Ministry for Primary Industries
Manatū Ahu Matua

Animal Products Notice

Specifications for National Microbiological Database

28 June 2016

Issued under the Animal Products Act 1999

New Zealand Government

TITLE

Animal Products Notice: Specifications for National Microbiological Database

COMMENCEMENT

This Animal Products Notice comes into force on [Effective Date]

REVOCATION

This Animal Products Notice revokes and replaces the Animal Products (National Microbiological Database Specifications) Notice 2015, issued on 19 August 2015, and the Animal Products (National Microbiological Database Specifications) Amendment Notice 2016, issued on 26 February 2016.

ISSUING AUTHORITY

This Animal Products Notice is issued pursuant to:

a) sections 45 and 167(1)(h)of the Animal Products Act 1999 with reference to regulation 15 of the Animal Products Regulations 2000; and
b) section 167(maa)(iii)of the Act

Dated at Wellington this ... day of 2016

Allan Kinsella
Director, Systems Audit, Assurance and Monitoring
Ministry for Primary Industries
(acting under delegated authority of the Director-General)

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Introduction

This introduction is not part of the Animal Products Notice, but is intended to indicate its general effect.

Purpose

This notice sets specifications relating to the National Microbiological Database (NMD) Programme that are necessary to give effect to, and amplify, standards provided in regulation 15 of the Animal Products Regulations 2000.

Background

The NMD Programme is a standardised microbiological sampling and testing programme to provide ongoing monitoring of microbiological process control across all industry participants.

The Programme began as a technical directive in 1997 in response to the United States Department of Agriculture Food Safety and Inspection Service's *1996 Pathogen Reduction; HACCP Systems; Final Rule* (also known as 'MegaReg'). Since then industry has adapted the Programme to cover more species of red meat and poultry.

The NMD Programme became a New Zealand standard by specification in 2005 and a notice that incorporated *Campylobacter* standards for poultry in 2007.

Under this notice, operators in the red meat and poultry industries must:

- ensure red meat and poultry samples are taken as specified;
- engage a laboratory to test the samples collected for microbiological risks;
- review microbiological test results to ensure they comply with microbiological targets and take appropriate actions to manage risks;
- report the test results to MPI; and
- work with MPI to resolve any compliance issues.

The notice provides for training and certification relating to sample collection and testing procedures for laboratories to ensure appropriate microbiological testing is undertaken and accurate results are produced. The notice also establishes performance targets that minimise microbiological risks in production to ensure food produced by the red meat and poultry industries is fit for its intended purpose.

Who should read this Animal Products Notice?

You should read this notice if you are:

- an operator who processes red meat or poultry intended for human consumption; or
- a laboratory that tests red meat or poultry intended for human consumption; or
- an NMD controller; or
- an NMD laboratory manager; or
- an NMD sample taker.

Why is this important?

A failure to comply with this notice may be an offence under section 135(c) of the Animal Products Act 1999.

Document history

Predecessors to this notice include:

- Animal Products Notice: NMD Specifications December 2012; and
- Animal Products Notice: NMD Specifications August 2015.

This notice consolidates microbiological quality control across species, aligning with current Codes of Practice under the Animal Products Act 1999, and is consistent with the Food Act 2014.

Other information

Animal Products Notice: Specifications for Laboratories.

Part 1: Preliminary provisions

1.1 Application

(1) This notice applies to:

a) an operator who processes red meat or poultry intended for human consumption; and
b) a laboratory that is a recognised agency under Part 8 of the Act and authorised to conduct NMD tests; and
c) a person who intends to take samples of red meat and/or poultry for an operator (in relation to the sample taker's training, certification and listing).

1.2 Interpretation

(1) In this notice, unless the context otherwise requires:

Act means the Animal Products Act 1999

approved sampler means a person trained by a certified trainer and currently listed under clause 2.3.3 by the Director-General

certified trainer means any person who has passed the NMD certified trainer course and is currently listed under clause 2.3.3 by the Director-General

CLT means the MPI Consolidated List of Tests for Animal Products: meat, poultry, honey, seafood, dairy, live animals and germplasm

data submitter means any person who submits sampling or testing data to the NMD on behalf of an operator or a laboratory

final report means a laboratory report that has the test results that are entered into the NMD

HACCP means Hazard Analysis Critical Control Point

Key Technical Person (KTP) means a person engaged under subclause 2.2.5 (2) by the senior management of the laboratory as a qualified expert in an NMD test

laboratory means a laboratory that is a recognised agency under Part 8 of the Act and that is permitted to undertake an NMD test

missed sample means a failure by the operator to ensure samples are collected as required under this notice

moving window means a set of samples taken over a set period of time in which the addition of the latest set of samples to the window displaces the oldest dated set of samples

NMD means the National Microbiological Database

NMD controller means a person appointed under subclause 2.1.3 (1) by an operator to be the point of contact with MPI and the laboratory in regard to the requirements of this notice

