^3 if any detected on composite	>10^3/g or >10/g in more than 1 unit
Raw fermented RTE sausage	5	0	10^2	10^3	>40/g on composite	>10^3/g or >10^2/g in more than 1 unit

5.3.8 Verotoxigenic *E. coli*

5.3.8.1 Description

Escherichia coli O157:H7, as well as several other related strains, are gram-negative facultatively anaerobic rod-shaped microorganisms with unusually severe pathogenic characteristics not normally observed for the genus of *Escherichia*.

5.3.8.2 Occurrence

These bacteria live in the intestines of animals such as cattle, pigs, sheep and poultry. During slaughter, they may spread to the outer surfaces of the meat. *E. coli* O157:H7 infection can also be spread by hand-to-hand contact with an infected person or by contact with a contaminated surface. Aside from the O157:H7, there are other dangerous strains of *E. coli*.

Although Hemolytic Uremic Syndrome (HUS) is commonly called "hamburger disease", other kinds of undercooked meat and poultry, fermented meat products, unpasteurized milk, non-chlorinated water, and raw apple juice contaminated with *E. coli* O157:H7 have made people ill. Ground beef may be easily contaminated, due in part to the grinding process which spreads the bacteria, generally found on the surface, throughout the meat.

5.3.8.3 Concern

Enteropathogenic *Escherichia coli* were not recognized as significant foodborne pathogens until the early 1970s, while the O157:H7 strain was first identified as causing human illness in

1982 in U.S. and Canadian outbreaks. While the former type is known to cause gastroenteritis with self-limiting non-bloody diarrhea due to toxin production, the latter strain is characterized by bloody diarrhea (hemorrhagic colitis) and, in 10% of all infected humans (notably children), by being causative of the HUS, which interferes with normal renal functions and the blood coagulation mechanism and may require blood transfusions and kidney dialysis. Chronic kidney failure in the aged and susceptible (diabetics) and child mortality due to HUS have been stated as reaching 30% of all affected cases. Seizures or strokes are not uncommon among the elderly.

Symptoms may develop as stomach cramps, vomiting and a mild fever within 2 to 10 days after ingesting contaminated food. Unless accompanied by severe complications, most people recover within 7 to 10 days.

5.3.8.4 Program

Raw or semi-cooked meat products, and more recently fermented products as well, are primary objects for monitoring, while ready-to-eat products remain prime suspects due to recontamination.

5.3.8.5 Sampling

Meat products are sampled and submitted for laboratory analysis to determine specific strains of verotoxic E. coli. In addition, rapid testing is employed to ascertain the presence or absence of these organisms.

Samples are interpreted as follows:

Analysis	Standard/guideline				Assessment	
	n	c	m	M	Investigative	Unsatisfactory
E. coli O157:H7	5	0	0	-	n/a	present in 65 g

5.3.9 *Salmonella*

5.3.9.1 Description

Salmonella organisms are known to exist in well over 2,000 serotypes. They are readily inactivated by pasteurization temperatures in foods with a water activity greater than 0.95. Heat resistance increases with lowering of the water activity. In dried foods, *Salmonella* survive longer at water activity values below 0.20 than at higher values. Dependent on acid type, they are generally killed by a pH below 4.5 and are injured by cooling to below 7^{o}C or freezing.

5.3.9.2 Occurrence

They are widely distributed in the environment through the discharge of natural animal and human waste to land and water. Raw poultry is often contaminated with at least one strain of *Salmonella*. Primary sources of human salmonellosis are foodstuffs of animal origin, particularly raw or undercooked meat and poultry and, in some instances, unbroken eggs and unpasteurized egg and dairy products. Red meat and poultry become contaminated during slaughter and processing from the gut content of healthy excreting animals. In a similar way, every food that is produced in a contaminated environment may become exposed to salmonella and may in turn be responsible for foodborne disease outbreaks as a result of faults in transport, storage or preparation.

5.3.9.3 Concern

Salmonella organisms are in many countries the most prevalent causative agent in foodborne

disease outbreaks. *Salmonella* act directly as a viable organism without producing an enterotoxin and the likelihood of illness is therefore proportional to the number of organisms ingested. The exact number or organisms necessary to produce human salmonellosis depends on the serotype; in some cases as little as a few viable cells per 100 g of minced meat have caused an outbreak of serious consequences. Symptoms include diarrhea, abdominal cramps, vomiting and fever. In more serious cases, salmonellosis may cause dehydration, or it may infect the entire body. These symptoms are usually not felt for 6 to 48 hours and last from one to three days.

5.3.9.4 Program

In spite of controls at the farm level (*Salmonella*-free livestock, breeding stock, feed and sanitary environment) and at the slaughterhouse (sanitation of holding pens, hygiene during slaughter, avoidance of cross-contamination), *Salmonella*-contaminated food commodities remain on the market and every possible opportunity must be taken to inform the food service industry and the general public about the basic principles of food hygiene.

5.3.9.5 Sampling

Salmonella evaluations are routinely performed on multiple analysis submissions of domestic ready-to-eat meat products including fermented commodities (sampling schedule M-200) and imported ready-to-eat products (sampling schedule M-203). For each sample of domestic product, five (5) subsamples of 150 g each or five units will be sent to the designated laboratory. A similar sample consisting of five (5) subsamples of 150 g each will be collected from every re-inspected shipment of imported ready-to-eat meat products and submitted to the designated laboratory.

Sample results are interpreted as follows:

Analysis	Standard/guideline				Assessment	
	n	c	m	M	Investigative	Unsatisfactory
Salmonella spp.	5	0	0	-	n/a	present in 125 g

5.3.10 *Yersinia enterocolitica*

5.3.10.1 Description

Yersinia enterocolitica is a rod-shaped organism that becomes non-motile at 37^{o}C. It has an optimum growth temperature of 22 - 29^{o}C, but will continue to grow at 4^{o}C for several weeks.

5.3.10.2 Occurrence

The organism is widely distributed in nature.

5.3.10.3 Concern

Human infections and isolations from foods have been reported since 1963. Infective symptoms include pain, fever, headache, sore throat, severe enteritis (sometimes mistaken for appendicitis), arthritis, peritonitis, meningitis and bacteremia. Yersiniosis occurs mainly in the very young, the very old and the debilitated or immuno-compromised. The disease is rarely fatal, except for bacteremic complications. It appears that a total of approximately 10^9 organisms is necessary to produce the disease.

5.3.10.4 Program

Only general hygienic measures are available for controlling the organism and monitoring efforts permit a better insight into the organism's distribution patterns in food commodities.

5.3.10.5 Sampling

Targeted monitoring (surveys) is undertaken on a rotating basis to discern changes and trends in prevalence and distribution.

5.3.11 *Listeria*

5.3.11.1 Description

Listeria monocytogenes is a Gram-positive, non-spore forming, rod-shaped bacterium. It is very hardy, resistant to drying, freezing, and high salt concentrations. It can grow readily at refrigeration temperatures and in vacuum-packaged meat and poultry products. *Listeria* can be destroyed by thoroughly cooking products.

5.3.11.2 Occurrence

Listeria monocytogenes is widely distributed in nature, occurring in soil, sewage, vegetation, water, silage, livestock, and humans. It is well adapted to survival in cold, moist environments commonly found in meat processing establishments. Foods most commonly associated with outbreaks of listeriosis include hot dogs, deli meats, pâté, dairy products, coleslaw, salted mushrooms, and fish. Cooked meat and poultry products can be contaminated from equipment, from the handling of raw products by personnel, or from reservoirs of *Listeria* in the ready-to-eat environment.

5.3.11.3 Concern

Immunocompromised individuals, pregnant women, neonates, and the elderly are most susceptible to infection. *Listeria monocytogenes* most often causes an influenza-like illness but can cause meningitis, septicemia, abortion, stillbirth, and death. Death is rare in immunocompetent persons affected with listeriosis, but is approximately 30% in the high-risk group. The dose response for *L. monocytogenes* in humans is not known exactly, but may be less than 1,000 organisms/g of food for some susceptible people.

5.3.11.4 CFIA Testing Program

There are four programs for *Listeria* monitoring/verification in federally registered establishments producing ready-to-eat (RTE) meat and poultry products:

1) *Listeria* environmental monitoring program for federally registered establishments (Sampling plan M205): Its purpose is to monitor the effectiveness of sanitation and good manufacturing practices (GMPs) in preventing contamination of RTE processing environments and product by *L. monocytogenes*

2) Ready-to-eat meat and poultry product monitoring/sampling program for domestic products (Sampling plan M200): This random sampling plan covers all RTE meat and poultry products produced in federally registered establishments.

3) The Risk-based Verification Sampling of RTE meat and poultry products: This is a CFIA sampling plan implemented by operators and is subject to CFIA supervision. It covers all RTE meat and poultry products that are exposed to the environment after processing (post-lethality exposed product).

4) Ready-to-eat product sampling for imported products (Sampling plan M203): Refer to instructions in the Guidelines for the Microbiology Sampling Plans for RTE Red Meat and Poultry Products distributed annually for imported RTE meat and poultry products and to the Meat Hygiene Manual of Procedures (MOP) Chapter 10 for additional information.

5.3.11.5 CFIA *Listeria* environmental monitoring of food contact surfaces – Sampling plan M205

All federally registered meat establishments producing a RTE meat or poultry product that is exposed in the post-lethality environment shall be tested by the CFIA under this sampling plan. RTE meat and poultry products are products that do not require any further preparation prior to consumption except, when applicable, washing, rinsing, thawing, or warming. Frankfurters and deli meats are automatically considered RTE products because of consumer's customary handling practices.

5.3.11.5.1 Sampling frequency

Sampling frequency is stated in the microbiological sampling guidelines under Sampling plan M205 (*Listeria* Environmental Monitoring Program). Establishments which seasonally manufacture a RTE product shall be tested during the production period.

5.3.11.5.2 Sampling procedures

The operational centre supplies *Listeria* sampling kits to the Inspector-in-Charge (IIC). Kit content information and instructions on sanitary sampling techniques are supplied with the kits, and should be reviewed by inspectors upon receipt of the kits and before taking samples. Any problems with the sampling kits should be reported immediately to the Area Program Specialist for processing/microbiology.

Samples shall be submitted in accordance with instructions on sampling plan M205. Pre-moistened swabs will be used to sample food contact surfaces (FCS: any surface or object that comes into contact with the RTE meat or poultry product) after the lethality treatment in the establishment. For fermented or dry cured products, FCS may be swabbed after the area where the operator considers the product has achieved RTE status. Ten swabs are used in each kit to swab ten different FCS sites. If ten sites are not available, a minimum of five sites must be swabbed. A 900 cm^2 surface should be swabbed whenever possible. Surfaces must be swabbed three hours (T3) or more after the start of the operations. If the time of production is less than three hours, the samples should be taken in the second half of the production period. The sampling sites should be documented on CFIA/ACIA 5165 (LSTS User Service, "Meat" Form) Food Environmental Sampling Submission Form which accompanies the shipment to the CFIA lab. Composite samples will be tested for the presence of *L. monocytogenes.*

The M205 sampling plan is conducted at the same time as the RTE product sampling under the M200 plan. In multi-line operations, a production line is randomly selected for sampling. Operators must be informed 24 hours in advance of sampling so that they can hold the product affected by the sampling.

5.3.11.5.3 Tracking of results

All CFIA results must be tracked, including result(s) from follow-up testing. The IIC shall verify results of *Listeria* testing until the establishment has corrected the problem. The Area Specialist, Meat Processing, and the Inspection Manager are to be informed of all unsatisfactory results.

5.3.11.5.4 CFIA Follow-up on unsatisfactory results

The IIC must inform the operator (or representative) of the unsatisfactory test result as soon as possible, either in person or electronically. An establishment which has an unsatisfactory result for *L. monocytogenes* under M205 is not considered to be operating according to GMPs.

All sampling activity will be tracked through Compliance Verification System (CVS) sampling tasks and any "Unsatisfactory" result will result in a Corrective Action Request (CAR).

The IIC will examine the test results of the product that was sampled simultaneously under the M200 plan from the same production lot and line that revealed unsatisfactory M205 results. The IIC and/or the complex supervisor will review the action plan submitted by the operator, verify the on-site activities proposed in the action plan, and oversee the operator's follow-up actions. The IIC may consult the Area Program Specialist when required for program clarification and advice and/or may submit the action plan to the Area Program Specialist for his review and comments. The IIC will collect FCS and/or product samples towards the end of the operator's follow-up testing to verify compliance (Table 1).

The Area Program Specialist will provide additional information on a case-by-case basis when the results of these additional tests are available.

5.3.11.5.5 Operator follow-up on unsatisfactory results under M205

Operators receiving a CAR because of an unsatisfactory result under sampling plan M205 are required to take immediate corrective actions. The operator must also submit an action plan to the IIC within 5 working days of the notification of the unsatisfactory result. The action plan must indicate all of the corrective measures that will be implemented to eliminate *L. monocytogenes* in the RTE environment. This includes the need to test the same FCS free of *Listeria* spp., including *L. monocytogenes,* for three consecutive times (Appendix 1 and 2). The first sample must be taken as soon as possible within the 5 working days after the notification of an unsatisfactory test result.

5.3.11.6 CFIA *Listeria monocytogenes* product testing under sampling plan M200

Product is also tested for *L. monocytogenes* under CFIA sampling plan M200. This plan applies to all RTE meat and poultry products, whether or not they are exposed to the environment after being processed. Only one type of RTE product is sampled from the selected production line on a given production day. CFIA inspection staff should make all efforts to test various types of RTE products during subsequent M200 sampling events.

Other organisms tested under this sampling plan include: *E. coli, Salmonella* spp.*, Staphylococcus aureus,* as well as *E. coli* O157:H7 if it is a dry or semi-dry fermented product containing beef.

5.3.11.6.1 Sampling frequency

The sampling frequency is stated in the Guidelines for the Microbiology Sampling Plans for RTE Red Meat and Poultry Products under sampling plan M200. Establishments that seasonally manufacture a RTE product shall be tested during the production period.

5.3.11.6.2 Sampling procedures

Samples must be collected aseptically by the IIC as per the guidance provided in the Guidelines for the Microbiology Sampling Plan. Five intact sample units of 250 g each are collected and submitted to the CFIA laboratory. Please refer to the available training material on sample collection for the complete information.

It is strongly recommended to hold the product affected by the sampling pending the reception of the laboratory Report of Analysis (ROA). As a minimum, all products produced under the same conditions as the tested lot are considered implicated (e.g., products processed on that day on the same processing line, or using the same equipment, between two full sanitation cycles). Distributed product may be subject to a recall in the event of an unsatisfactory result.

5.3.11.6.3 Tracking of results

All CFIA results must be tracked, including result(s) from follow-up testing. The IIC shall verify results of *Listeria* testing until the establishment has corrected the problem. The Area

Specialist, Meat Processing, and the Inspection Manager are to be informed of all unsatisfactory results.

Table 1: Follow-ups by CFIA for unsatisfactory results obtained under CFIA sampling plans

RTE product testing (M200)	FCS testing (M205)	Verification sampling done by CFIA towards the end of operator's follow-up testing under plan:	
Unsatisfactory	Unsatisfactory	M200D	M205D
Satisfactory	Unsatisfactory	M200I	M205D
Unsatisfactory	Satisfactory	M200D	M205I

Note: D is "Directed sampling", and I is "Investigative sampling."

5.3.11.6.4 CFIA follow-up on unsatisfactory results under M200

The IIC must inform the operator (or representative) of the unsatisfactory test result as soon as possible, either in person or electronically. An establishment which has an unsatisfactory result for *L. monocytogenes* under M200 is not considered to be operating according to GMPs. The IIC will examine the results of M205 sampling associated with the unsatisfactory M200 product test result.

All sampling activity will be tracked through CVS sampling tasks and any "Unsatisfactory" result would result in a CAR.

A "hold-and-test (5-3-2-1)" end product testing will be initiated immediately by the operator under CFIA supervision. The IIC and/or the complex supervisor will review the action plan submitted by the operator and verify on-site activities proposed in the action plan. The IIC may consult the Area Program Specialist for program clarification and advice and/or may submit the action plan to the Area Program Specialist for his review and comments. The IIC must keep track of all follow-up samples associated with an unsatisfactory result. The IIC will also collect follow-up product and/or FCS samples towards the end of the "hold-and-test" period to verify compliance (Table 1).

Depending on the circumstances, additional measures may be taken, such as intensified CFIA inspection and in depth review at the establishment.

5.3.11.6.5 Operator's follow-up on unsatisfactory results under M200

Operators receiving a CAR because of an unsatisfactory result under sampling plan M200 are required to take immediate corrective actions and to submit an action plan to the IIC within 5 working days of the unacceptable result (Appendix 3). The action plan must indicate all the corrective measures that will be implemented to prevent product contamination by *Listeria monocytogenes*. This includes the "hold-and-test (5-3-2-1)" end product testing which must start immediately on all new production lots produced on the affected line after the notification of the unsatisfactory result. The action plan must also indicate how the contaminated product will be disposed of.

5.3.11.6.6 End product sampling under "Hold-and-Test"

Operators must implement "hold-and-test (5-3-2-1)" end product testing whenever a RTE meat and poultry product tests unsatisfactory for *L. monocytogenes* for any reason (e.g. CFIA

sampling, Operator's testing, process control, client initiated testing, etc.). This is to ensure that the new product lots produced on the affected line are safe prior to their distribution. The same product that was judged unsatisfactory under M200 should be sampled under "hold-and-test", if not available, a similar product or other high-risk product can be selected from the affected line in consultation with the IIC. Five sample units, each weighing 100 g, are sampled by the operator and submitted to an accredited laboratory for analysis of *L. monocytogenes*.

The sampling frequency over 4 production weeks should be:

- one sample every day in the first week (total 5 samples);
- one sample on alternate days in the second week (total 3 samples);
- one sample after two days interval in the third week (total 2 samples); and
- one sample in the fourth week.

A "week" refers to 5 consecutive production days on the affected line. If a sample tests unsatisfactory during the follow-up testing, the "hold-and-test" procedure starts from the beginning.

5.3.11.7 CFIA's Risk-based Verification Sampling of Ready-to-Eat (RTE) meat and poultry products

This is a CFIA sampling plan but implemented by the operator. This sampling plan targets RTE meat and poultry products that are exposed to the environment after the production process is complete.

It takes into consideration the level of risk inherent to the product (with reference to its composition, pH, a_w, salt content, etc.) as well as the level of control used by the operator with regards to *Listeria* (the alternative under which the establishment falls).

This sampling plan is implemented by operators and is conducted under the supervision of the CFIA. Please refer to Annex I as well for all the relevant information.

Unsatisfactory results are handled in the same way as those from the CFIA's M200 sampling plan.

5.3.11.8 CFIA's action during extended non-compliance

Operators producing RTE meat and poultry products must implement satisfactory control measures when there is on-going occurrence of *L. monocytogenes* or *Listeria* spp. on FCS or in the product. CFIA inspection staff will take appropriate actions, such as intensified inspection, in-depth review etc., when the continuous presence of *Listeria* on the FCS or in the product is encountered. The situations that warrant immediate action are:

a) **Repetitive:** Two consecutive unsatisfactory sampling events from samples taken from the same production line for either the product or FCS, regardless of the sampling plan i.e. operator's sampling (mandatory or not), CFIA sampling or follow-up sampling etc.

b) **Recurrent:** Two unsatisfactory sampling events from samples taken from the same production line for either the product or FCS in a moving window of the five latest sampling events on that line, regardless of the sampling plan.

c) **Systemic:** Multiple unsatisfactory sampling events from samples taken from different production lines for either the product or FCS. For example:

    - Three or more production lines have unsatisfactory results from samples taken during the same week;
    - Two or more production lines have recurrent problems.

Note: Only one sampling event can take place on a production line between two complete sanitation cycles.

5.3.11.8.1 Intensified CFIA inspection

Intensified CFIA inspection is proposed whenever a repetitive, recurrent or systemic problem is identified. Intensified inspection may involve actions such as reassessment of the action plan, intensified follow-ups to verify implementation and effectiveness of the corrective actions and preventative measures, and increased frequency of specific CVS tasks related to CCPs, equipment design, process validation, maintenance and calibration, sanitation, GMPs, employee/product traffic pattern, ventilation, etc.

5.3.11.8.2 CFIA's in-depth review

The in-depth review is triggered when intensified inspections do not resolve the situation. The goal of an in-depth review is to identify deficiencies which may be responsible for the unsatisfactory conditions and continuing presence of *Listeria* in either the post-processing environment or the product. An in-depth review will also assess if the operator's HACCP system:

- Is designed to effectively control *Listeria* hazards;
- Meets the FSEP and program requirements; and
- Is reassessed to ensure *Listeria* hazards remain under control.

Please refer to MOP Chapter 18 for further guidance and information concerning in-depth review.

5.3.11.9 Operator program

Operators producing RTE meat and poultry products must implement adequate controls in their establishment to control the risk posed by *L. monocytogenes*. Their HACCP system must therefore include, without being limited to, the following information as it pertains to controlling *L. monocytogenes*:

1. Use of a post-lethality treatment, when one is used (including its validation)

2. Use of an antimicrobial agent or process, when used (including its validation)

3. Sanitation guidelines:
   - General cleaning
   - Determining the effectiveness of Sanitation Standard Operating Procedures (Visual examination and testing)
   - Procedures (Sanitation Standard Operating Procedures (SOP))
   - Employee/product traffic control (Including prevention of cross-contamination)
   - Employee hygiene
   - Sanitizers (including the need to alternate product)
   - Sources and control

   Note: It is not acceptable to clean, maintain or repair the equipment while conducting operations in the same room because of the potential for cross-contamination.

4. Equipment design and maintenance. Particular attention must be paid to the equipment used in the RTE processing area. More precisely, the equipment must be fit for the proposed use, well designed so it is easy to clean, and be evaluated after sanitation. Operators must provide a detailed description of procedures that will ensure proper disassembly, maintenance and sanitation of the inner gear-housings for all equipment used for slicing and/or cutting RTE products.

5. Control of the environment during construction activities such as cleaning of a clogged up drain, preventative maintenance of equipments, employee/product traffic flow when only one section of the facility is operating, etc.

6. Take into consideration the end user of the RTE products they put on the market (e.g., whether or not the population at risk is an important proportion of the clientele).

7. For processes which do not include a kill step (such as the production of prosciuttos or uncooked fermented products), control of the microbiological quality of the raw ingredients used in the manufacturing process.

8. All establishments using the same facility or common equipment to produce RTE products that support the growth of *L. monocytogenes* and others that do not support growth of *L. monocytogenes* (according to current Health Canada policy) must review their HACCP plans, GMPs, control documents, product segregation and sanitation steps. This is important because as per Health Canada policy, RTE products that do not support *L. monocytogenes* growth are allowed to be sold when there is occasional presence of organisms in the product, provided the level of *L. monocytogenes* is below 100 cfu/g and the GMPs are in place. Such products can contaminate products that support the growth of *L. monocytogenes* when both types of products are produced in the same facility or using common equipment. The cross-contamination can be prevented by using dedicated equipment throughout the process or by processing the products that support the growth of *L. monocytogenes* at the beginning of the operation or after complete satisfactory sanitation.

In order to demonstrate product compliance, operators have to verify the effectiveness of their HACCP controls by implementing the following sampling procedures:

1) Mandated environmental sampling of FCS as per section 5.3.11.10.

2) The Risk-based Verification Sampling of RTE Meat and Poultry Products according to Annex I. This sampling applies only to products exposed to the environment after processing.

5.3.11.9.1 Laboratory procedures

The following requirements are applicable to both the mandated environmental FCS testing as well as any product testing performed by operators as part of the *Listeria* verification:

1. All samples have to be analyzed in an accredited laboratory.

2. The methods of analysis that will be used by the laboratories have to be within the scope of their accreditation OR evidence must be available to demonstrate that the process is underway for adding the method to the scope of accreditation with the accrediting body (e.g., Standards Council of Canada).

3. The operator shall indicate, for each sample submitted, the method of analysis that is to be used by the laboratory (Authorized methods are listed under Appendix 4). The method used must be appropriate to the sample analyzed.

4. The operator must inform the CFIA of all the test results by electronic notification as soon as they are aware of them.

5. Laboratory analysts must have demonstrated technical competence in the approved methods.

6. Compliance to these criteria will be audited by the CFIA.

Note: Requirements 1, 2 and 3 above do not apply to the operator's FCS tests which are

not mandated (for example, tests done over and above the ones required by the CFIA as per section 5.3.11.10.4).

5.3.11.10 Mandated operator sampling of Food Contact Surfaces

Operators can develop their own written sampling plan based on their operations, or have a processing authority develop a sampling plan. The testing frequencies specified below (5.3.11.10.4) for FCS must be met or exceeded.

Although not mandated, it is strongly recommended that operators also test non-food contact surfaces to locate potential sources of contamination. This can be done according to Industry Best Practices.

5.3.11.10.1 Target organism for the mandated operator sampling of Food Contact Surfaces

Operators may test FCS for *L. monocytogenes* or *Listeria* spp. Operators should indicate whether or not they will confirm a presumptive positive result to species level. If they decide to consider the presumptive positive result as the final result, then it must be considered as "unsatisfactory".

5.3.11.10.2 Sample collection for the mandated operator sampling of Food Contact Surfaces

Operators must follow industry best practices when implementing their environmental sampling of FCS. Operators should collect samples from ten (10) different FCS sites from each line which will be considered as one sampling event for the selected production line. If ten FCS sites are not available, a minimum of 5 sites must be sampled. Operators must also provide a rationale for testing less than ten (10) sites. No more than 10 (ten) samples should be composited as this process makes it more difficult to trace the source of the contamination. In addition, for operators who also test for non-FCS, it is strongly recommended not to mix FCS and non-FCS samples together. Should the operator decide to mix different surfaces, the result will be considered as affecting a food contact surface, but will not count toward the minimum number of tests that have to be taken. The individual locations for the composite sample should be noted to assist in determining the site of contamination when an unsatisfactory result is obtained.

The surfaces must be swabbed three hours (T3) or more after the start of the operations. This will provide a reliable assessment of the working conditions as the elapsed time will have allowed surfaces to be inoculated. If the time of production is less than three hours, the samples must be taken in the second half of the production shift. Should operators wish to specifically verify the sanitation of a specific structure or equipment, additional samples may be taken prior to start-up (T0).The CFIA strongly encourages this practice. A 900 cm^2 surface should be swabbed whenever possible.

When confirming the presence/absence of *L. monocytogenes* on a FCS and/or when the next sampling is scheduled before the results of the previous FCS test are received, it is strongly recommended to hold the product pending the reception of the laboratory report, since an unsatisfactory result will trigger the need to sample this product.

5.3.11.10.3 Methods of analysis for the mandated operator sampling of Food Contact Surfaces

Please refer to Appendix 4 for sampling methodology requirements.

Requests to use alternate methods of analysis must be presented to Health Canada.

5.3.11.10.4 Testing frequency for the mandated operator sampling of Food Contact Surfaces

Food contact surfaces on each production line must be tested at the following minimum frequencies. A lower testing frequency may be considered for dedicated production lines used exclusively for the production of a lower risk alternative product. For an establishment

producing RTE products falling in more than one alternative category, the testing requirement of the establishment defaults to the highest risk category product. For Alternatives 1 and 2, the tests must be spread out throughout the year.

Establishment Category		Food Contact Surface Testing
Alternative 1*		2/year/line
Alternative 2*		4/year/line
Alternative 3*: See below		
Non-deli, non-hot-dogs		1/month/line
Deli and hot-dogs	Very Small volume est.**	1/month/line
Deli and hot-dogs	Small volume est.**	2/month/line
Deli and hot-dogs	Medium volume est.**	3/month/line
Deli and hot-dogs	Large volume est.**	4/month/line

* : Refer to Annex I, section 3 for additional information.
**: Very small: up to 100,000 kg of RTE meat products produced per year
Small: from more than 100,000 kg to up to 2,000,000 kg of RTE meat products produced per year
Medium: from more than 2,000,000 kg to up to 6,000,000 kg or RTE meat products produced per year
Large: more than 6,000,000 kg of RTE meat products produced per year

5.3.11.10.5 Results and follow-up for operator sampling of Food Contact Surfaces

The finding of *Listeria* spp. or *L. monocytogenes* on a FCS must trigger corrective actions by the operator. Any follow-up testing required by the operator in response to an unsatisfactory test result is considered mandatory testing. When confirming *Listeria* spp., two consecutive unsatisfactory tests on the same FCS, including follow-up tests, will be considered equivalent to *L. monocytogenes*. Therefore, the same FCS must be tested and found negative for *Listeria* spp., including *L. monocytogenes*, for three consecutive tests. It is strongly recommended to hold the product when doing these follow-up tests, as an unsatisfactory result will trigger the need to analyse the product. In addition, the first of the required follow-up tests must be done as soon as possible within the 5 (five) working days of the unsatisfactory result notification. Appendixes 1 and 2 explain the follow-up procedure whenever the operator gets an unsatisfactory result while testing FCS for *Listeria* spp. or *Listeria monocytogenes*, respectively. This is applicable to all FCS testing done by the operator, whether mandated or not.

As indicated under section 5.3.11.9.1, operators must inform the CFIA as soon as they are aware of unsatisfactory results applicable to food contact surfaces, whether the result indicates *Listeria monocytogenes* or *Listeria* spp. Once informed of an unsatisfactory result, the IIC must forward this information to the Area Processing Specialist. All subsequent laboratory results related to that unsatisfactory result must be evaluated by the IIC in collaboration with the complex supervisor and the Area Processing Specialist.

The finding of *L. monocytogenes* on a FCS will also trigger the following actions:

- Product testing for *L. monocytogenes*; this must cover all of the products that were potentially in contact with the tested FCS that generated the unsatisfactory result. The test is done by the operator as per section 5.3.11.7.
- Since the finding of *L. monocytogenes* on a FCS indicates that the establishment is not operating under GMPs, the CFIA will issue a CAR. The action plan must be presented to the CFIA within 5 working days.

- The IIC will inform the complex supervisor and the Inspection Manager of the *L. monocytogenes* result.

The IIC and the complex supervisor shall ensure that results of *Listeria* testing are tracked until the establishment has corrected the problem. The IIC will collect FCS swab samples at the end of operator's follow-up testing to verify compliance (Table 2). An evaluation may be done to determine whether or not intensified CFIA inspection or an in-depth review should be conducted.

Note: Operators must also address unsatisfactory results for non-food contact surfaces, especially if *L. monocytogenes* is identified. All sampling results from non-food contact surfaces are to be tracked by the operator and must be available to the CFIA upon request.

Table 2: Follow-ups by the CFIA for unsatisfactory results obtained under operator's sampling plans

RTE product testing	FCS testing	Verification sampling done by the CFIA towards the end of the operator's follow-up testing under plan:	
Unsatisfactory	Unsatisfactory	MX200	MX200
Unsatisfactory	Satisfactory	MX200	MX200
Satisfactory	Unsatisfactory	None	If needed, based on previous history

5.3.11.11 Operator implementation of the CFIA Risk-based Verification Sampling of Ready-to-Eat (RTE) meat and poultry products

All operators producing RTE meat or poultry products which are exposed to the environment after processing must implement the CFIA's "Risk-based Verification Sampling of Ready-to-Eat (RTE) Meat and Poultry Products". All the details concerning this sampling plan, including follow-up measures, can be found in Annex I.

All product sampling must be done for the detection of *L. monocytogenes* and *Salmonella* spp. If the product is a dry or semi-dry fermented sausage and contains beef, it will also be analysed for *E. coli* O157:H7. All the requirements stated under 5.3.11.9.1 "Laboratory procedures" apply. The additional following requirements also apply to this product testing:

1. Samples must be collected under direct CFIA supervision.

2. Prior to their shipment to the accredited laboratory, samples must be appropriately sealed under direct CFIA supervision (tamper proof).

3. The chain of custody must be maintained.

4. The accredited laboratory must also send the test results to the CFIA as indicated in Annex I.

If at any time unsatisfactory results are obtained for RTE meat and poultry products, the CFIA must be informed of the results as soon as the operator is aware of them. The operator will perform follow-up procedures as described in Appendix 3 and will implement the "hold-and-test" policy for end product testing as per section 5.3.11.6.6 should the results be

unsatisfactory for *L. monocytogenes*. Each case will be individually reviewed by the IIC in consultation with the complex supervisor and the Area Program Specialist. The IIC must inform the Inspection Manager of all unsatisfactory results under this sampling plan. When other pathogens are detected, the follow-up procedures will be determined on a case-by-case basis.

The IIC and the complex supervisor must keep track of all follow-up samples associated with an unsatisfactory result. The IIC will also collect RTE product samples towards the end of "hold-and-test" follow-up sampling to verify compliance (Table 2).