NMD laboratory manager means a person appointed under subclause 2.2.2 (1) by a laboratory to be the point of contact with MPI and the operator in regard to the requirements of this notice

NMD test means any of the following tests:

a) APC Petrifilm™ as described in clause 3.15.5 in relation red meat; or
b) APC spiral plater as described in clause 3.15.6 in relation to red meat; or
c) APC spread plate as described in clause 3.15.4 in relation to red meat; or
d) *Campylobacter* as described in clause 4.10 in relation to poultry; or
e) *Escherichia coli* Petrifilm™ as described in clause 3.16 in relation to red meat; or
f) *Salmonella* as described in clause 3.17 in relation to red meat; or

g) *Salmonella* as described in clause 4.11 in relation to poultry

NZRM means the New Zealand Reference Culture Collection, Medical Section, Catalogue of Strains

operator means an operator of a premises that carries out:

a) primary processing of red meat or poultry for human consumption; or
b) secondary processing by cutting and boning of bovine (including bobby calf), caprine, or cervine, products intended for human consumption

poultry means, in relation to primary processing, a bird of any of the following species intended for human consumption:

a) a chicken of the species *Gallus gallus*;
b) a duck of the species *Anas platyrhynchos* domestica or *Anas pekin* or *Cairina moschata;*
c) a turkey of the species *Meleagris gallopavo*

premises means the place at which the operator is carrying out processing as described under the operator's risk management programme (RMP)

processing period means:

a) in relation to standard throughput poultry, a set sampling period of a block of 5 consecutive processing days, not overlapping with the previous or next block of 5 processing days;
b) in relation to VLT poultry, 3 samples taken from 1 processing day randomly selected that week

processing week means:

a) in relation to red meat and VLT poultry, a week starting on a Monday during which a species of red meat or VLT poultry is processed;
b) in relation to VLT red meat, a week within a month during which a species of VLT red meat is processed

quarter means a period of 13 or 14 weeks:

a) beginning with the first Monday in January and ending with:
b) the last day in March, if that day is a Sunday; or
c) the first Sunday in April, if the last day in March is not a Sunday:
d) beginning with the first Monday in April and ending with:
e) the last day in June, if that day is a Sunday; or
f) the first Sunday in July, if the last day in June is not a Sunday:
g) beginning with the first Monday in July and ending with:
h) the last day in September, if that day is a Sunday: or
i) the first Sunday in October, if the last day in September is not a Sunday:
j) beginning with the first Monday in October and ending with:
k) the last day in December, if that day is a Sunday: or
l) the first Sunday in January the following year, if the last day in December is not a Sunday.

red meat means:

a) in relation to primary processing, meat of any the following species intended for human consumption:
b) bovine (including bobby calf);
c) caprine;
d) cervine;
e) ovine;
f) porcine;
g) ratite
h) in relation to secondary processing by cutting and boning, meat of any the following species intended for human consumption:
    (i) bovine (including bobby calf);
    (ii) caprine;

(iii) cervine

regulatory limit means a measurable regulatory requirement that is critical to fitness for intended purpose of animal material or animal product (ref. s 4, Animal Products [Risk Management Programme Specifications] 2008)

RMP means risk management programme

sample taker means a person qualified in NMD sampling, either on the approved sampler list or certified trainer list under clause 2.3.3

set of samples means:

a) in relation to red meat, the samples taken over 1 week for standard throughput or taken over 1 month for VLT;
b) in relation to poultry, the samples taken in 1 processing period

technical failure means that there is no result following sampling due to samples not being delivered to the laboratory in the required time, or within the correct temperature range, or a laboratory error

TNTC means too numerous to count

verifier means a person or agency recognised under Part 8 of the Act to undertake verification activities in relation to a risk management programme (RMP)

VLT means very low throughput

zero dilution means the initial suspension of the bulk meat or poultry carcass rinsate sample.

(2) Further terms and expressions used in Part 3 and Part 4 are defined in those Parts.

(3) Any term or expression that is defined in the Animal Products Act 1999, or regulations made under that Act and used, but not defined, in this notice has the same meaning as in that Act or regulations.

1.3 Material incorporated by reference

(1) Under section 168 of the Act, the current edition of the Meat Industry Microbiological Methods (MIMM) is incorporated into, and forms part of, this notice as a standard work of reference.

Part 2: General requirements

2.1 Operator requirements

2.1.1 Application

(1) An operator who processes red meat must comply with Parts 1, 2, and 3 of this notice.

(2) An operator who processes poultry must comply with Parts 1, 2, and 4 of this notice.

2.1.2 Initial information required

(1) An operator must not process any species of red meat or poultry if the information specified in subclause (2) has not been provided to the Director-General.