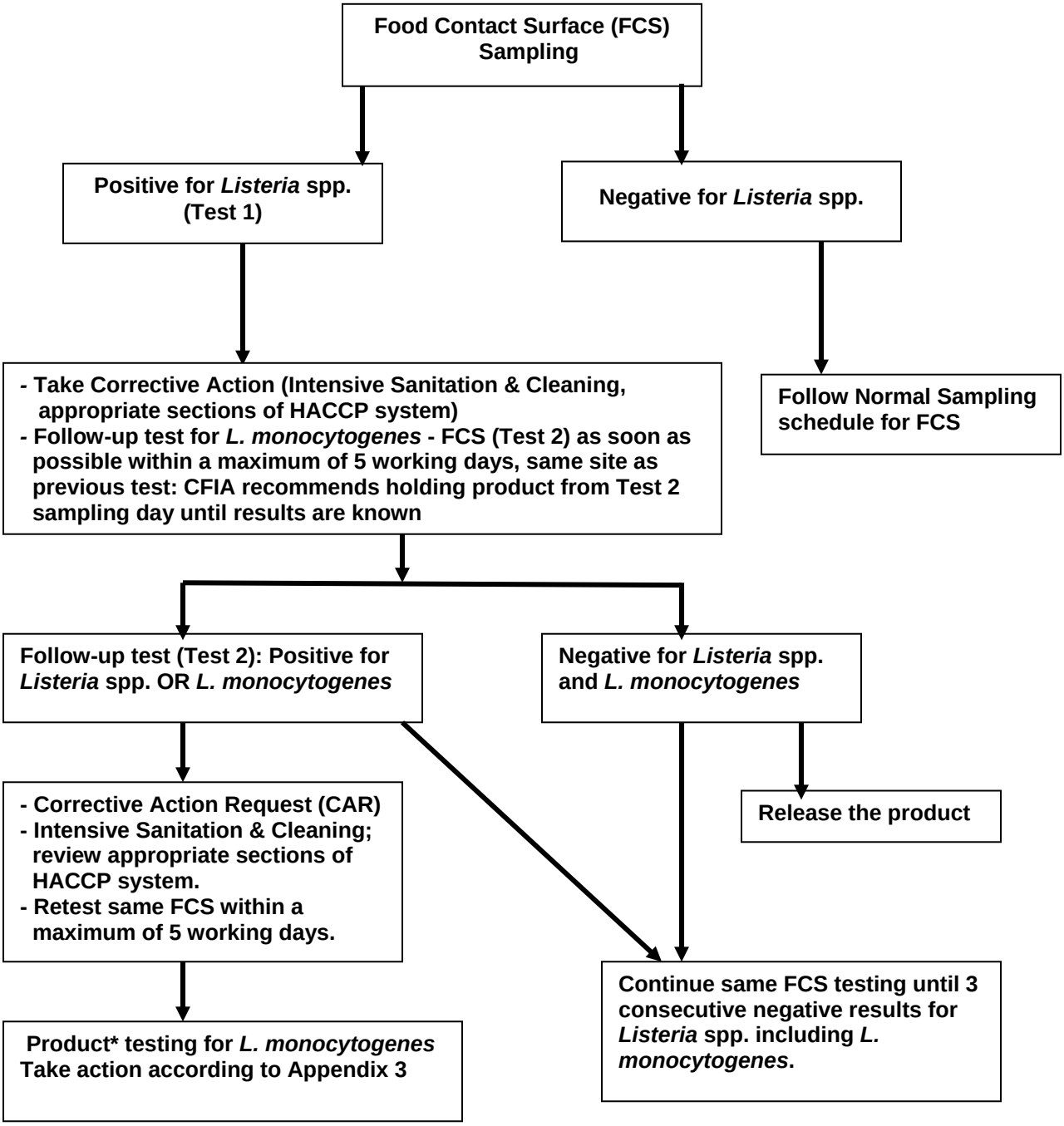
5.3.11.12 Operator's trend analysis of results

Performing trend analysis on test results is an essential component of any sampling program designed to monitor a microbiological risk. Operators are therefore required to include this procedure in their HACCP system. They must also indicate the parameters they will use to assess whether or not the risk is controlled. When the risk is not controlled, corrective actions must be taken in order to bring the situation back to normal.

Particular attention must be paid to the follow-up actions taken when the number of unsatisfactory results obtained is either high or on the increase, as well as when the *Listeria* detection is moving from a non-FCS to a FCS. The operator must react to these situations in a rapid and efficient way. In addition, if the establishment often finds itself in such a situation, it would indicate that the provisions of the HACCP system are not stringent enough to control the risk posed by *Listeria*. All pertinent aspects of the HACCP system must then be re-evaluated and the required adjustments done.

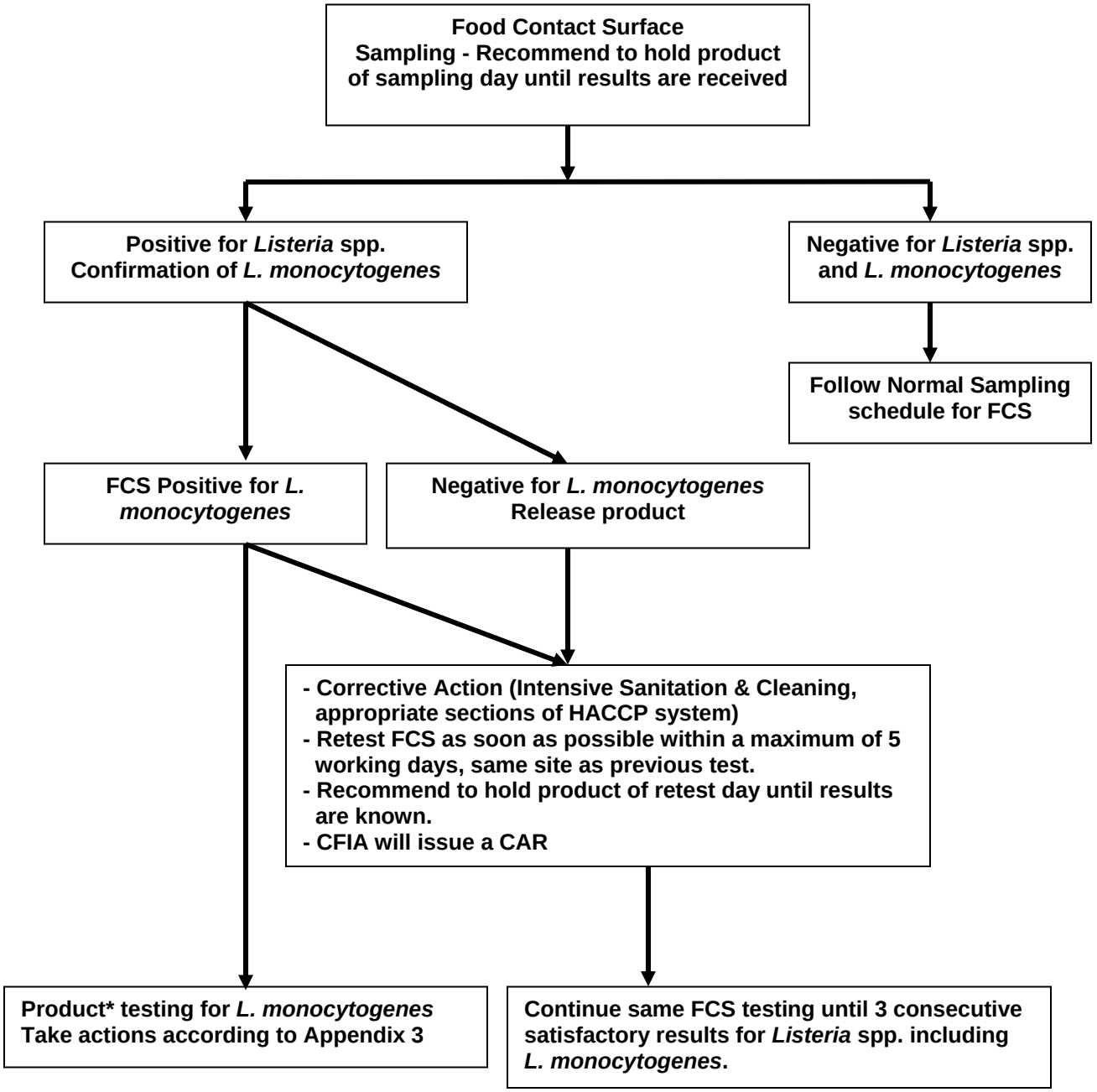
Finally, it is of the utmost importance that not a single unsatisfactory test result be ignored. In order to be efficient, the ensuing follow-up actions will need to take into consideration the origin of the result (e.g., a non-FCS, a FCS or a product).

Appendix 1 – Operator's Procedure when Food Contact Surfaces are Tested for *Listeria* spp.



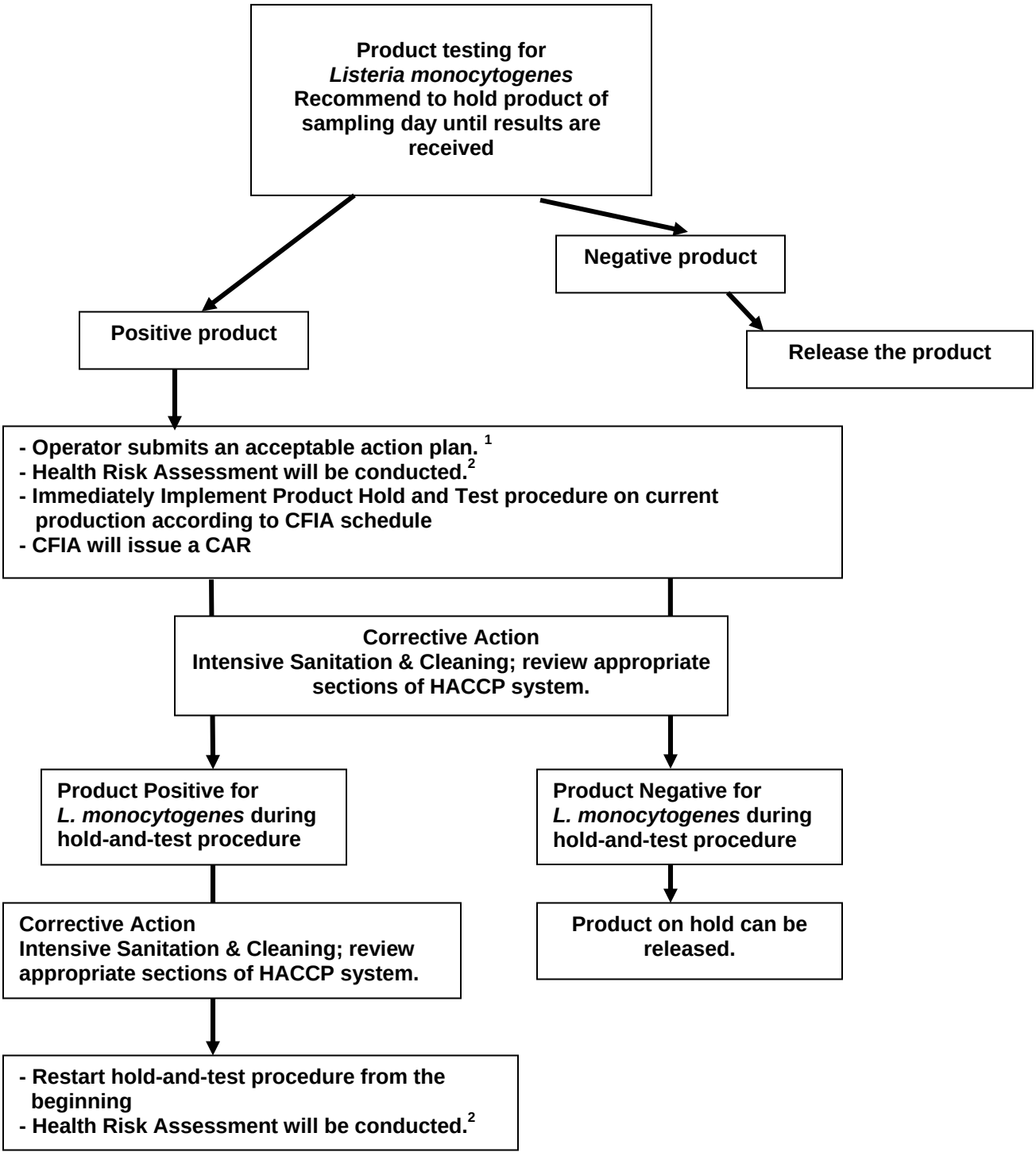
*: **Product from the lot produced when FCS was sampled for "Test 2".**

Appendix 2 – Operator's or the CFIA's Procedure when Food Contact Surfaces are Tested for *Listeria monocytogenes*



*: **Product from the lot produced when FCS was sampled.**

Appendix 3 – Operator's or CFIA's Procedure when Product is Tested for *Listeria monocytogenes*



[1;] Operator must present an action plan, including a risk management plan for the involved product, to the CFIA.
[2:] Contact the Area processing specialist for Health Risk Assessment.

Appendix 4 - Methods of Analysis for *Listeria monocytogenes* in RTE meat and poultry products and FCS samples, and *Listeria* spp. in mandated FCS samples.

All testing of environmental food contact surface samples mandated by the CFIA, as well as any product testing performed by operators as part of *Listeria* verification procedures in their establishment must be done following the procedures outlined in Section 5.3.11.9.1 of this document.

In addition to these requirements, all testing must be performed using approved methodology as outlined below.

Approved methodology can be found in the Health Canada Compendium of Analytical Methods.

The most recent version of the following methods are approved for use when testing for either *Listeria monocytogenes* (in product or environment) or *Listeria* spp. (in environment).

NOTE: Positive results from any rapid screening methods are considered presumptive. *Listeria* spp. confirmation and speciation of *L. monocytogenes* can be accomplished by using motility agar, hemolysis and carbohydrate testing as a minimum, as described in **MFHPB-30**.

Appropriate methods for the testing of *Listeria monocytogenes* include:

Ready-to-eat meat and poultry products

- **MFHPB- 30:** Isolation of *Listeria monocytogenes* from all food and environmental samples.
- **MFLP- 28:** The Qualicon Bax® System Method for the Detection of *Listeria monocytogenes* in a Variety of Food.
- **MFLP- 74:** Enumeration of *Listeria monocytogenes* in foods (to use as per Policy on *Listeria monocytogenes* in ready-to-eat foods).

For environmental testing (testing for *Listeria* spp. and/or *L. monocytogenes*)

- **MFHPB- 07:** Detection of *Listeria* spp. in foods and environmental samples using Palcam Broth.
- **MFHPB- 29:** Detection of *Listeria* spp. in foods and environmental samples by the Vidas Listeria™ method.
- **MFHPB- 30:** Isolation of *Listeria monocytogenes* from all food and environmental samples.
- **MFLP- 15:** The detection of *Listeria* spp. from environmental surfaces using the DuPont Qualicon Bax® System method and direct plating.
- **MFLP- 34:** Detection of *Listeria* spp. in Foods and Environmental Samples by the VIP Method.
- **MFLP- 71:** Detection of *Listeria* spp. in foods using the Oxoid Listeria rapid test (the Clearview kit).

All analysis must be performed in an accredited laboratory as defined in Section 5.3.11.9.1.

Other methods of analysis (e.g., from the Health Canada's Compendium, AOAC, ISO, NMKL, FSIS, BAM etc.), for both *L. monocytogenes* in food product and environmental samples and *Listeria* spp. in environmental samples, will be considered with the provision of validation data to support the requested method. A system to notify both industry and private laboratories of newly approved methods that are accepted by CFIA and Health Canada for testing *L. monocytogenes* and/or *Listeria* spp. in meat products and environmental samples is under development and will be implemented shortly.

As with any methods, as new data and innovative methods become available, methods in the Compendium will continue to be revised, and then reviewed by the Microbiology Methods Committee.

5.3.12 *Mycobacterium bovis*

5.3.12.1 Introduction

Mycobacterium bovis and the closely related *M. tuberculosis* are the agents of tuberculosis in both animals and humans. Mycobacteria are slow-growing, gram-positive, acid-fast slightly curved or straight rods. Because they invoke a weak host response, the infection is persistent and slowly progressive, and characterized by small, rounded granulomas (tubercles), which consist of a translucent mass, grey in colour, with a caseous core.

Although once widespread, bovine tuberculosis is now relatively uncommon. Nonetheless, isolated lesions of tuberculosis are still seen periodically in both pigs and cattle, and disseminated tuberculosis is occasionally seen.

Cattle are most often infected by inhalation, resulting in lesions in the lungs and bronchial and mediastinal lymph nodes. Swine are most often infected orally, resulting in lesions in the retropharyngeal and mesenteric lymph nodes.

A related species associated with poultry, *M. avium*, can cause identical lesions in cattle or swine, but is not usually considered pathogenic for humans. Lesions of *M. avium* are usually solitary, but cannot be differentiated from those of *M. bovis* except by culture.

For guidance on dispositions, see Chapter 17.

5.3.12.2 Sample selection

All lesions compatible with tuberculosis should be sampled, along with the surrounding tissues; including caseous or purulent thin-walled abscesses (especially in Cervidae and Camelidae), lymphadenitis, granulomas, and actinomycosis-like lesions. Tuberculosis cannot reliably be identified or ruled out based solely on gross appearance of lesions.

Because tuberculosis is a potentially zoonotic disease, no attempt should be made to pre-screen lesions, such as by impression smears.

If there are multiple lesions, collect representative samples of each one. Each lesion must be bisected and submitted for both histopathological examination and culture. Do not send the lymph node from one side of the animal for histology and the corresponding one from the other side for culture.

5.3.12.3 Testing

Histopathology is conducted on all specimens, and cultures are performed when indicated.