(2) An operator must submit a completed questionnaire for each species processed to the Director-General, covering:

a) name, RMP identifier, physical and postal addresses of premises; and
b) name of operator and contact details (phone, cell phone and email); and
c) name of NMD controller and contact details (phone, cell phone and email); and
d) name and identification number of the laboratory conducting NMD testing and coordinating the NMD sampling programme; and
e) name of laboratory contact person, contact details (phone and email), and whether this is a person employed by the operator or the laboratory; and
f) name of the data submitter, contact details (phone and email), and whether this is a person employed by the operator or the laboratory; and
g) whether the operation is a standard throughput or VLT premises; and
h) procedural details of the processing operation; and
i) for poultry only, the location and reference number for each farm and reference number for each poultry shed.

(3) If any of the details change, the operator must notify the Director-General in writing within 1 week from the date the change occurred.

Guidance
- Questionnaire forms are available at: NMD Documents: Forms & Templates
- Submit completed forms and notifications to the Director-General: nmd@mpi.govt.nz

2.1.3 NMD controller

(1) An operator must appoint a person (NMD controller) to be the point of contact for MPI and the laboratory in relation to this notice.

(2) An NMD controller may be the operator him/her self.

(3) An NMD controller must not be an NMD laboratory manager.

(4) An operator must notify the laboratory that undertakes the NMD tests for the operator and the Director-General in writing of:

a) the name and contact details of an appointed NMD controller within 1 week from the date of the appointment; and
b) any changes to the appointment within 1 week from the date the change occurred.

(5) An operator must ensure that an NMD controller or competent deputy oversees requirements of this notice during any processing week/period.

2.1.4 Sample takers

(1) An operator must ensure that a sample taker, who has been appropriately trained, samples each species/product type of red meat/poultry processed by the operator as required under Parts 3 and 4 of this notice.

(2) An operator must notify the laboratory in writing of:

a) the name and details as per subclause 2.2.3(2) of an appointed sample taker within 1 week of the appointment; and
b) any changes to the appointment within 1 week from the date the change occurred.

2.1.5 Testing samples and laboratories

(1) An operator must engage the services of a laboratory.

(2) An operator must ensure that the laboratory conducts the NMD tests that are required for the operator under Part 3 and Part 4 of this notice.

(3) An operator must provide refrigeration, storage facilities and any other equipment required to store samples, if necessary, prior to transport to the laboratory.

(4) An operator must provide any sample that has been taken under Part 3 or Part 4 of this notice to the laboratory within 30 hours from the time the sample was collected.

(5) An operator must ensure that any sample provided to a laboratory:

a) is the appropriate sample (as detailed in Part 3 and Part 4) for the relevant NMD test to be performed; and
b) has not deteriorated in any material respect since the sample was collected.

(6) An operator must notify the laboratory within 24 hours of knowing that he/she will not be providing a sample that meets the requirements in subclause (5) in order to facilitate re-sampling.

(7) An operator must inform the laboratory in writing of production schedules and plant closures that could impact on NMD sampling.

2.1.6 Sampling

(1) An operator must ensure that sampling is carried out in accordance with the sampling requirements specified in Part 3 and Part 4 of this notice for all species and product types of red meat/poultry processed at the operator's premises.

(2) If an incident or omission occurs at any stage during sampling, storage, transport, or upon notice from the laboratory, and a test result cannot be obtained from the sample, an operator must make every effort to re-sample in the same processing week (for red meat and VLT poultry premises) or processing day (for standard throughput poultry premises) in order to meet the obligations under this notice.

Guidance

- If no other time to re-sample is available in the same processing week or processing day, an operator does not have to provide 2 sets of samples to the laboratory the following processing week or processing day.

(3) An operator must ensure that any incident or omission that occurs during sampling, storage, or transport of samples that results in a sample not meeting NMD sampling requirements specified in Part 3 and Part 4 is reported to the Director-General in writing within 1 week, including details of the non-compliance.

(4) An operator must take corrective actions to address failures to meet the sampling requirements in this notice and keep records of actions taken for 4 years.

2.1.7 Results

(1) An operator must ensure that the verifier is informed of any detection or non-compliant result (if required in accordance with Part 3 and Part 4 of this notice) in writing within 24 hours after receiving results from the laboratory.

(2) An operator must review the NMD test results received from a laboratory on samples taken under Part 3 and Part 4 of this notice within 7 days from the date the samples were taken to:

a) check that results accurately represent processing done; and
b) respond as required to limits specified in clauses 3.20, 3.21 for red meat and 4.13, 4.14 for poultry.

(3) An operator must review NMD data in a manner that facilitates analysis of trends and early identification of loss of process control.

Guidance

- If an operator enters authorised NMD results into a database other than the NMD database for analysis of data, trends etc, alterations may be made to the format or presentation of the results provided that such alterations do not affect the results themselves in any substantive way.

2.2 Laboratory requirements

2.2.1 Application

(1) A laboratory that is engaged to do an NMD test by an operator who processes red meat must comply with Parts 1, 2, and 3 of this notice.

(2) A laboratory that is engaged to do an NMD test by an operator who processes poultry must comply with Parts 1, 2, and 4 of this notice.

2.2.2 NMD laboratory manager

(1) A laboratory must appoint an NMD laboratory manager to be the point of contact for MPI and the operator in relation to this notice.