Samples submitted for the diagnosis of tuberculosis must be submitted using form CFIA/ACIA 1528, Pathology Specimen Submission. This form should be generated using the LSTS Sample Submission Forms application. Use one submission form (and therefore one form reference number) per animal. Fresh (or fresh frozen) samples and formalin samples from the same animal are submitted using the same submission form. Note that borate solution is no longer used as a transport medium for mycobacteria, as it frequently resulted in false negative cultures.

Samples should be collected using a TB Sample Kit. See the instructions in Annex D or E, as applicable. The TB kits can be ordered by completing and faxing in the media and material order form (see Annex F).

It is imperative that all forms of identification associated with animals exhibiting these lesions be recorded on the CFIA/ACIA 1528 to facilitate herd tracebacks.

Forward three copies of each submission form to the laboratory (one is for the histology lab,

one for the culture lab, and one for data entry purposes).

Although the instructions at Annexes D and E allow for freezing samples prior to shipping, this should be avoided, as the rate of isolation will be reduced.

5.3.12.4 Follow-up

Because culture and identification of mycobacteria can take up to six months, carcass disposition must be made based solely on gross pathology. See Chapter 17.

Herd tracebacks will be conducted by Animal Health inspectors on all histopathology-positive lesions. The inspection staff submitting such lesions will be informed of the results of the investigation.

5.4 PRIONS

This section is currently under review.

5.5 PARASITES

5.5.1 Cysticercosis

5.5.1.1 Introduction

Cysticercosis is the presence in tissues of the immature form of various species of tapeworm. Each is associated with particular host species, as follows:

Cyst form	Adult form	Intermediate host
Cysticercus bovis	*Taenia saginata*	Cattle
Cysticercus cellulosae	*Taenia solium*	Swine

C. cellulosae is of particular public health significance, because humans can act as both a definitive and an intermediate host, and therefore develop cysts in tissues and organs.

5.5.1.2 Sample selection

Lesions appear as clear or white spheres, 6 to 10 mm in diameter, with a hollow centre containing clear fluid. Old lesions may be calcified. Predilection sites are the masseter, tongue, heart, and diaphragm. When a lesion is found, a thorough search of these sites should be conducted for additional lesions.

See Chapter 4, Section 4.6, and Chapter 9, Section 9.5.5 of the MOP for further guidance.

5.5.1.3 Testing

Lesions of suspected cysticercosis should be submitted to the Centre for Food-Borne and Animal Parasitology (See Annex G) for laboratory confirmation. All lesions should be submitted fresh, with ice packs. Do not freeze.

If a definitive diagnosis cannot be made on fresh specimens, the Centre for Food-Borne and Animal Parasitology will fix the tissues in formalin and forward them to the St. Hyacinthe laboratory for histopathology. Do not submit samples directly to St. Hyacinthe.

5.5.1.4 Follow-up

Cysticercosis is a reportable disease under the *Health of Animals Regulations*. Suspected cases should be reported to the appropriate Area program specialist. Determine the origin of

the animals to the best of your ability, as a traceback will be conducted by Animal Health inspectors to determine the source of the infection.

5.5.2 *Trichinella*

5.5.2.1 Description

The parasitic nematode *Trichinella spiralis* is still enzootic in several parts of the world. It is one of the smallest of all nematodes, measuring only 1.5 mm in length. Feeding of uncooked or inadequately heat-processed garbage to swine and poor sanitary conditions (e.g. rat infestation) in affected parts of the world are primarily responsible for the persistence of the parasite. This parasite also circulates in wild carnivores. Some of the subspecies which circulate in wildlife are more tolerant to freezing than that normally seen in swine.

5.5.2.2 Occurrence

Trichinosis is caused through the ingestion of raw and undercooked meat. At one time, pigs were the main species implicated, but with modern production methods of confinement raising and the control of garbage feeding, this has become quite rare. Cases in the arctic regions involve bear meat and walrus flesh. Horse meat has been implicated in some outbreaks in Europe.

5.5.2.3 Concern

Human infection with *T. spiralis*, or trichinosis, has a latency period of 4 to 28 days (average of 9 days). Symptoms include gastroenteritis, colic, nausea, fever, sweating, edema about eyes, muscular stiffness, swelling and pain, chills, insomnia, prostration and laboured breathing. As the ingested trichinae burrow through the intestinal wall, abdominal pain and mild diarrhea appear, followed by rheumatic muscular pains as the parasites migrate to and settle in the muscle, where they become encysted and remain stationary for the lifetime of the host. Trichinosis (heavy infestation) can be an extremely painful and long-enduring disease.

5.5.2.4 Program and sampling

The Canadian Food Inspection Agency's present policy to manage hazards related to the potential presence of *Trichinella spiralis* in pork is that of protecting the Canadian consumer through the use of appropriate processing techniques, i.e. cooking, freezing, or curing according to guidelines set out in Chapter 4, Annex B. While the results of routine monitoring of Canadian pork indicate that the risk of infection is virtually nonexistent, these precautions must remain in effect due to the presence of *Trichinella spiralis* in rats and other wildlife and the potential for this parasite to find its way into a domestic herd on a sporadic basis. Current advice to consumers in Canada regarding the need to ensure that pork is cooked at a minimum of 58ºC is consistent with this precaution.

For the purposes of this section, pork is defined as the meat derived from all swine: market hogs, breeder hogs and wild boars raised in captivity.

The CFIA *Trichinella* control program includes the following elements:

- Listing of pig trichinellosis as a reportable disease under the *Health of Animals Act*.
- Conducting of regular serological surveys of the mature pig population in Canada (15,000 sows every 5 years).
- Testing of approximately 30,000 market hog carcasses at registered abattoirs each year using digestion test methods.
- Testing of approximately 3,000 breeder hog carcasses at registered abattoirs each year using digestion test methods.
- Testing of approximately 200 wild boar carcasses at registered abattoirs each year using digestion test methods.
- Promptly implementing eradication measures, which include herd quarantine and depopulation, when a positive case is found.

- Controlling the feeding of food wastes or garbage under the provisions of the *Health of Animals Regulations* (sections 111-113). All pork producers who use food wastes (e.g. from grocery stores, bakeries, etc.) must be registered and be issued a permit. Meat and restaurant waste may not be fed to pigs, and premises are regularly inspected by CFIA officials.

This program, which is consistent with World Organization for Animal Health (OIE) guidelines, allows the CFIA to demonstrate that Canada's hog population is almost free of trichinae. Sporadic cases are promptly eradicated. To satisfy OIE/Animal Health surveillance needs and to maintain market access of Canadian pork products to other countries, it is necessary to test pigs *at a monitoring level*. It is sometimes also a requirement to test pigs or horses *at a surveillance (screening) level* to provide market access for Canadian pork products or horse meat to some countries or to identify potentially infected carcasses in quarantined or suspect herds.

Importing countries may have their own requirements regarding *Trichinella* testing. For more information on specific export requirement with regard to *Trichinella* controls, please consult the individual country requirements in Chapter 11, section 11.7.2, or the "Importing Country Requirements" module in the Meat Electronic Certification system, available to subscribers.

5.5.2.5 Control program - monitoring

5.5.2.5.1 Introduction

Monitoring is performed by CFIA staff to provide information on the prevalence of *Trichinella* infections in pork. There are three sampling plans in place: for market hogs; for sows and boars (breeder hogs); and for wild boars. Specimens are collected in abattoirs in adherence to centrally prepared sample submission schedules and are shipped to designated laboratories. Sample submission schedules are reviewed and modified as required on a yearly basis to reflect changes that have taken place during the previous year (e.g. variation in the number of slaughter establishments).

There is no hold and test requirement for monitoring programs. However, traceability (owner identification) must be maintained for follow-up actions in the case that specimens do react positive at the laboratory. Specimens should be individually wrapped and marked to ensure that trace-back to the infected farm of origin can be undertaken.

The cost for monitoring tests is borne by plant operators and is prorated according to slaughter volume. Costs for the testing are invoiced monthly by the Veterinarian in Charge for specimens collected during that period.

5.5.2.5.2 Market hogs

All market hogs slaughtered in abattoirs under federal inspection throughout a fiscal year are eligible for testing (a population of about 15,000,000 market hogs). The sampling size is about 30,000 carcasses, i.e. large enough to ensure that a prevalence in excess of 0.01% is detected with a confidence of 95%. For testing purposes, and to minimize shipping costs, the required 30,000 specimens are randomly divided into pools of 100 animals. Therefore, 300 sampling units are distributed among market hog establishments that slaughter more than 5,000 carcasses a year. The number of sampling units to collect is prorated according to slaughter volume. For establishments that slaughter less than 5,000 carcasses a year, specimens are collected in a random selection of establishments (100 specimens in each of four establishments per year).

As outlined, a sampling unit corresponds to a maximum of 100 specimens collected from 100 carcasses in one abattoir, during a randomly selected week. Specimens will be shipped to the Centre for Food-Borne and Animal Parasitology in Saskatoon early the following week. Every fiscal year, a detailed sample submission schedule is provided to all federally registered establishments slaughtering market hogs.

5.5.2.5.3 Breeder hogs

All sows and boars slaughtered in federal abattoirs throughout a fiscal year are eligible for testing. The sampling size is about 3,000 carcasses, i.e. large enough to ensure that a prevalence in excess of 0.1% is detected with a confidence of 95%. For testing purposes, and to minimize shipping costs, the required 3,000 specimens are randomly divided into pools of 100 animals. Therefore, 30 sampling units are distributed among breeder hogs abattoirs all across Canada. Because of the export of live animals to the U.S., the distribution of sampling units is not prorated according to slaughter volume. Instead, three sampling units per abattoir that slaughter sows and boars are required.

As mentioned, a sampling unit corresponds to a maximum of 100 specimens collected from 100 carcasses in one abattoir. Due to low slaughter volume in some cases, the Veterinarian in Charge may have to postpone the sampling from one week to meet the assigned quota. Specimens will be shipped to the Centre for Food-Borne and Animal Parasitology in Saskatoon early the following week after collection. It is expected that in some cases the 100 specimens quota will not be met. Each fiscal year, a detailed sample submission schedule is provided.

5.5.2.5.4 Wild boars

All wild boars slaughtered in federal abattoirs throughout a fiscal year are eligible for testing (a population of about 3,000 wild boars). The sampling size is about 200 carcasses, i.e. large enough to ensure that a prevalence in excess of 1.5% is detected with a confidence of 95%. For testing purposes, and to minimize shipping costs, the required 200 specimens are randomly divided into a pool of 10 animals. Therefore, 20 sampling units are distributed across wild boars abattoirs. The number of sampling units to collect is prorated according to slaughter volume. A sampling unit corresponds to a maximum of 10 specimens collected from 10 carcasses in one abattoir. Due to low slaughter volume, the Veterinarian in Charge has to purposely select different weeks spread over the year for the collection of the required number of specimens (refer to sample submission schedule for exact number). Specimens will be shipped to the Centre for Food-Borne and Animal Parasitology in Saskatoon early the following week after collection. It is expected that in some cases, the 10 specimen quota will not be met. Each fiscal year, a detailed sample submission schedule is provided to all federally registered establishment slaughtering wild boars.

5.5.2.5.5 Specimen collection for monitoring purposes

Consult the sample submission schedule to determine which week has been assigned to your establishment. For each week assigned, collect specimens from 100 market hogs, 100 sows or boars, or 10 wild boars at any time during the assigned sampling week. Collect 10 g of muscle from the pillars of the diaphragm from each animal selected. Animals from different herds should be selected as much as possible. *Specimens should come from animals that the Veterinarian in Charge feels are at higher risk of being infected with T. spiralis*. Animals from poorly managed herds (those with poor health status, poor feed conversion, etc.) or small operations (because of greater likelihood of contact with rats, illegal garbage feeding, outside grazing, etc.) can be considered at higher risk of being infected.

See 5.8.9 for specimen submission procedure.

The sample plan number is the fiscal year and an underscore, followed by "M215", for example "2009_M215".

5.5.2.6 Surveillance (screening) programs

5.5.2.6.1 Surveillance for export purposes

Surveillance or screening of individual pork carcasses may be required for domestic or international trade reasons (e.g. export to Russia). Screening of horse carcasses is required

for international trade only (export to the European Union or to Switzerland). Testing procedures to allow international trade are prescribed by importing countries. The testing of horse meat for export to the European Union is to be performed by the plant operator in an on-site laboratory that has successfully completed the process for CFIA accreditation described below. For export to the European Union, the testing method used must be one of the methods listed in Directive 77/96/EEC.

The Centre for Food-Borne and Animal Parasitology in Saskatoon is the designated authority to ensure that the methods used are adequate and that technicians conducting tests are competent. Plant operators wishing to become accredited to perform *Trichinella* testing must apply to the CFIA. Upon acceptance of the application, the following steps will have to be successfully completed:

- establishment of a Quality System through creation of a Quality Manual (QM) and supporting quality documentation;
- review and approval of the QM by the Centre for Food-Borne and Animal Parasitology;
- training of technicians at the Centre for Food-Borne and Animal Parasitology in Saskatoon;
- provision of an adequate laboratory facility and equipment at the designated test location;
- on-site audits of the laboratory facility and Quality System;
- on-site completion of proficiency samples; and
- once accreditation is granted, certified technicians (trained by the Centre for Food-Borne and Animal Parasitology) will receive quarterly proficiency verifications and the laboratory will be subject to a site audit every two years.

In order to avoid freezing requirements imposed by some importing countries, hog plants may screen hog carcasses using a pooled digestion method. The plant operator is responsible for testing under a certified quality system (e.g. ISO 17025).

5.5.2.6.2 Surveillance of suspect pigs

Surveillance (screening) of pigs is also performed by the CFIA whenever animals from suspect herds are sent for slaughter at federally registered establishments. Porcine trichinellosis is a reportable disease under the *Health of Animals Act* and *Regulations*. When trichinellosis is reported by Public Health Authorities and suspected of originating from an animal slaughtered in an abattoir under federal inspection, or further to positive results from abattoir testing (monitoring or surveillance), follow-up screening of all animals from suspect herds must be initiated through regional and headquarters offices. All carcasses from suspect herds are identified and held from their arrival at the abattoir until final results are known. CFIA regional authorities shall be provided with the coordinates (producer ID, farm location, etc.) of the farm of origin of any pigs found positive. Herd mates of positive carcasses must be located and tested. As recommended by Health Canada, the testing of suspect carcasses should involve the examination of at least 5 g of tissue per animal in order to increase the sensitivity of the test. Carcasses found positive must be condemned.

5.5.2.7 Testing

5.5.2.7.1 Testing facilities

The following facilities should be available in establishments where trichina testing is performed in-plant:

- A laboratory separate from other operations but attached to or within the associated establishment. Walls, ceiling and floor to be smooth and easily cleanable. For trichinoscopic examination, the inspection office is adequate for testing purposes, provided there is sufficient space to accommodate the additional equipment.

- There should be adequate area to prepare and examine specimens, including area to clean and disinfect equipment after use.
- There should be adequate ventilation, temperature, natural or artificial light that does not alter colour, and ability to darken the examination room.
- There should be adequate facilities and disinfectants for staff to wash hands and to clean equipment and tools used after processing of samples.

5.5.2.7.2 Inspector's responsibilities in overseeing and controlling testing performed by plant operator

The Veterinarian in Charge should be familiar with the content of the quality manual produced by the operator as approved by the Centre for Food-Borne and Animal Parasitology in Saskatoon. CFIA inspectors should ensure:

(i) that a Quality System as described in the Quality Manual is in place;
(ii) that each carcass under the current Quality System is properly tested;
(iii) that internal audits of the Quality System are performed at least once a year, external audits at least once every other year, and audit results are readily available and are satisfactory;
(iv) that check samples are run four times a year by personnel performing the testing and that corrective actions are taken whenever results are unsatisfactory;
(v) that each carcass is properly identified and segregated in a way that at any time until completion of testing a correlation can be established between carcasses being tested, specimens being analysed and the producer's identity;
(vi) that technicians performing such testing are qualified by the Centre for Food-Borne and Animal Parasitology;
(vii) that tested carcasses as well as boxes containing meat derived from carcasses tested and found negative are marked. The mark must be round with a diameter of 2.5 cm. In the centre must be the capital letter T with arms 1 cm long and 0.2 cm wide. Under the letter T the initials CA must appear (0.4 cm high). The mark is a controlled item and must be handled in the same manner as meat inspection legend stamps. It is acceptable to use the carcass serial number applied at the time of slaughter in lieu of the mark just referred to provided that this method of identification is part of the Quality System of the establishment and can offer sufficient guarantee that the meat packaged and labelled with the mark T is derived from carcasses tested with negative results.
(viii) in case of a presumptive positive, refer to section 5.5.2.6, Surveillance (screening) programs.

5.5.2.7.3 Testing methods recognized by the CFIA

Testing procedures for international trade are determined by trading partners and the CFIA. For specific requirements concerning acceptable testing methods for each country, please consult Chapter 11, section 11.7.2, or the "Importing Country Requirements" module in the Meat Electronic Certification system.