(2) A laboratory must notify the operator and the Director-General in writing of:

a) the name and contact details of an appointed NMD laboratory manager within 1 week from the date of the appointment; and
b) any changes to the appointment within 1 week from the date the change occurred.

Guidance

- Submit notifications to the Director-General to: nmd@mpi.govt.nz

2.2.3 Sample takers

(1) A laboratory must ensure all sample takers are listed.

(2) A laboratory must maintain current records containing the following details relating to sample takers it employs/contracts or relating to sample takers for which the information has been provided to the laboratory by the operator under 2.1.4:

a) name of sample taker; and
b) species and product types for which the sample taker has been trained; and
c) date of the sample taker's training; and
d) name of the sampler taker's trainer and a copy of their certificate; and
e) operator or operators for whom the sample taker takes samples.

(3) A laboratory must provide the Director-General with sample taker listing information as specified in subclause (2).

(4) If there is a change to any of the list information, the laboratory must notify the Director-General in writing within 1 week from the date the change occurred.

(5) Every 12 months a laboratory must review the work of a sample taker employed to undertake NMD sampling by the laboratory or their client premises to ensure requirements in subclauses 2.1.5 (4) and (5) are being met.

(6) A laboratory must advise the operator of the results of the review and any change in status of sample takers who work at the operator's premises in writing within 1 week from the date of the review.

(7) A laboratory must notify the Director-General of any changes in relation to sample takers in writing within 1 week from the date it was notified of the change.

2.2.4 Samples

(1) A laboratory must not accept a sample for an NMD test unless the sample:

a) has been collected by a sample taker; and
b) is in a condition that is suitable for the requested NMD test, as specified in Part 3 and Part 4 of this notice, to be performed.

(2) If a laboratory does not accept a sample for an NMD test because the sample does not meet the requirements in subclause (2), the laboratory must notify the operator in writing within 24 hours from the time the sample was received.

(3) A laboratory must enter sample descriptors as per clauses 3.11 and 4.7 in the NMD if they are not entered by the sample taker.

(4) Every 6 months the laboratory must confirm (by means of data loggers) that immediately following sampling all samples are:

a) rapidly reduced below 10°C, and kept above 0°C and below 10°C for the entire time between sampling, receipt by the laboratory, and NMD testing; and
b) subjected to sufficient coolant during sample collection and transport to keep the samples cold, but not frozen, regardless of whether the sample is to be immediately analysed, transported off-site or held for a period of time; and
c) transported in an insulated container that is maintained between 0°C and 5°C and must not exceed 10°C.

(5) If the data logger review shows requirements in subclause (4) are not being met, the laboratory must notify the operator and the Director-General in writing within 1 week from the date of the review.

2.2.5 Testing and results

(1) A laboratory must ensure that all NMD tests are conducted and results are calculated in accordance with the requirements in Parts 3 and 4 of this notice.

(2) A laboratory must appoint a person to be a KTP who is an expert for each NMD test conducted within the laboratory's approval.

(3) A laboratory must ensure that a KTP for the NMD test:

a) reconciles the results calculated under Parts 3 or 4 of this notice with the original colony counts or presence/absence results recorded at the conclusion of the test; and
b) signs the final report.

(4) A laboratory must ensure the results:

a) identify the premises from which the samples were taken, the process descriptors, and the sample descriptors (as per clauses 3.11 and 4.7); and
b) are submitted to the operator and to the Director-General:

i) within 24 hours of completion of testing, but no later than 1 week after receipt of samples; and
ii) in the case of a test for detection of *Salmonella*, no later than 2 weeks after receipt of samples.

(5) A laboratory must, within 24 hours of completion of testing, notify the operator of any presumptive results that indicate that the limits specified in clauses 3.20, 3.21 for red meat and 4.13, 4.14 for poultry have been exceeded.

(6) A laboratory must ensure that any incident or omission that occurs during testing of samples that results in a sample not meeting testing requirements in this notice is reported to the Director-General in writing within 1 week after receipt of samples.

2.3 Sample takers

2.3.1 Certified trainers

(1) The Director-General may approve any certified trainer course if the Director-General is satisfied that the course covers criteria for sample collection, sample packaging, and sample transport as set out in Part 3 for any species/product type of red meat and Part 4 for any species/product type of poultry.

(2) The Director-General may issue a certificate to a person deemed competent to train other persons for a species/product type of red meat or poultry NMD sampling if the person:

a) attends a training course in relation to the species/type of red meat or poultry for which the certificate is issued; and
b) passes a course assignment that covers the content of that course; and
c) has at least 12 months' experience in taking samples under Part 3 or Part 4 of this notice in relation to the species/product type of red meat or poultry for which the certificate is issued.

(3) The laboratory must engage the services of at least 1 certified trainer.