5.5.2.7.4 Trichinoscope

Notwithstanding the extensive use of the pooled digestion methods, and in agreement with requirements of the importing country, the trichinoscopic examination can be used occasionally as an acceptable alternative for certification (e.g. export of frozen pork to Russia). The following section describes operating instructions when using a trichinoscope.

Sample Collection:

- Collect approximately 50 g of tissue from both pillars of the diaphragm into clean plastic bags, or onto a clean tray.
- Record the tattoo or other markings of the carcass to maintain the identity of the sample.

- If samples are to be sent for laboratory confirmation, see section 5.8.9, Samples for parasitology.
- If the plant has in-plant testing, monitored carcasses are to be held pending results. If the plant does not have testing facilities, and sampling units must be collected in order to obtain a representative sampling, carcasses should not be retained.

Equipment Required:

- trichinoscope (overhead, Leitz or Zeiss) or Microscope, 30-100X magnification, preferably stereoscopic;
- compressorium (heavy glass plates with screws and bolts);
- curved scissors (8-10 cm in length; nail scissors);
- forceps 8-12 cm; and
- tray or plastic bags for samples.

Operating Procedures:

- Use one compressorium for seven animals, identify sample and compressorium by number.
- Cut slivers of muscle approximately 2 x 2 x 5 mm and place one sliver on each field of the bottom plate of the compressorium. The pieces should be cut parallel to the muscle fibers and close to the insertion of the muscle to the tendinous part. Slivers should be cut from various parts of both pillars. Four slivers are to be examined per animal, and seven animals per plate.
- Press top plate on bottom plate by applying slight lateral movements, then tighten the screws. The tissue should form a thin, transparent layer through which print is legible.
- Clean the lenses and light source of the trichinoscope and then examine each field systematically. The extruded tissue fluid, especially that in close vicinity to muscle, should also be closely examined. The samples should be scanned at low magnification (x30 or x40), using the higher magnification for more detailed examination.

5.5.2.7.5 Trichomatic-35

For domestic purposes, the Trichomatic-35 is no longer an acceptable testing alternative and its utilization should be discontinued.

5.5.2.7.6 Double separatory funnel

The Double Separatory Funnel Procedure for the Detection of *Trichinella* larvae in horse meat as well as in pork is an acceptable method to the CFIA. Details about this method can be obtained from the Centre for Food-Borne and Animal Parasitology in Saskatoon. This method is currently in the process of being accepted by the European Union and will be used as the method of choice to certify horse and pork meat for export to those countries. In the interim, the pooled digestion method as described in Directive 77/96/EEC should be used.

5.6 HISTOPATHOLOGY

5.6.1 Introduction

Histopathological examination can provide considerable information about disease processes that cannot be inferred solely by gross examination. Reasons that a veterinarian should submit samples for histology include:

- to confirm the accuracy of a diagnosis which has been made on the basis of gross pathology;
- to confirm or rule out a condition suspected on gross examination;

- to identify a condition which is unfamiliar to the referring veterinarian. Besides allowing the veterinarian to determine the disposition of the carcass and offal, this may lead to the discovery of a previously unrecognized condition;
- to determine the extent of a condition, for the purpose of making a disposition, such as by identifying the invasiveness of a neoplasm, or the presence of metastasis.

5.6.2 Sample selection

Any carcass in which the diagnosis is uncertain should be sampled. In addition, veterinarians should occasionally submit samples of conditions for which they are certain of their gross diagnosis, to ensure that their diagnosis is correct. Unusual conditions may sometimes resemble familiar ones.

Samples must be representative of the condition; if multiple lesions are present, and appear to represent various stages in progression, then early, middle, and late stages should be sampled.

Sample multiple tissues. Organs which appear grossly normal may still show histological changes which will affect the diagnosis. The selection of appropriate organs to sample will, of course, be based on the veterinarian's knowledge of the pathogenesis of the disease or diseases suspected.

Include the edges of lesions. If a lesion is large, both the edge and centre should be sampled.

5.6.3 Testing

Samples from the Western Area should be sent to the Lethbridge Laboratory. Samples from Ontario, Quebec, and Atlantic Areas should be sent to the St. Hyacinthe Laboratory (Laboratoire d'Hygiène Vétérinaire).

Samples should be submitted in 10% formalin. The volume of formalin should be 10 to 20 times the volume of tissue. Specimens should be no more than 1 cm thick, in order to ensure adequate penetration of the fixative. The specimens should be fixed for at least 24 hours prior to processing; however, the time required for the sample to reach the lab will usually take care of this requirement.

The submission should be accompanied by form CFIA/ACIA 5439 Disease Control Specimen Submission, which is available on the LSTS Sample Submission Form application. An adequate description of the gross pathology must be provided in the block marked "Submission comments/history". Ensure that the "submitter" block is fully completed, including a telephone number at which the submitter can be contacted in the event that the pathologist requires additional information. If applicable, an email address should also be included. If the submitter's name is entered in the electronic version while on line, this information will be completed automatically; make sure it is correct and legible.

If the carcass has been held pending histopathology, record the held tag number in the space marked "Sample/vial no.", and include the phrase "CARCASS HELD" at the start of the "Submission comments/history" block. Ship the samples for overnight delivery. The submitting inspector should inform the operator of the expected time period before results are available; this would normally be 10 working days.

If the carcass is held, it is the responsibility of the operator to determine the necessary steps to maintain the integrity of the meat product. This might include boning, packaging, refrigeration, or freezing. As with any held product, the operator must request permission, and these measures must take place under CFIA supervision. Alternatively, the operator may request permission to treat the product as inedible and dispose of it.

See section 5.8.10 for guidance on packaging and shipping specimens.

5.6.4 Follow-up

If the condition suspected is such that the outcome of the histopathology could affect the disposition, then the carcass and offal must be detained pending the result, or discarded. Results can usually be obtained within 5 working days of the time of shipment. Additional time may be required for specimens which are mineralized or require special stains to make a diagnosis.

See Chapter 4, Section 4.7, for guidance on carcass disposition.

5.7 COMPOSITIONAL AND PROCESS TESTING

5.7.1 Introduction

Products for which a standard has been set under the *Meat Inspection Regulations, 1990* (Schedule I) or the *Food and Drug Regulations* are subject to random testing to ensure that the specified standards are being complied with.

The Guidelines for Additives, Compositional and Irradiation Sampling Plans in meat products are distributed at the start of the fiscal year together with the sampling plans. These documents indicate the date on which the sample is to be collected, the type of product, the sample number, and the lab to which the sample is to be submitted. There are plans for both domestic and imported products.

5.7.2 Nitrates/nitrites

5.7.2.1 Introduction

Cured meat products use sodium or potassium nitrite as a preservative, particularly to inhibit the growth of *Clostridium botulinum*. It is usually added to the raw emulsion as potassium or sodium nitrate; bacterial fermentation and chemical reactions convert much of this to the nitrite form.

See also Chapter 4 of the MOP.

5.7.2.2 Sample selection

On the day indicated in the sampling plan, select a product for which nitrate or nitrite is one of the declared ingredients. Collect 500 g of the raw product after addition of the cure, either emulsion or pieces. Freeze the raw product to prevent microbial growth and ship frozen. Freezer packs should be included in the shipping container.

Submit the sample to the lab indicated in the annual guidelines and sampling plan.

Samples should be submitted through LSTS using form CFIA/ACIA 5164, Food Product Sampling Submission Form. Indicate in the label claim field of the LSTS form if the list of ingredients states nitrates, nitrites, or both. The sampling plan number is the fiscal year, followed by an underscore and "M104" (for domestic product) or "M105" (for imported product).

Please ensure that the form is completed in sufficient detail to permit a rapid and efficient identification of the production lot sampled. In the case of an unsatisfactory laboratory result, the submission form must provide Ottawa with all necessary product information to initiate a recall or follow-up investigation.

5.7.2.3 Follow-up

If the analysis of the raw product shows a total nitrate/nitrite (sum of the nitrate and nitrite levels) exceeding 200 ppm, or the finished product shows an unusually elevated level of

nitrate/nitrite (over 70 ppm), review the company's formulation activities and related controls, and the status of the company's HACCP plan for nitrites. Re-sample to confirm that the product is in compliance.

5.7.3 Protein

5.7.3.1 Introduction

The *Food and Drug Regulations* and the *Meat Inspection Regulations, 1990* set minimum protein levels for a variety of meat products.

5.7.3.2 Sample selection

On the day indicated in the sampling plan, collect a sample of the targeted product as specified in the sampling guidelines.

Samples should be submitted through LSTS using form CFIA/ACIA 5164, Food Product Sampling Submission Form. The sampling plan number is the fiscal year, followed by an underscore and "M122" (for domestic product) or "M123" (for imported product).

Please ensure that the form is completed in sufficient detail to permit a rapid and efficient identification of the production lot sampled. For imported products, the Import Inspection Report (IIR) number must also be entered in the "identification code" field.

In the case of an unsatisfactory laboratory result, the submission form must provide Ottawa with all necessary product information for the follow up investigation and in the case of imported products, to advise the foreign country.

5.7.3.3 Follow-up

If the analysis of the product shows a protein level below the acceptable minimum, review the operator’s formulation activities and related controls. Then re-sample to confirm that the product is now in compliance.

5.7.4 Mechanically separated meat

5.7.4.1 Introduction

There are several methods of recovering edible product from bones. Depending on the method, this product may be termed mechanically separated meat (MSM) or finely textured meat. Such product is sampled for total protein, calcium, and bone particles, to ensure that the product meets the composition standards.

5.7.4.2 Sample selection

On the date specified in the sampling plan, collect 500 g of the raw product. Freeze it to prevent microbial growth, and ship frozen. Freezer packs should be included in the shipping container.

Ensure that the sample is shipped to the correct lab as specified in the sampling plan and guidelines.

Samples should be submitted through LSTS using form CFIA/ACIA 5164, Food Product Sampling Submission Form. The sampling plan number is the fiscal year, followed by an underscore, and "M110" (for domestic product) or "M111" (for imported product).

The form must be completed in sufficient detail to permit a rapid and efficient identification of the production lot sampled. For imported products, the Import Inspection Report (IIR) number must also be entered in the "identification code" field.

In the case of an unsatisfactory laboratory result, the submission form must provide all necessary product information for the follow up investigation and in the case of imported products, to advise the foreign country.

5.7.4.3 Follow-up

If any of the measured properties are out of compliance, review the operator's procedures, including the equipment adjustment. Re-sample to confirm that the product is now in compliance. Refer to Chapter 4 MOP for product disposition information.

5.7.5 Species Verification

5.7.5.1 Introduction

Species verification is conducted to detect adulteration of meat products derived from one species with meat products derived from another species. An operator may make such substitutions fraudulently, in order to substitute a less expensive meat for some or all of the meat declared on the label. Adulteration may also occur accidentally due to improper cleaning of grinders or other equipment.

In addition to fraud, species adulteration may pose a health hazard through allergic reactions, or violate religious dietary laws of some population segments. Species verification has also been an important criterion in international trade.

Species verification sampling plans and guidelines are included with the annual Microbiology Sampling Plans.

5.7.5.2 Sample selection

All meat products of Canadian or foreign origin, received in registered establishments, where the meat product cannot be readily identified by visual inspection are subject to sampling. Products labelled as "100% pure" beef, pork, chicken, etc. should be targeted.

Species verification is customarily done on products in which the species cannot be readily determined by visual inspection, such as:

- boneless beef, veal, mutton, lamb or trimmings.
- ground meat such as ground beef, veal, pork, lamb, etc.
- mechanically separated beef, pork or chicken, etc.
- processed products, cooked or cured, where meat from other species than those declared may be present.

Domestic and imported raw meat commodities to be subjected to species verification sampling.

Raw meats are sampled in accordance with plan M208 for domestic products and M210 for imported products.

Ready-to-eat meat products are sampled in accordance with sampling plans M209 for domestic and M211 for imported product.

To avoid contamination, peel the outer wrapper to expose a clean area for sampling from boxed meats.

Disinfect collecting equipment (drill, forceps, scalpel) by thorough cleaning, dipping in alcohol and flaming before taking sample, where applicable.

The inspector will submit a sample of at least 100 g for submission to the laboratory designated in the annual sampling plan. Samples for species verification may be shipped in the frozen state to the laboratory.

5.7.5.3 Testing

Submit samples for species verification to the laboratory assigned on the annual Microbiology Sampling Plan.

Samples should be submitted through LSTS using form CFIA/ACIA 5164, Food Product Sampling Submission Form. The form must be completed in sufficient detail to permit a rapid and efficient identification of the production lot sampled. For imported products, the Import Inspection Report (IIR) MCAP number **must** also be entered in the "identification code" field. Under "analysis requested", indicate "Species Verification". Under "submitter comments", indicate the species name (e.g. beef) that the product is purported to contain. **Whenever possible, attach a label or photocopy of a label with an ingredients listed**.

5.7.5.4 Follow-up

In the event that species verification testing on a domestic product finds the presence of a species which was not declared on the label, the inspector must take action in accordance with the appropriate CVS task. Where an imported meat product contains an undeclared species, the result must be reported to the Area Import Specialist.

The inspector should take compliance samples to ensure that the problem has been corrected.

5.7.6 Irradiation

5.7.6.1 Introduction

Food may be exposed to ionizing radiation for a variety of purposes, including:

- improve the safety of food by reducing levels of pathogens associated with food-borne disease such as *E. coli* and *Salmonella*;
- reduce microbiological growth causing spoilage and, thereby, extend shelf-life;
- reduce insect infestation; and
- delay ripening of fruit and vegetables.

Three different energy sources may be used: gamma rays, electron beams and x-rays. The sources of gamma rays are cobalt-60 and cesium-137.

The amount of radiation energy used or needed for a particular application varies depending on the food and the reason for irradiating. Typically, to increase shelf life or to prevent spoilage a low dose of irradiation is required, only 1 kilogray (kGy) of absorbed energy. To prevent food poisoning, the dose will depend on the type of bacteria being targeted and the type of food. An absorbed dose of up to 3 kGy is usually sufficient to kill *Salmonella* in fresh chicken. Generally, it takes higher levels of radiation to kill parasites and insects. Viruses, for the most part, are not destroyed by the irradiation levels that are suitable for use in foods.

Irradiation is regulated under Division 26 of the *Food and Drug Regulations*. Industry may make submissions to Health Canada to allow new uses of food irradiation. Health Canada will permit new uses of food irradiation only after a safety assessment, and only listed items may be irradiated.

Currently, this list includes:

- potatoes and onions, to inhibit sprouting during storage, up to 0.15 kGy;
- spices and dehydrated seasonings, to reduce microbial load, up to 10 kGy; and
- wheat, flour and whole wheat flour, to control insect infestation, up to 0.75 kGy.

Irradiation of meat products is currently permitted in some other countries, but not for product imported into Canada. Therefore, imported meat products are monitored for indications of irradiation.

5.7.6.2 Sample Selection

The test can be conducted on raw products (fresh or frozen) with high fat content, including ground meat and trimmings. Blocks of sample numbers are assigned to reinspection points where the appropriate type of product is received. Samples should be collected randomly throughout the fiscal year.

The sample selection procedures are described in the annual Guidelines for Additives, Compositional and Irradiation Sampling Plans in meat products.

5.7.6.3 Testing

Meat products are tested for irradiation under sample plan M127 (e.g. 2009_M127). Samples should be submitted through LSTS using form CFIA/ACIA 5164, Food Product Sampling Submission Form. The form must be completed in sufficient detail to permit a rapid and efficient identification of the production lot sampled. Enter the import control number in the "Import no." block and in the "identification code" field.

5.7.6.4 Follow-up

Any positive test is followed by intensified inspection. This means that the next 15 shipments of a weight at least equal to that of the shipment found in violation will be held and tested for irradiation. The exporting establishment has an option of having the product pre-tested, in an official laboratory.

5.7.7 Can integrity - imported (M206)

5.7.7.1 Introduction

Food preserved by canning has a shelf life of over two years. However, improper sealing of the cans, or improper thermal processing, can create conditions which permit bacterial growth inside the can. Of particular risk is *Clostridium botulinum*, whose growth and toxin production are favoured by the anaerobic environment inside the can and the lack of competing organisms.

5.7.7.2 Sample selection

Use the Metal Can Defects Manual as a reference. Samples are to be submitted in accordance with the annual Microbiology Sampling plan. Assigned samples under plan M206 may be selected from a shipment selected through the Import Control and Tracking System for full inspection. Randomly select 200 cans for visual inspection using "Low-Acid and Acidified Low-Acid Foods In Hermetically Sealed Containers - Visual Inspection Protocol". (See Chapter 10, Annex P-5). If any visual defect (major or minor) is detected, select ten cans (five with defects and five with no defects) and send them to the laboratory for container integrity and commercial sterility analysis. If visual defects are not detected, select 10 good order cans (with no visual defects) and send them to the laboratory.

5.7.7.3 Testing

Samples should be submitted using LSTS and form CFIA/ACIA 5164, Food Product Sampling Submission Form. The form must be completed in sufficient detail to permit a rapid and efficient identification of the production lot sampled. Enter the import control number in the "Import no." block and in the "identification code" field.