2.3.2 Approved samplers

(1) A person may be listed as an approved sampler if the person:

a) has process experience in the species and product type concerned as required under Part 3 or Part 4 of this notice; and
b) has been trained by a certified trainer with that species and product type as demonstrated in his/her current certified trainer listing.

2.3.3 Sample taker lists

(1) The Director-General for MPI may keep the following lists:

a) a list of NMD Certified Trainers that includes:

i) certified trainer's name; and
ii) location (premises or laboratory); and
iii) species and product types they are qualified to train.

b) a list of NMD Approved Samplers:

i) approved sampler's name; and
ii) location (premises or laboratory); and
iii) species and product types they have been trained by a certified trainer to sample.

Guidance

- The sample taker lists are: NMD Approved Samplers and NMD Certified Trainers.

- A laboratory may contact the Director-General at nmd@mpi.govt.nz to include a sample taker on one of these lists.

Part 3: NMD Red Meat Programme

3.1 Interpretation

(1) In this Part, unless the context otherwise requires:

bobby calf means an unweaned bovine calf that is less than 45 kilograms in weight as a dressed carcass (note: for NMD purposes, bobby calf is considered a species)

bovine means a head of cattle not including a bobby calf

BPW means buffered peptone water

bulk meat means a piece of red meat that is packed by the operator into a carton in which there are 2 or more pieces of meat and they are not individually wrapped

caprine means a goat

cervine means a deer

dsBPW means double strength buffered peptone water

initial item means the first carcass, primal cut, or carton of bulk meat to be sampled

initiation of analysis means:

a) in relation to APC and generic *E. coli* analysis, from the time the sample is suspended and ready for dilution; and
b) in relation to *Salmonella* analysis, from the time the BPW suspension is placed in the incubator

missed sample means a failure by the operator to collect samples as required under this notice

ovine means a sheep or a lamb

porcine means a pig

primal cut means a main muscle from a red meat carcass

product type means a:

a) carcass; or
b) primal cut; or
c) bulk meat product

PSW means a primary sampling window of 16 consecutive clear composite samples in relation to the *Salmonella* sampling programme (clause 3.2.3)

ratite means an ostrich or an emu

run means a period of processing of up to 2 hours within a processing shift

season means an annual period beginning the first Monday in October and ending the Sunday before the first Monday in October of the following year

ssBPW means single strength buffered peptone water

standard throughput premises means premises at which, at the beginning of a season, it can reasonably be expected:

a) in relation to bovine, caprine, cervine, ovine, or porcine species an operator will process 10,000 or more animals of that species in the season; or
b) in relation to bobby calf, an operator will process 10,000 or more animals in a calendar year; or
c) in relation to ratites, premises at which an operator processes 1 or more animals of that species in the season

SW means sampling window of 6 consecutive clear processing weeks in relation to the *Salmonella* sampling programme (clause 3.2.3)

VL means visual lean, which is the observed fat content of the red meat

very low throughput (VLT) premises means premises at which, at the beginning of a season, it can reasonably be expected:

a) in relation to bovine, caprine, cervine, ovine, or porcine species, an operator will process fewer than 10,000 animals of that species in the season; or
b) in relation to bobby calf, an operator will process fewer than 10,000 animals in the calendar year.

3.2 NMD red meat sampling and testing requirements

3.2.1 Tests required

(1) An operator must ensure the NMD required tests listed are completed for each product type to be sampled for each species listed below:

Species	Product type to be sampled	NMD required tests
Bovine Caprine	Carcass, primal cut, and bulk meat	APC and generic *E. coli* A *Salmonella* composite of each product type sampled during a PSW, or SW
Cervine	Carcass, and primal cut	APC and generic *E.coli*
Porcine	Carcass	APC and generic *E. coli*
Bobby calf	Carcass, primal cut, and bulk meat	APC and generic *E. coli* A *Salmonella* composite of each product type sampled during a SW
Ovine	Carcass	APC
Ratite	Carcass	APC and generic *E. coli* A *Salmonella* composite of carcasses sampled each week for PSW, or SW

3.2.2 Number and frequency of samples required

(1) An operator of a standard throughput premises must ensure that the number of each product type are taken for sampling at the stated frequency for each species listed below:

Standard Throughput Premises		
Species	Product type	Number of product type to be sampled and frequency of sample taking
Bobby calf, bovine, caprine, ovine, porcine, ratite	Carcass*	5 on 1 processing day in each processing week
Cervine	Carcass*	3 on 1 processing day in each processing week
Bobby calf, bovine, caprine	Primal cuts	5 on 1 processing day in each processing week
Cervine	Primal cuts	2 on 1 processing day in each processing week
Bobby calf, bovine, caprine	Bulk meat product	5 on 1 processing day in each processing week
Bobby calf, bovine, caprine	Post-chill carcass* (EU and US listed premises)	5 per week for the first 6 weeks of each season
* NOTE: For most species that require carcass sampling, several sites must be sampled. See clause 3.9 for specific requirements.		