Samples are submitted to the laboratory assigned according to the annual Microbiology sampling plans.

5.7.7.4 Follow-up

Shipments for which can defects were identified during the visual inspection shall be detained pending laboratory results. The Chief, Import Programs, Meat Programs Division, should be notified immediately of unsatisfactory laboratory results.

If laboratory results are unsatisfactory for can integrity a minimum of ten subsequent shipments of similar products from the same foreign establishment will be subject to intensified inspection (surveillance inspection), which requires that they be detained pending the results of visual inspection and laboratory evaluation. For each shipment, randomly select 200 cans for visual inspection using the Visual Inspection Protocol. If any major visual defect is identified, select 10 cans (five with defects and five without) and send to the laboratory for evaluation. The specific testing requested will be determined by the Chief, Import Programs, following consultations with the Director, Food Microbiology and Chemical Evaluation.

5.8 SAMPLE SUBMISSION PROCEDURES

5.8.1 Laboratory Sample Tracking System (LSTS)

There are four components to the LSTS which are of importance for field staff.

5.8.1.1 Sample Submission Form generator (LSTS/SSF)

5.8.1.1.1 Introduction

Samples for CFIA laboratories should be entered directly into the LSTS electronically. The Sample Submission Form generator is the tool used for this purpose.

The CFIA is in the process of introducing new software to handle the LSTS. During the transition period, both old and new systems are in use. The system to use depends on the type of sample being submitted.

The following sample submission forms are on the old (Citrix Metaframe) system.

- Meat Inspection Sampling (CFIA/ACIA 5258)
- Food Product Sampling (CFIA/ACIA 5164)

The following sample submission forms are on the new (Web-based) system:

- Animal Health Disease Control (DC) Specimen Submission (CFIA/ACIA 5439), for tuberculosis, granulomas, pathology, cysticercosis, and suspected diseases other than TSE & Rabies
- Animal Health Rabies (RAB) Specimen Submission (CFIA/ACIA 2908)
- Animal Health Transmissible Spongiform Encephalopathy (TSE) Specimen Submission (CFIA/ACIA 5420)
- Animal Health Import, Export and Artificial Insemination (IEA) Specimen Submission (CFIA/ACIA 5473)

5.8.1.1.2 Sample submission forms (metaframe)

If you have never used this application before, you will have to apply for access, by completing form CFIA/ACIA 5190, Request for System Access, and submitting it to your Regional Director for approval. Under "System requested", select "Input Application - PRODUCTION (LSTS)". Under "database", select "Prod". You may also wish to request access to the test/training database, to gain familiarization with the application.

Once access has been granted to run the application, first log on to the network. Then go to the Start menu on your computer, and select Start -> All programs -> CFIA Applications -> Lab sample tracking system (LSTS) -> Submission forms - Metaframe (LSTS).

For testing of samples collected at slaughter, select "Food Products", then select "Meat Inspection Sampling". This will lead you through the generation of a form CFIA/ACIA 5258 (Meat Inspection Sample Submission Form).

For samples of imported or processed product, select "Food Products", then select "Food Product Sampling". This will lead you through the generation of a form CFIA/ACIA 5164 (Food Product Sampling Submission Form).

For samples for histopathology or parasitology, select "Pathology". This will lead you through the generation of a form CFIA/ACIA 1528 ("Pathology Specimen Submission").

Once you have "submitted" the form, print off two hard copies, one to accompany the shipment and one for your records. You must also affix a form CFIA/ACIA 1461 - Specimen Identification Tag to the sample, giving the job system number and other applicable information.

5.8.1.1.3 Sample submission forms (Web-based)

To log into LSTS and generate a submission form, click the "Start" button at the bottom left corner of your screen, and choose All Programs -> CFIA Applications -> Lab Sample Tracking System (LSTS) -> LSTS User Services (2006). The Login page will be displayed. Enter Username and Password to enter the application.

If this is the first time that you are logging in, click on "First time User" at the bottom left of the page. Click the link in the e-mail and follow the online prompts. Your password and user name will be e-mailed to you.

Select English or French. The Landing page, showing the Web forms menu and the "other utilities" menu, is displayed. Use this page to create Web submission forms, perform a search, print a blank form, and to request Report of Analysis notification through PENMan or find test reports.

The first time you log in to LSTS User Services, you must select the submission forms that you want to work with. This is done by clicking on the "my preferences" link under "My LSTS". To add a form, select it in the "Default list" and click the "Add" arrow. The form is moved to the "User Selection" list. To remove a form, select it in the User Selection list and click the "Remove" arrow. Click Save to update your changes. The forms added to your User Selection list remain selected until you remove them. The forms that you select are then displayed on the Landing page and in the left-hand navigation tree on other pages. You can change your preferences at any time.

5.8.1.2 Reports of Analysis

The Reports of Analysis application is the tool for viewing test results. It is located on Merlin under LSTS User Services at: http://webapp/lsts/login.asp. The use of Merlin hyperlinks refer to an internal CFIA Intranet site for staff use only. A password is required to access this application.

If a notice of report of analysis is received electronically, the email message will contain a hypertext link which will take you directly to the result. Otherwise, you can search for a result by the reference number or system ID number, which are on the hard copy of the submission form.

5.8.1.3 Submission Status Inquiry

The Submission Status Inquiry tool is the tool for checking on a sample that you have submitted, and for which you have not yet received a result. It is located on Merlin under LSTS User Services at: http://webapp/lsts/login.asp. The use of Merlin hyperlinks refer to an internal CFIA Intranet site for staff use only. Select "Food Meat Inspection", then enter your search criteria. If you submitted the sample electronically using the Sample Submission Form generator, then you will have a "System no." from the hard copy of the submission form (CFIA/ACIA 5439, CFIA/ACIA 5164 or CFIA/ACIA 5258), and this will be the easiest way to locate the correct sample.

5.8.1.4 Personal Email Notification Manager (PENMan)

The Personal Email Notification Manager is the tool which you can use to have LSTS automatically notify you of test results submitted by you or your establishment. It has not yet been implemented for samples from the meat program.

If you enter your name on the sample submission form and you have an individual email account, a report of analysis notification is sent to you automatically by LSTS without requiring the use of PENMan.

5.8.2 Recording of livestock identification

When submitting samples collected at slaughter to CFIA laboratories, ensure that the animal identification number is recorded on the sample submission form, to permit traceback if necessary. On either form CFIA/ACIA 5258 (Meat Inspection Sample Submission Form) or form CFIA/ACIA 5439 (Disease Control Specimen Submission), enter it in the field marked "eartag" or "tattoo", as applicable. Also indicate the type of tag: Canadian Cattle Identification Agency (CCIA), Agri-Traçabilité Québec (ATQ), Canadian Sheep Identification Program (CSIP), etc.

For samples collected under the National Chemical Residue Monitoring Program, the animal identification number must be recorded on the page in the sampling plan booklet.

5.8.3 Samples for chemical residue analysis

5.8.3.1 Collection and preservation

Each tissue (skeletal muscle, liver, kidney, fat, etc) for a particular sample must be in a separate bag, to prevent any residue which may be present from diffusing from one subsample into another.

Samples must be frozen and shipped in an insulated container with freezer packs, unless the product is shelf-stable.

5.8.3.2 Documentation

Each bag must be clearly identified using a form CFIA/ACIA 1461 Specimen Identification label. See section 5.8.1 for detailed instructions.

If the sample is from a **carcass** sampled during slaughter, and being submitted to a **CFIA lab**, the sample must be accompanied by form CFIA/ACIA 5258 Meat Inspection Sample Submission Form, which is generated when you enter the samples into LSTS. See section 5.8.1.1.

If the sample is from **portions or processed product** not traceable to a single animal or place of origin, and being submitted to a **CFIA lab**, the sample must be accompanied by form CFIA/ACIA 5164 Food Product Sampling Submission Form, which is generated when you enter the samples into LSTS. See section 5.8.1.1.

In each case, a hard copy must accompany the sample. Alternatively, if the sampling submission form has been electronically generated and submitted, you can affix a form CFIA/ACIA 1461 - Specimen Identification Tag to the sample, giving the job system number and other applicable information. This will allow the lab to match the sample to the corresponding sample submission information in LSTS.

Samples submitted to **private labs** under the domestic National Chemical Residue Monitoring Program are not currently tracked in LSTS, and therefore do not require a CFIA sample form; the lab will match the sample to the sampling plan based on the sample number affixed to the sample. Because there is no accompanying submission form, it is critical that each bag have a CFIA/ACIA 1461, fully completed with NCRMP sample number, Establishment registration number, actual date sampled, sampling plan, species or production class, name of the inspector, and an identification of the tissue sampled ("Sample of").

5.8.3.3 Submission

Only the laboratory which is scheduled to receive the sample will have all the necessary information to complete the testing. It is therefore absolutely essential to submit the sample to the correct laboratory. The name and address of the correct lab is provided on every sheet in the sampling plan booklet. One establishment may make use of several different labs, so check each sheet carefully and ensure that the sample goes to the correct lab.

Ship the sample by courier for overnight delivery. Do not ship on a Friday unless you have verified that someone will be at the lab to receive the sample the next day. Product which arrives off condition will not be analyzed.

5.8.4 Samples for antibiotic confirmation

5.8.4.1 Collection and preservation

Each tissue (skeletal muscle, liver, kidney, fat, etc.) for a particular sample must be in a separate bag, to prevent any residue which may be present from diffusing from one subsample into another. Each bag must be clearly identified using a form CFIA/ACIA 1461 Specimen Identification label. See section 5.8.1 for detailed instructions. Ensure that the sample number or held tag number has been included.

Do not submit injection sites. Levels measured at the injection site cannot be used to determine carcass disposition, and the sample can act as a source of contamination for other tissues and for the lab.

The sample must be frozen and shipped in an insulated container with freezer packs, unless the product is shelf-stable.

5.8.4.2 Documentation

The sample must be accompanied by form CFIA/ACIA 5258 Meat Inspection Sample Submission Form, which is generated when you enter the samples into LSTS. See section 5.8.1.1.

Alternatively, if the sampling submission form has been electronically generated and submitted, you can affix a form CFIA/ACIA 1461 - Specimen Identification Tag to the sample, giving the job system number and other applicable information. This will allow the lab to match the sample to the corresponding sample submission information in LSTS.

If the carcass is held, ensure that "under detention" is selected under "sample priority" on the submission form.

Whether the carcass is detained or not, when the sample is sent to the lab, ensure that the owner's name and address are included under "submitter comments". This will simplify traceback in the event that the laboratory confirms a violative result.

5.8.4.3 Submission

Samples for antibiotic residue analysis should be shipped to the Centre for Veterinary Drug Residues, Saskatoon.

Ship the sample by courier for overnight delivery. Do not ship on a Friday unless you have verified that someone will be at the lab to receive the sample the next day. Product which arrives off condition will not be analysed.

5.8.5 Samples for compositional analysis

5.8.5.1 Collection and preservation

The sample must be frozen and shipped in an insulated container with freezer packs, unless the product is shelf-stable.

5.8.5.2 Documentation

Samples must be accompanied by a form CFIA/ACIA 5164 Food Product Sampling Submission, which is generated when you enter the samples into LSTS. See section 5.8.1.1. In the box marked "Sampling plan no.", enter the number of the applicable sampling plan, prefixed by the fiscal year and an underscore, for example "2009_M104".

The form must be completed in sufficient detail to permit a rapid and efficient identification of the production lot sampled. For imported products the Import Inspection Report number **must** also be entered in the "identification code" field.

A hard copy must accompany the sample. Alternatively, if the sampling submission form has been electronically generated and submitted, you can affix a form CFIA/ACIA 1461 - Specimen Identification Tag to the sample, giving the job system number and other applicable information. This will allow the lab to match the sample to the corresponding sample submission information in LSTS.

In the case of an unsatisfactory laboratory result, the submission form must provide Ottawa with all necessary product information to initiate a recall or follow up investigation and in the case of imported products, to advise the foreign country.

5.8.5.3 Submission

Ensure that samples for compositional analysis are sent to the correct lab, as indicated on your sampling plan. Other labs will likely not be set up to perform the requested assay.

Ship the sample by courier for overnight delivery. Do not ship on a Friday unless you have verified that someone will be at the lab to receive the sample the next day. Product which arrives off condition will not be analysed.

5.8.6 Samples for microbiological analysis

5.8.6.1 Collection and preservation

Micro-organisms from the environment, hands, clothing, sample containers, sampling devices, etc., may lead to erroneous analytical results. Stringent requirements for microbiological sampling are necessary. Use of aseptic sampling techniques and clean, sanitized equipment and supplies are of utmost importance.

Sterile gloves should be used for collecting samples. The only items which may contact the external surface of the glove are the exposed sample being collected and the sterile sample utensil. Keep in mind that the outside surfaces of the sample container are not sterile. Do not handle the inside surface of the sterile sample containers. Do not touch anything else.

Sampling and packaging instructions are to be found in the individual sections for each program. If special requirements should arise, they will be communicated in writing to all inspectors concerned.

Samples should be cooled down to refrigeration temperatures (4 - 8ºC) as quickly as possible, which can be facilitated by using pre-chilled shipping containers and packing material. Samples in an individual bag or container can be put inside a second bag filled with insulation and ice or other coolant. Under no circumstances should the samples be subjected to freezer temperatures! Ice bags or freezer-packs are recommended to maintain a low enough temperature during shipping.

5.8.6.2 Documentation

A CFIA/ACIA 5164 Food Product Sampling Submission Form should be completed by the inspector and accompany the sample submission. The box marked "Sample plan no." must contain the sampling plan number (e.g. 2009_M200) and the "analysis requested" box must also be filled in. If completing a form manually for samples collected under MASS, this section should be filled in with the word "Bacteriology". If using the Sample Submission Form application, click on the button marked "Load per plan". The receiving laboratory will automatically subject the sample submission to the necessary test procedures called for by the program, based on the sampling plan number.

The form must be completed in sufficient detail to permit a rapid and efficient identification of the production lot sampled. For imported products the Import Inspection Report number **must** also be entered in the "identification code" field.

In the case of an unsatisfactory laboratory result, the submission form must provide Ottawa with all necessary product information to initiate a recall or follow up investigation and in the case of imported products, to advise the foreign country.

Two copies of the form should accompany the sample, and one copy should be retained by the submitter. Alternatively, if the sampling submission form has been electronically generated and submitted, you can affix a form CFIA/ACIA 1461 - Specimen Identification Tag to the sample, giving the job system number and other applicable information. This will allow the lab to match the sample to the corresponding sample submission information in LSTS.

The submitter should have an individual GroupWise email account to receive email notifications when the electronic Reports of Analysis (results) are available.

5.8.6.3 Submission

All samples, except cans, should be shipped refrigerated. The internal temperature should not exceed 10ºC upon arrival at the laboratory.

Samples should arrive at the designated laboratory within 24 hours accompanied by the proper form. Several courier and express companies offer an overnight service. Stickers or labels of "Overnight Delivery By Air" should be put on cardboard boxes. These samples do not fall under the *Transport of Dangerous Goods Regulations*.

5.8.6.4 Acceptance criteria – CFIA food laboratories

Food samples submitted to CFIA laboratories for microbiological examination must be transported in a manner that will maintain the stability of sample characteristics

(e.g. microflora, pH, moisture content, etc.) from the point of collection to reception by the laboratory.

5.8.6.4.1 Foods stored at room temperature

Foods usually stored or sold at room temperature (e.g. canned food, dried herbs and spices, etc.) should be sent using appropriate procedures to prevent any temperature abuse that could affect sample characteristics; the temperature should not fall below 0°C or exceed 35°C.

This type of food may include:

- canned foods
- dry mixes (soups, sauces, etc.)
- spices (dried)
- products without a “Keep refrigerated” declaration

“Dry cured” meats or other similar products that are stable at room temperature should be sent using the procedure for “Refrigerated Foods”, below.

5.8.6.4.2 Refrigerated foods and environmental samples

Refrigerated foods include all commodities that are stored, shipped or presented to the consumer under refrigerated conditions.

Refrigerated samples, except shellfish and shellstock should be cooled and transported in a sample chest with suitable refrigerant capable of maintaining the temperature of the sample between **0°C and 7°C** until arrival at the laboratory.

This type of food may include:

- raw meats; or
- processed meats.

Do not freeze refrigerated products unless otherwise specified. Frozen environmental samples will not be accepted for lab analysis.

5.8.6.4.3 Frozen foods

Do not allow sample units that are usually frozen to thaw during shipment; keep frozen samples solidly frozen at all times. Transport samples in a suitable container using ice packs or dry ice, where necessary to keep product in a frozen state.

This type of product may include:

- frozen dairy
- frozen fruits and vegetables
- frozen dinners
- ice (pre-packaged)
- all types of frozen fish

5.8.6.4.4 Special samples

In some cases where the sample has a “high priority” status and **it cannot be re-sampled**, (e.g. food poisoning incidents, limited availability of imported product), and the above conditions are not met, the laboratory supervisor shall inform the submitter of the situation (e.g. frozen sample thawed, refrigerated sample higher than 7° or 10°C or in a frozen state, etc.) and agree on the action to be taken by the laboratory.