(2) An operator of a VLT premises must ensure that the number of each product type are taken for sampling at the stated frequency for each species listed below:

VLT Premises		
Species	Product type	Number of product type to be sampled and frequency of sample taking
Bobby calf, bovine, caprine, ovine, porcine, ratite	Carcass*	5 on 1 processing day in each processing month
Cervine	Carcass*	3 on 1 processing day in each processing month
Bobby calf, bovine, caprine	Primal cuts	5 on 1 processing day in each processing month
Cervine	Primal cuts	2 on 1 processing day in each processing month
Bobby calf, bovine, caprine	Bulk meat product	5 on 1 processing day in each processing month
Bobby calf, bovine, caprine	Post-chill carcass* (EU and US listed premises)	5 per month for the first 6 months of each season
* NOTE: For most species that require carcass sampling, several sites must be sampled. See clause 3.9 for specific requirements.		

3.2.3 *Salmonella* sampling programme

3.2.3.1 Initial Salmonella sampling programme for bovine, caprine, and ratite

(1) All operators who process bovine, caprine, or ratite must undertake *Salmonella* sampling when first commencing slaughter and dressing of each species until such time as there are 16 consecutive clear composite samples (as per clause 3.17.2) for each product type (PSW).

> Guidance
> - This would apply when an RMP is first registered for a new premises or when a significant amendment to an existing RMP is made to include slaughter and dressing of an additional species to which *Salmonella* sampling applies.

3.2.3.2 Seasonal Salmonella sampling programme for bovine, caprine, and ratite

(1) After achieving 16 clear consecutive samples under clause 1, in each season every standard throughput premises operator who processes bovine, caprine, or ratite must conduct *Salmonella* sampling until there are 6 consecutive clear samples (as per clause 3.17.2) for each product type (SW).

(2) Once 16 clear composite samples are obtained, VLT operators may stop sampling and testing.

(3) VLT operators who have completed a PSW will be notified by the Director-General if they must continue *Salmonella* sampling and testing.

> Guidance
> - An operator would initially complete a PSW and, generally, in the next and subsequent seasons an SW. If the PSW is completed over 2 seasons (e.g. the premises begins operating near the end of a season), a minimum of 6 weeks of sampling must be carried out in the second season. This may mean sampling for longer than 16 weeks initially.

3.2.3.3 Salmonella sampling programme for bobby calves

(1) In each year every operator who processes bobby calves must conduct *Salmonella* sampling until there are 6 consecutive clear composite samples (as per clause 3.17.2) for each product type (SW).

3.3 Sampling

3.3.1 Carcasses

(1) The operator must ensure that:

a) samples are taken no later than 30 minutes after post-mortem examination of carcasses; and
b) carcasses are sampled before any procedure that may impact on the NMD sampling sites is undertaken; and
c) samples are not taken from carcasses detained by post-mortem examiners; and
d) carcass descriptors as per clause 3.11 are recorded at time of sampling directly into the NMD database or on the sample submission form.

> Guidance
> - Procedures that may impact on sampling sites include ones that redistribute contaminants (such as carcass contact), or add contaminants (such as handling by workers), or remove contaminants (such as carcass washing or gross hot trimming).

3.3.2 Primal cuts

(1) The operator must ensure that:

a) only fresh boned primal cut product is sampled; and
b) samples are taken from a fell (outside) surface of the primal cuts; and
c) the primal cut selected corresponds to the equivalent hindquarter NMD carcass sampling site as per clause 3.9 for the species concerned, with the exception of cervine primal cuts where both hindquarter and forequarter primal cuts can be selected, and
d) samples are taken immediately prior to vacuum packaging, wrapping, or packing into cartons; and
e) primal cut descriptors as per clause 3.11 are recorded at time of sampling directly into the NMD database or on the sample submission form.

3.3.3 Bulk meat product

(1) The operator must ensure that:

a) only fresh boned bulk meat product is sampled; and
b) if a premises produces product in the 85-95 VL range, samples are taken from product in this range; and
c) if a premises does not produce product in the 85-95 VL range, samples are taken from product in the 65-85VL range; and
d) samples are taken immediately prior to closing and strapping the carton before chilling or freezing; and
e) bulk meat product descriptors as per clause 3.11 are recorded at time of sampling directly into the NMD database or on the sample submission form.

3.4 Sample selection

3.4.1 Sample selection plan

(1) The operator must ensure that:

a) a plan covering the sample selection requirements in this clause is in place for each species processed; and
b) sampling is be conducted according to the plan and the requirements of this notice.

(2) Sample selection must be random/rotational as per the provisions of this clause to include all of the following:

a) processing day for standard throughput premises (as per clause 3.4.3) or processing week for VLT premises (as per clause 3.4.2);
b) shift;
c) class;
d) run;
e) time;
f) chain/boning room.

(3) All records relating to sample selection criteria must be kept for 4 years.

Guidance

- If multiple species are processed at a premises, a single selected time period to sample all species may be used (same day, shift and run for all species) if you have enough sample takers and laboratory personnel to process the samples. Alternatively, a different day of the week or time in the day may be randomly selected for the other species from the remaining days or part days of that week.