Any sample submitted to the laboratory that does not comply with the above guidelines shall be declared unfit for testing and the inspector notified.

5.8.7 Samples for BSE

5.8.7.1 Collection and preservation

Brain samples for BSE surveillance may be collected using the spatula technique or the spoon technique. **The flushing technique is considered unacceptable because of the risk of generating a contaminated aerosol.**

These techniques are described in the Bovine Spongiform Encephalopathy Manual of Procedure, Appendix 1 (Section 6.1), which is available on line at

http://merlin.cfia-acia.inspection.gc.ca/english/anima/heasan/man/bseesbe.asp

Samples derived from BSE surveillance cases are classified as "Biological Samples - Non Regulated", and can be packaged and shipped accordingly. The availability of the rapid tests allows for submission of fresh tissue samples. **Do not** fix BSE surveillance samples in formalin. **Do not** freeze tissue samples.

1. Inner packaging

Samples should be submitted inside a leak-proof primary container such as a Whirl-pak™ bag. The primary container is to be placed inside a secondary receptacle containing sufficient absorbent material to absorb the entire liquid contents of the primary receptacle(s). The secondary receptacle could also be a Whirl-pak™ bag. Attach animal identification to the outer Whirl-pak™ to identify the specimen. Record this identification on the CFIA/ACIA 5420. The dry submission form and any other paperwork should be submitted outside the immediate sample container.

2. Outer packaging

The inner packaging and, depending on the number of samples, one or two freezer packs is placed in an outer packaging to protect its contents from outside influences such as physical damage and heat while in transit. The green metal "rabies can" may be used as an outer packaging if desired and available. A styrofoam cooler is also acceptable.

5.8.7.2 Documentation

Enter the sample information in the Laboratory Sample Tracking System (LSTS), by clicking on CFIA applications->Lab sample tracking system (LSTS)->User services 2006. Then select the "Create" link under "TSE". Under "Reason for test", select "Surveillance." Under "Disease category", select "Bovine Spongiform Encephalopathy." Then click on "Load all".

In all cases, ensure that all the animal's identifiers have been recorded on the laboratory submission form in order to facilitate traceability of the animal to the farm of origin, if required. In the "Samples" tab, under "National animal ID", record the CCIA tag or ATQ tag, as applicable. If there is a Health of Animals eartag, enter this number under "Health of Animals tag". If there is an auction or sale backtag, enter this under "Other ID". Any other identifying information, such as a Dairy Herd Improvement tag, herd management tag, or brand, should also be recorded under "Other ID".

Report the clinical abnormalities observed on ante mortem examination in the "Sample comments" section for that sample. Also indicate the category of risk animal that has been sampled (found dead, non ambulatory, emergency slaughter, ante mortem suspect). Categorizing the sample according to the risk population is important to allow verification that the high-risk populations of adult cattle are being included in the surveillance program.

Attach the LSTS Transmissible Spongiform Encephalopathy Specimen Submission form and any additional documentation to the outside of the outer packaging. This will ensure that the laboratory personnel are aware of the package contents upon receipt and prior to opening the outer packaging.

The shipper's waybill or form GC47 Government Bill of Lading documentation must accompany the shipment. Under "description of articles", indicate "Biological Sample – Non Regulated".

5.8.7.3 Submission

Routine BSE surveillance samples may be sent to any of the following CFIA laboratories: Lethbridge, Winnipeg, St-Hyacinthe. Select the laboratory to which you can most quickly ship samples.

The outer package must indicate the name, address, and phone number of the shipper and consignee.

In addition, the following statement should appear:
Emergency 24 Hour Number: 613-239-4604

These samples are not considered infectious substances (section 2.4.1 of the *Transportation of Dangerous Goods Regulations*) if the contents do not exceed 10 kg in weight.

5.8.8 Samples for scrapie

5.8.8.1 Collection and preservation

Brain samples for scrapie surveillance may be collected using the spoon technique as described above for BSE. Sample collection technique is described in more detail in Appendix 1A of the Animal Health Scrapie manual of procedures and on the training CD titled "Transmissible Spongiform Encephalopathies: Surveillance and Specimen Collection" published by the CFIA and distributed to all CFIA District Offices during the summer of 2005.

Place each sample in a Whirl-Pak™ bag, and attach a CFIA/ACIA 1461 Specimen Identification Tag. The four tissues from one animal may be placed in a single bag. Place this inside a second bag along with sufficient paper towel, cotton, or other absorbent material to hold any liquid which escapes from the inner bag.

These samples must be frozen prior to shipping.

5.8.8.2 Documentation

Enter the sample information in the Laboratory Sample Tracking System (LSTS), by clicking on CFIA applications->Lab sample tracking system (LSTS)->User services 2006. Then select the "Create" link under "TSE". Under "Reason for test", select "Surveillance." Under "Disease category", select "Scrapie." Then click on "Load all".

In all cases, ensure that all the animal’s identifiers have been recorded on the laboratory submission form in order to facilitate traceability of the animal to the farm of origin, if required. In the "Samples" tab, under "National animal ID", record the CCIA tag or ATQ tag, as applicable. If there is a Health of Animals eartag, enter this number under "Health of Animals tag". Any other identifying information, such as a herd management tag, should also be recorded under "Other ID".

Report any clinical abnormalities observed on ante mortem examination in the "Sample comments" section for that sample.

5.8.8.3 Submission

Place the samples in a styrofoam container along with a freezer pack.

Submit the sample to the Ottawa Laboratory, Fallowfield. These samples do not fall under the *Transport of Dangerous Goods Regulations*. Follow instructions for shipping an "exempt animal specimen" published in the *Shipping Biological Samples Guidebook*.

Samples must be shipped by courier for overnight delivery. Samples must arrive at the designated laboratory within 24 hours accompanied by the proper form. Several courier and express companies offer an overnight service. Stickers or labels of "Overnight Delivery By Air" should be put on cardboard boxes.

5.8.9 Samples for parasitology

5.8.9.1 Collection and preservation

Specimens should be individually wrapped in a plastic bag and marked. They should be chilled to 4-8ºC immediately. Do not freeze!

Samples should be shipped in bulk with sufficient ice or other coolant and insulation to ensure that samples remain in a fresh state while in transit. A double bag system is recommended. Samples in an individual bag or container can be put inside a second bag filled with insulation and ice or other coolant.

5.8.9.2 Documentation

Use form CFIA/ACIA 5439, Disease Control Specimen Submission. Ensure that the sampling date and animal identification for each specimen are reported. For farm trace-back, it is essential that the animal's identification, such as a tattoo or CCIA ear tag number, be recorded. If positive cases are found, the Veterinarian in Charge will be contacted in order to get the complete address of the affected producer for follow-up action at the farm. Traceability is critical for follow-up action.

A hard copy of the form must accompany the shipment. Alternatively, if the sampling submission form has been electronically generated and submitted, you can affix a form CFIA/ACIA 1461 - Specimen Identification Tag to the sample, giving the job system number and other applicable information. This will allow the lab to match the sample to the corresponding sample submission information in LSTS.

5.8.9.3 Submission

Samples should arrive at the Centre for Food-Borne and Animal Parasitology in Saskatoon within 24 hours accompanied by the proper form. Several courier and express companies offer an overnight service. Stickers or labels of "Overnight Delivery By Air" should be put on cardboard boxes. Specimens must be shipped to the laboratory according to the sampling schedule. These samples do not fall under the *Transport of Dangerous Goods Regulations*.

5.8.10 Samples for histopathology

5.8.10.1 Collection and preservation

Specimens for histopathology are normally forwarded in fixative. Specimens should be collected into wide-mouthed glass, or preferably sturdy plastic, jars with tight fitting lids, with fixative. As a rule, a jar should contain 20 volumes of fixative to one volume of tissue. Specimens should be collected as soon as possible after death of the animal and contain all stages of the lesion. For quick fixation, each specimen should be no thicker than 1 cm. The exception to this is brain, which should be placed entire and intact in formalin, while maintaining the ratio of 10 to 20 parts of fixative for one part of tissue.

A 4% formaldehyde (10% formalin) solution may be prepared as follows:

Ingredient	Volume of ingredient
Commercial formalin (40% formaldehyde in water)	50cc
Water	450cc
Table salt	3.8g

Containers must be leakproof. The cartons containing the samples must contain sufficient absorbent material (cotton, absorbent paper) to prevent leakage of contents in case of breakage.

Formaldehyde is exempt from the provisions of the *Transport of Dangerous Goods Regulations*, provided the quantity is less than 50 kg (Schedule VIII Table III) and the concentration is less than 25% (Schedule II List II). The package does not have to bear any special marking, but the waybill/bill of lading shall be marked with the statement: "Preserved Material, Non Hazardous, Unregulated".

If the volume of fixative is too large, tissues can be fixed locally for 24 hours, removed from formalin, and wrapped in paper towel previously soaked in formalin, then placed in a Ziplok® type of bag and send along with the CFIA/ACIA 5439 form to the lab. Do not use this procedure for whole brains; adequate fixation for brains may take up to 1 week, and premature removal from formalin for shipping may create artifacts which could affect the histology.

5.8.10.2 Documentation

Identify the submission "for histopathology" on the outside of the package, so that it will be sent directly to the pathology unit on receipt.

Samples must be accompanied by form CFIA/ACIA 5439, Disease Control. Under "Reason for test", select "Meat inspection pathology". Enter the history and gross pathological description under "Submission Comments/History." Alternatively, if the sampling submission form has been electronically generated and submitted, you can affix a form CFIA/ACIA 1461 - Specimen Identification Tag to the sample, giving the job system number and other applicable information. This will allow the lab to match the sample to the corresponding sample submission information in LSTS.

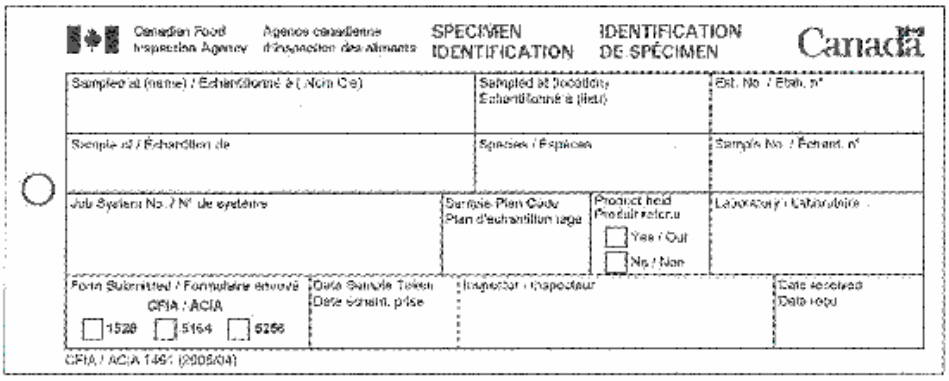
5.8.10.3 Submission

Samples from Western Area should be shipped to the Animal Disease Research Institute, Lethbridge. Samples from Ontario, Quebec, and Atlantic Areas should be shipped to the Laboratoire d'Hygiène Véterinaire, St.-Hyacinthe.

Note that samples in formalin can be shipped immediately, since they will continue to fix while in transit. It also does not matter if samples are shipped on a Friday, since they will not deteriorate in transit.

5.9 FORMS

5.9.1 CFIA/ACIA 1461 specimen identification (label)


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

SPECIMEN IDENTIFICATION / IDENTIFICATION DE SPÉCIMEN

Canada

Sampled at (name) / Échantillonné à (Nom de)	Sampled at (location) / Échantillonné à (lieu)		Est. No. / Étab. n°
Sample of / Échantillon de	Species / Espèces		Sample No. / Échant. n°
Job System No. / N° de système	Sample Plan Code / Plan d'échantillonnage	Product held / Produit retenu ☐ Yes / Oui ☐ No / Non	Laboratory / Laboratoire
Form Submitted / Formulaire soumis CFIA / ACIA ☐ 1528 ☐ 5164 ☐ 5256	Date Sample Taken / Date échant. prise	Inspector / Inspecteur	Date received / Date reçu

CFIA / ACIA 1461 (2005/04)

PURPOSE:

Identification label to be attached to sample, when submitted to laboratory. See section 5.8 (Sample submission procedures).

GUIDELINES FOR COMPLETION:

This form is printed on Tyvek™, so that it will not disintegrate if it becomes wet.

It must be written on using ballpoint pen, permanent marker, or other non-water-based ink which will not easily dissolve or rub off.

Print clearly.

Sampled at (name): The name of the company at which the sample was collected. For example: "Jones Meats Ltd.".

Sampled at (location): The municipality in which the establishment is located.

Est. No.: If a registered establishment, the establishment registration number.

Sample of: Identify the specimen. Be as specific as possible. For example, "diaphragm", "kidney", "liver".

Species: The species of animal from which the sample was collected. Where appropriate, identify the production class, for example "Veal", "Broiler", "Sow".

Sample no.: If the sample was collected as part of a monitoring plan, indicate the sample identification number, for example "H2009MPM1234".

Job system number: The system number assigned by the Lab Sample Tracking System when the sample was entered and the sample submission form was generated. This allows the sample to be matched up with the sample submission form, and with the data entered in LSTS. This is particularly important if more than one sample is included in one shipping container.

Sample plan code: If the sample was collected as part of a monitoring plan, indicate the sample plan code, for example "2009_M8BEF01".

Product held: Indicate whether there is product under detention awaiting the results of analysis. This can affect sample priority.

Laboratory: The name or location of the laboratory to which the sample is being submitted.

Date sample taken: The date on which the sample was collected. In the case of carcasses, give the date of slaughter, even if the sample was collected from the carcass at some subsequent date.

Inspector: Print the inspector's name.

Date received: Leave this space blank. It is for use at the lab.

The form should be affixed to the sample bag in a manner that won't easily come loose during shipping. The hole can be used to tie the label to the bag. For histopathology, the label can be taped to the outside of the formalin jars.

5.10 RESIDUE, ANTI-MICROBIAL AND MICRO-ORGANISMS SYSTEM (RAMS)

5.10.1 Introduction

The Residue, Antimicrobial, and Micro-organisms System (RAMS) is a computerized tracking system for CFIA responses to the detection of chemical residues. It was implemented in the fall of 2005.

Residues may be reported by various sources, including a CFIA laboratory, a private contract laboratory, a provincial meat sampling and testing program, or the United States Department of Agriculture (as a result of the testing of Canadian animals exported for slaughter). When a residue is reported, it is entered into RAMS either automatically via the Laboratory Sample Tracking System (LSTS) or manually by national or Area program staff, and directed to the Program Specialist, Chemical Residues.

Violative residues are normally traced back to a farm of origin in order to determine the possible cause of the residue and determine corrective measures. As part of that process, the program specialist will refer the traceback to the abattoir where the sample was taken so that farm of origin information can be entered.

5.10.2 Notification

When a traceback is referred to an abattoir, RAMS automatically generates an email message and sends it to the person listed in RAMS as the contact for that abattoir. In most cases, that will be the Veterinarian in Charge.

The message will say:

> “This message has been generated automatically by RAMS
>
> Owner information requested
>
> On behalf of your abattoir, you have been assigned to identify the Owner details of the sample(s) as defined in the above Traceback. The Traceback will be placed in your Inbox. Please use the link below to access RAMS. You will be re-directed to the appropriate page.”

This tells you that there is a traceback waiting for you in RAMS. The message will also contain a link. If you click on the link, the computer will launch the RAMS application, take you to the log on screen, and then to the applicable traceback.

5.10.3 Logging on

The log on screen will prompt you for your user name and password. Your user name will normally be the same as for other CFIA applications, consisting of your last name and first initial.

RAMS shares a common password with other CFIA Web-based applications. If you use any of these, you may wish to try this password first. If you have never entered RAMS before, your password will be the same as your user name. This password must be entered in ALL CAPITALS. If the application will not accept this password, contact your Area Program Specialist, Chemical Residues, or the RAMS administrator to verify that you are listed as a user for this application.

When you enter for the first time, RAMS will require you to provide a new password before continuing. The new password can be in lower case, or a combination of upper and lower case characters.

Once you have provided your password, click on your language preference. You should be taken to the traceback referred to in the notification message.

5.10.4 Traceback detail

In the Traceback Detail screen, you are able to see the details regarding the violative sample.

In the first section, "Job Information", you can see the "Date sampled". If the test result came from a CFIA laboratory, you can click on the link for "Lab Job No." This will take you into the Lab Sample Tracking System (LSTS) and allow you to view the Report of Analysis. In order to do this, you will require a password for LSTS. See section 5.8.1.2.

In the second section, "Sample information", you can see the details on the violative result. The "Insp. Sample No." and the "Date sampled" should allow you to match the traceback to the corresponding sample that you submitted.

In the third section, "Identification", you can see the type of animal that was sampled (species), and the abattoir and inspector that the traceback has been assigned to. If the Program Specialist had any additional information or instructions, it will appear under "Message".

The final section is "Owner Identification Form." If you are unable to determine the owner, check off the box next to "The abattoir was unable to identify the owner", and click on "submit" at the bottom of the form.

5.10.5 Reassigning

You can assign a traceback to someone else. This feature would most often be used by a Veterinarian in Charge to give the task of finding owner information to one of his inspectors. This feature is helpful for keeping a record of the person who actually provided the owner information. If you wish to assign the traceback to another inspector, you can do so at this point by clicking on "Reassign identification." This will take you to a search screen in which you can enter last name and first name.

Because first names can often take several different forms, it is usually better to search on last name only. You can also enter only the first part of the last name, followed by the percent sign. Click on "Search" and you will get a list of matching names.

Click on the circle at the start of the name, then click on "submit."

Note that the system will not send your inspector an automated notice. You will have to advise the inspector that you have assigned a traceback.

5.10.6 Animal information

In this section, enter the information that you have about the animal.

In the field marked "Species", select the species or type of animal from the drop-down list. Although this information appears under "Animal type" earlier in the form, it is requested here as a confirmation, in case it was not reported correctly when the sample was submitted.

Under "Permanent ID", record the national livestock identification eartag number or other equivalent identification.

Under "Other animal ID", record any other identification, such as a back tag, lot number, producer eartag, or tattoo. Besides the number, you can enter a brief description of the tag, such as "backtag" or "yellow eartag."

Note that the fields marked with an asterisk (Species, date of slaughter) are mandatory.

5.10.7 Owner information

In this section, enter the information that you have about the owner of the animal.

The field marked "Code" is for a premises or producer identification code, if applicable.

Note that the fields marked with an asterisk (name, address, city, country, province) are mandatory.

When you have entered all the information, click on the "submit" button.

You can then click on the logout button to exit the application.

5.11 REFERENCES

Animal Health Disease Control Manual of Procedures, CFIA

Bovine Spongiform Encephalopathy Manual of Procedures
http://merlin.cfia-acia.inspection.gc.ca/english/anima/heasan/man/bseesbe.asp

Compendium of Medicating Ingredient Brochures (MIB), CFIA.
http://www.inspection.gc.ca/english/anima/feebet/mib/cmibe.shtml

Directive 77/96/EEC, European Union.

Food and Drugs Act and *Regulations*

Laboratory Biosafety Guidelines, Health Canada, Third Edition, 2004.
http://www.phac-aspc.gc.ca/publicat/lbg-ldmbl-04/index-eng.php

Low-Acid and Acidified Low-Acid Foods In Hermetically Sealed Containers - Visual Inspection Protocol
http://www.inspection.gc.ca/english/fssa/fispoi/product/visue.shtml

Metal Can Defects Manual - Identification and Classification
http://www.inspection.gc.ca/english/fssa/fispoi/man/canboi/canboie.shtml

Performing the Swab Test on Premises (STOP) for Antibiotic Residues. A Self-Instructional Guide. CFIA, May 2002 (only available to CFIA inspectors and staff)
http://merlin/english/fssa/microchem/stopeepe.pdf

Performing the Sulfa on Site Test. A self-instructional guide. CFIA, Oct. 1997

Policy on *Listeria monocytogenes* in Ready-to-Eat Foods. Health Canada, July 2004
http://www.hc-sc.gc.ca/fn-an/legislation/pol/policy_listeria_monocytogenes_politique_toc-eng.php

Scrapie - Manual of Procedures. Appendix 1A Brain Sampling Procedures, December 2004
http://merlin.cfia-acia.inspection.gc.ca/tech/exthum.asp?url=2513219&VERSION=1

Shipping Biological Samples Guidebook (only available to CFIA inspectors and staff) (RDIMS# 1798720)

Transmissible Spongiform Encephalopathies - Surveillance and Specimens Collection (Training CD). 2005

ANNEX I

Risk-based Verification Sampling of Ready-to-Eat (RTE) Meat and Poultry Products

Version 3.0

1. Introduction and scope

The following sampling plan must be implemented by operators who produce ready-to-eat (RTE) meat and poultry products that are exposed to the environment after processing.

The implementation date for this sampling plan was April 1, 2009.

2. Classification of products

The operator must indicate under which of the following alternatives each eligible product falls:

Alternative 1: Employ both a post-lethality treatment and an antimicrobial agent or process for control of *L. monocytogenes* on RTE products.
Alternative 2A: Employ a post-lethality treatment that achieves at least 1-log lethality.
Alternative 2B: Employ an antimicrobial agent or process for control of *L. monocytogenes* on RTE products that allows no more than 2-log increase through shelf life.
Alternative 3: Employ sanitation measures only.

The establishment is then classified according to the highest risk alternative product produced. For example, should there be products in more than one alternative, Alternative 3 has priority, followed by Alternative 2B, Alternative 2A and Alternative 1, respectively.

3. Frequency of testing

The testing frequency increases as the level of safety associated with the alternative decreases. This means that establishments under Alternative 3 need to test more frequently than establishments under Alternative 1, regardless of the product type and production volume.

Alternative	***Control measure****	***Risk level***	***Sampling frequency***
Alternative 3	Sanitation only	Highest risk	12 samples per year (1 per month)
Alternative 2B	Antimicrobial agent or process (AMA/P)	Medium-high risk	6 samples per year (every other month)
Alternative 2A	Post-lethality treatment after the primary lethality process (PLT)	Medium-low risk	3 samples per year (1 per 4 months)
Alternative 1	AMA/P and PLT are in place	Lowest risk	1 sample per year

* Please refer to the glossary for the explanation of the different control measures.

Note:
- The alternative under which the establishment falls must be confirmed by the Canadian Food Inspection Agency (CFIA; Inspector in Charge/Program Specialist) and this information must be kept on record by the operator.
- Any change in the alternative under which the establishment is classified must be documented by the operator and approved by the CFIA.

Once the testing frequency is determined, the selection of the product that will be tested must be done as per Appendix A.

4. Sample collection

The operator is responsible for the sample collection process that includes the following steps:

4.1. Training of the designated employee(s) who will work with the sampling plan in order to meet the sampling plan's objectives and specifications.

4.2. Collecting samples in the post-processing area of the establishment as per Appendix B. This must be done under direct CFIA supervision.

4.3. The sample must be properly identified. This includes the name of the product, the production date or code, and the lot of production it represents (in the event that the laboratory result should be unsatisfactory).

4.4. The sample must be kept and shipped refrigerated so that its internal temperature does not exceed 7°C upon its arrival at the laboratory.

4.5. Operators shall prepare and have a written sampling program for risk-based testing of RTE products that covers sample collection, preparation and shipping procedures. It shall also cover means to tamper-proof and protect the integrity of samples (e.g., how samples are handled, packaged and shipped to ensure temperature maintenance and tamper proofing).

Samples must be appropriately sealed under CFIA supervision.

The shipping procedures shall specify:

- who packages the samples and where the packaging is done;
- where samples are kept pending shipment;
- who ships the samples; and
- where samples are shipped (laboratory) and how samples are shipped (shipping agent).

4.6 The chain of custody must be maintained.

After the program has been reviewed by the CFIA V/IIC (Veterinarian/Inspector-in-Charge), the establishment is required to conduct their sampling activities in accordance with their written program. The procedures shall be detailed to the extent necessary to enable CFIA V/IIC on-site verification. The general guideline for the sample collection, shipping and integrity protection is provided in Appendix B.

Note:
- Step 4.3: The CFIA must approve the lot as defined by the operator. Please refer to the glossary for lot definition.
- Steps 4.4 - 4.5: For this purpose the V/IIC uses the appropriate inspection tasks as per Compliance Verification System (CVS) tasks. In cases where the V/IIC finds that a condition is not being met, he or she is to document the situation and advise the Inspection Manager and the Area Program Manager, Meat Programs.

It is recommended to hold the production lot pending reception of the laboratory result.

5. Target Pathogens

The samples will be analysed for *L. monocytogenes* and *Salmonella* spp. If the product is a dry or semi-dry fermented sausage and contains beef, it will also be analysed for *E. coli* O157:H7.

6. Methods of analysis

For each sample, a 25 g test portion (50 g for category risk 1 products, as defined in Health Canada's "Policy on *Listeria monocytogenes* in Ready-to-Eat Foods") will be analysed for *L. monocytogenes* and a 325 g test portion will be analysed for *Salmonella* spp. The analysis for *E.*

coli O157:H7, when required, will be conducted on five 65 g test portions.

The following analytical methods are to be used:

- *Listeria monocytogenes*

  The Compendium methods MFHPB-30 and MFLP-28. Alternate methods*: the FSIS MLG 8.04 and 8A.01.

- *Salmonella* spp.

  The Compendium methods MFHPB-20 and MFLP-29. Alternate methods*: the FSIS MLG 4.03 and 4C.01.

- *E. coli* O157:H7 and O157:NM (Nonmotile)

  The Compendium methods MFLP-80 and MFLP-30. Alternate methods*: the FSIS MLG 5.03 and 5A.00.

The samples must be analysed in a laboratory accredited by the Standards Council of Canada (SCC) and the required methods included in the laboratory scope of accreditation. The operator must therefore ensure that the methods used which are not yet in the scope of accreditation are included in the scope for the next SCC audit.

*Note: Alternate methods will be considered exclusively for products to be exported to the US.

7. Laboratory reports

- The laboratory report must clearly indicate the common name of the product tested as well as the date on which the sample was collected by the operator.

- The laboratory report must be sent simultaneously to both the operator and CFIA's National Micro Sampling Plans Unit in Ottawa at the following address:

  National Micro Sampling Plans
  Floor 4, Room 250
  1400 Merivale Road, Tower 2
  Ottawa, (ON), K1A 0Y9
  or fax: (613) 773-5957
  or email: RTE-PAM@inspection.gc.ca

- The operator must also advise the IIC upon reception of the laboratory analysis.

Please note that if, for whatever reason, the laboratory is unable to analyse and make an evaluation of the sample submitted for analysis, a replacement sample must be sent as soon as possible.

8. Follow-up on positive results

When pathogens are detected in a sample, the sampled lot is considered contaminated (adulterated) and following measures must be taken:

8.1. The contaminated lot must remain under the operator's control.

8.2. The IIC will issue a corrective action request (CAR). The operator will submit an action plan within five working days of the notification of an unsatisfactory test result. The action plan must cover the following points:

- action that will be taken on the unsatisfactory product to control the risk associated with the presence of pathogens in the product (e.g.: cooking schedule that will be applied to the unsatisfactory product to destroy *Listeria monocytogenes*)
- ascertain that no other product should be affected by the unsatisfactory result
- results of the investigation done to identify the cause of the deviation
- take appropriate corrective actions (including, if applicable, amending the HACCP plan)
- evaluate the efficacy of the corrective actions (this must include additional final product testing)
- measures to prevent recurrences.
- the subsequent lots will be sampled and tested for the pathogen detected.

Please refer to the Manual of Procedures (MOP) for additional information on specific follow-ups.

8.3. The CFIA notification procedures must be clearly outlined in the written sampling program (e.g., who in the company will notify the V/IIC when the analysis is completed and the result is unsatisfactory, e.g., *Listeria monocytogenes* was detected in a sample).

8.4. In the unlikely event that the sampled lot was distributed before the positive result was received or if it is determined that there are other products in distribution that are implicated by the positive result, the CFIA will immediately notify the OFSR (Office of Food Safety and Recall). If any of the involved product was exported, the regulatory authority of concerned countries would also be immediately notified (e.g.: FSIS (Food Safety and Inspection Service) would be informed and provided with the distribution details if the products had been exported to the USA).

8.5. For RTE meat and poultry products zero tolerance applies for tested pathogens including *Listeria monocytogenes* in products which support its growth.

9. Record keeping

All laboratory reports should be kept for at least one year after the end of the sampled product's shelf life.

Other records should be kept as per what is indicated in the operator's HACCP plan.

Appendix A

The following list must be used when two or more products are produced on the day of testing.

The highest risk post-lethality exposed RTE product produced at the time of collection must be sampled. The products are listed in decreasing order of risk (sliced deli meats being the highest risk):

1. Deli meats that are sliced in the federal registered establishment
2. Deli meats shipped whole from the federal establishment. (This does not include cook-in-bag products; only those exposed post-lethality.)
3. Hotdog products
4. Deli salads, pâtés, and meat spreads
5. Fully cooked type products (other than cooked products in 1-4 above)
6. Fermented products
7. Dried products
8. Salt-cured products
9. Products labelled as “Keep Frozen”

Appendix B

The following general guidelines should be followed for sample collection and shipping procedure, and for the maintenance of the integrity of samples:

1. Sample collection must be carried out on the RTE finished products that were post-lethality exposed.

2. Sample collection will be carried out by the individual who is designated in the establishment's written protocol and has received the required training. Sampling supplies, such as sterile gloves, sterile sampling solutions, hand soap, sanitizing solution, etc., as well as specific materials needed for sampling, will need to be assembled prior to beginning sample collection.

3. A sample consisting of five sample units shall be drawn at random from each lot selected for sampling. Each sample unit shall consist of 150 g or five intact units weighing at least a total of 750 g. Do not sample the same lot for both Non risk-based (M200 - managed by the CFIA) and Risk-based (managed by industry) programs.

4. Unopened, original containers shall be sampled, when possible.

5. If the product is in bulk, several sample units can be collected from one container, while ensuring that the total number of sample units is not collected from one container. More than one sample unit may also be collected from large institutional or bulk containers when the total number of sample units required exceeds the number of containers in the lot. The collected sample units shall be placed in sterile containers. A sample unit will consist of more than one container when the lot consists of containers smaller than 150 g (e.g., six - 25 g containers in each sample unit).

6. Aseptic techniques shall be employed in collecting the sample units.

7. Depending on the nature of the product, the sample units must either be kept refrigerated (0-4°C) or frozen at all times. The temperature of refrigerated samples must not exceed 7°C upon its arrival at the laboratory.

8. The establishment’s operators must have a written procedure explaining how they ensure that samples are protected from temperature abuse during sampling, storage and transportation to the laboratory, as well as from potential tampering.

9. Samples must be sent to a laboratory accredited to perform the analysis by the methods considered acceptable.

Glossary

Antimicrobial agent
A substance in or added to a RTE product that has the effect of reducing or eliminating a microorganism, including a pathogen such as *L. monocytogenes*, or that has the effect of suppressing or limiting growth of *L. monocytogenes* in the product throughout the shelf life of the product. Examples of antimicrobial agents which can be added to RTE products: Sodium diacetate, sodium lactate and potassium lactate either alone or in combination.

Antimicrobial process
An operation, such as freezing, applied to a RTE product that has the effect of suppressing or limiting the growth of a microorganism, such as *L. monocytogenes*, in the product throughout the shelf life of the product.

Deli product
A ready-to-eat meat or poultry product that is typically sliced, either in an official establishment or after distribution from an official establishment, and is typically assembled in a sandwich for consumption.

Hotdog product
A ready-to-eat meat or poultry frank, frankfurter, or wiener.

Lethality treatment
A process, including the application of an antimicrobial agent, that eliminates or reduces the number of pathogenic microorganisms on or in a product to make the product safe for human consumption. Examples of lethality treatments are cooking or the application of an antimicrobial agent or process that eliminates or reduces pathogenic microorganisms.

Lot
For the sampling purpose, a lot is defined as all products produced under the same conditions using the same equipment, which are produced between two satisfactory complete sanitation operations. A sanitation operation is considered satisfactory if it cuts off the transfer of microbial contamination from one lot to another. The lot size should be the same as the one used by the operator in normal circumstances for commercial purposes. The operator cannot reduce the size of the lot in anticipation of testing requirements.

Post-lethality exposed product
A ready-to-eat product that comes into direct contact with a food contact surface after the lethality treatment in a post-lethality processing environment. (This excludes cook-in-bag products.)

Post-lethality processing environment
The area of an establishment into which product is routed after having been subjected to an initial lethality treatment. The product may be exposed to the environment in this area as a result of slicing, peeling, re-bagging, cooling semi-permeable encased product with a brine solution, or other procedures.

Post-lethality treatment
A lethality treatment that is applied or is effective after post-lethality exposure. It is applied to the final product or sealed package of product in order to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure.

Ready-to-eat (As per the *Meat Inspection Regulations, 1990*)
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 food borne pathogenic bacteria so that the meat product does not require further preparation before consumption except washing, thawing or exposing the product to sufficient heat to warm the product without cooking it.

Note:

i) For heat treated products which may be mistaken as RTE products, section 94 (6.1) of *Meat Inspection Regulations, 1990* would apply in regard to “cooking instructions” and “labelling requirement.”

ii) Frozen Assembled Convenience (FAC) meat products will be considered RTE meat products if they meet the following criteria:

a) the meat used to manufacture the FAC product was in the RTE stage prior to its use in the FAC product; and

b) by virtue of its appearance, there is a high probability that the consumer might eat the FAC meat product without first cooking the product to ensure that any pathogens introduced during product assembly would be destroyed.