3.4.2 Selection of sampling week in the month for VLT

(1) VLT operators must estimate the number of weeks in which processing will take place that month and randomly select from the available weeks.

(2) If there is significant uncertainty as to when product will be sent for processing, the VLT operator must select the first available processing week of that month for sampling.

3.4.3 Random/rotational selection of day of week

(1) The operator must ensure that:

a) all processing or part processing days in the week are eligible for selection when each particular species is being processed; and
b) one day is randomly selected for sampling, and then the remaining days are selected in random order until all days of the processing week have been selected; and
c) once all days have been selected, the selection process starts again with all processing days eligible.

Guidance

- For example, if a premises processes Monday - Friday, an initial random selection of 1 of the 5 days is completed, e.g. Wednesday. The next week the random selection will exclude Wednesday and 1 of the 4 remaining days will be selected, and so on. After 5 weeks all processing days will have been selected.

3.4.4 Rotational sampling of operating shifts, chains, and boning rooms

(1) The operator must ensure that rotational sampling of the following occurs:

a) all shifts; and
b) all slaughter chains; and
c) all boning rooms.

Guidance

- If personnel rotate onto various shifts as a group, this needs to be taken into account in rotational sampling. For example, if there is a red shift and a blue shift, then red shift would need to be sampled both day and night and blue shift would need to be sampled both day and night.

3.4.5 Rotational selection of class

(1) The operator must ensure that rotational sampling of class occurs as described below:

a) ovine – 2 classes with no rotation: Lamb must be sampled each processing week, except on processing weeks where only sheep are being processed, in which case sheep must be sampled; and
b) ratite – 2 classes: ostrich and emu; and
c) cervine – 2 classes: fallow and 'other' (e.g. wapiti, red, hybrid and sika); and
d) bovine – 3 classes: bull, cow, prime; and
e) porcine – 4 classes: sucklers, porkers, baconers, choppers (due to the relatively infrequent processing of choppers, these must be targeted for sampling when processing occurs to ensure coverage of all classes processed within the month).

(2) The operator must not use the proportion of livestock classes in any species processed to deliberately bias the selection of class for that species.

(3) VLT operators must rotate through classes each month rather than weekly.

Guidance

- The rotational selection of processing day and shift during the processing week and random selection of run and time will permit a cross-section of classes to be sampled during each quarter. The exception to this is porcine choppers, which are selected during 1 processing week each month to ensure coverage.

3.4.6 Random selection of run

(1) The run chosen for sampling must be randomly selected from all runs available that processing day.

3.4.7 Random selection of time

(1) The operator must ensure that the time for sampling the initial item is randomly selected.

(2) If there is an ongoing practical constraint, such as a period of time when no courier services are available for transport, the operator may apply to the Director-General for an exemption to exclude that time period from random sampling.

(3) Random selection must be made by selecting one of the following:

a) a time during the run; or
b) a carcass ticket number from the run; or
c) a processing segment of the run no greater than 20 minutes.

(4) The actual sampling time must not vary by more than 10 minutes either side of the originally selected time or, if a processing segment is selected, the actual sampling must be done within that segment.

(5) The actual sampling time must be recorded in a format that can be converted to 24-hour clock units for submission to NMD.

Guidance

- The time may be chosen by the 24-hour clock system or minutes into the run with a sampling tolerance of 10 minutes either side. For example, 15:33±10 minutes, the sampling period is between 15:23 and 15:43.

  Example of random/rotational selection of day, random selection of run and time for a week with 5 processing days. Random/rotational selection begins again at week 6.

Week Number	1	2	3	4	5	6	
Day	Wednesday	Friday	Monday	Thursday	Tuesday	Tuesday	
Run	4	3	1	4	2	2	
Time (using ticket number)	*4045*	*3125*	*0215*	*3701*	*2245*	*1523*	
Time (24 hour clock)	15:33	13:01	08:22	14:45	11:55	10:37	
Time (minutes into run)	15	78	61	23	42	36	

3.4.7.1 Selection of sample

(1) The initial item must be randomly selected.

(2) The remaining items are selected at time intervals equivalent to the time required to sample.

(3) If the carcass, primal cut or carton of bulk meat available at that time is unsuitable (e.g. carcass goes on to detain rail), then select the next available appropriate carcass, primal cut or carton.

(4) Selecting the required number of carcasses, primal cuts or cartons of bulk meat at once from the process and putting them aside to sample at the same time is only acceptable if there is insufficient product type remaining.

3.4.8 Departure from the original sample selection

(1) The operator must ensure that any changes in the original sample selection are:

a) noted in their own records with the reason for the change; and
b) reported to the laboratory in the relevant processing week and no later than the day the change occurs.

(2) If insufficient product is available to be sampled at the selected sampling time, the operator must ensure that the required samples are collected from available product in that processing week in the following order of priority:

a) incomplete cartons;
b) from the next run within the shift;
c) multiple product types: bulk 95VL, 65VL, 80VL within a class;
d) different classes;
e) across both shifts within a processing day;
f) from the next day within the processing week.

(3) If the required samples are not collected, this will be considered a "missed" sample.

3.4.9 Collecting additional samples

(1) The operator may take additional samples routinely to allow for practical constraints and potential technical failures.

(2) If additional samples are taken, the operator must ensure that:

a) the original NMD selection and the additional sample(s) are identified; and
b) the results are entered in the NMD database in the following order:
c) the original NMD samples; and
d) the additional sample(s), if necessary, to give the required total of results over 1 processing week.

3.5 Sampling equipment

(1) The operator must ensure that the sample taker has appropriate sampling equipment as follows:

a) general sampling equipment:
b) a means to record sampling details; and
c) a method to label vials; and
d) spare sterile templates, vials, swabs and gloves; and
e) insulated containers with ice packs (slicker pads or bags of shaved ice); and
f) ladders or step-stools for access to sampling sites if necessary; and
g) alcohol or wipes if required for sterilising templates; and
h) swabbed site sampling equipment:
i) templates as specified in clause 3.6; and
j) sterile vials containing 4 - 9 glass beads with or without diluent; and
k) volume required (either included at time of sampling or later at time of testing; and
l) sterile cotton-tipped swabs; and
m) for composite *Salmonella* sampling of carcasses, swabs wetted in ssBPW.

3.6 Templates for swab sampling

3.6.1 Use of templates required

(1) The operator must ensure that templates to delineate the site to be swabbed are used for sampling as per all provisions in this clause.

3.6.2 Template materials

(1) Templates must be made of one of the following inert materials capable of delineating the correct sized sample area:

a) stainless steel rod (made into circular or square hoops with handle that can be hooked over a finger); or
b) flexible material (plastic or cardboard); or
c) flat, rigid sheet metal for 5 cm^2 or 25 cm^2 templates.

(2) The template must conform to the area measurements for the area to be sampled for each species listed below:

Species		Ovine, caprine	Bobby calf, cervine, ratite, and porcine	Bovine
Area to be sampled		5cm^2	25cm^2	100cm^2
Area measurements	Circular – diameter	25.2mm	56.4mm	112.8mm
	Square – side	22.4mm x 22.4mm	50.0mm x 50.0mm	100.0mm x 100.0mm

(3) The operator must ensure that the laboratory calibrates dimensions of all templates used for sampling at least once every 6 months and records results in their equipment records.

3.6.3 Sterile templates

(1) Templates must be sterile when used for sampling.

(2) Sterilisation can be achieved by using:

a) pre-sterilised (autoclaved) multiple templates; or
b) ethanol/iso-propanol based disinfectant wipes; or
c) 70% ethanol for flame sterilisation.

3.6.4 Sterile cotton-tipped swabs

(1) Swabs must be sterile when used for sampling.

(2) Sterilisation can be achieved by:

a) autoclaving; or
b) purchasing pre-sterilised swabs.

(3) If commercial swabs supplied in individual plastic tubes are used and the swabs are returned to those tubes after sampling, the laboratory must ensure that the suspension buffer required for each site sampled is used to rinse out the inside of all the tubes of swabs associated with that site to remove any bacteria that may have been smeared onto the inner walls by the swabs during sampling and transport.

3.7 Diluents

(1) The operator must ensure that diluents are prepared and used as per all provisions in this clause.

(2) Sterile diluents must be correctly prepared as below, labelled, and provided to sample takers.

(3) Sterile diluents used for sampling and testing must not be cloudy, loose lidded, odorous, or have passed their expiry dates.

(4) The sample taker must use the appropriate diluent according to whether antibacterial agents, such as chlorinated compounds, were applied to the product prior to sampling or not.

3.7.1 Peptone diluent

(1) Peptone diluent, which is used for moistening of swabs for collection of carcass and primal cut swabs and generic *E. coli* samples, must be prepared with the following composition and sterilised:

0.1% Peptone Diluent	Amount
Peptone	1.0g
Sodium chloride (NaCl)	8.5g
Distilled water	1000ml

3.7.1.1 Single strength buffered peptone water (ssBPW)

(1) ssBPW, which is used for moistening swabs for collection of carcass samples solely for *Salmonella* testing and for moistening swabs for collection of primal cut samples for APC, generic *E. coli* and *Salmonella* testing, must be prepared with the following composition and sterilised:

ssBPW Diluent	Amount
Peptone	10.0g
Sodium chloride (NaCl)	5.0g
Disodium phosphate (Na_2HPO_4)	3.5g
Potassium phosphate (KH_2PO_4)	1.5g
Distilled water	1000ml
Final pH 7.2±0.2 at 25ºC	

3.7.1.2 Double strength buffered peptone water (dsBPW)

(1) dsBPW, which is used for composite *Salmonella* primal cut swabs and bulk meat samples, must be prepared with the following composition and sterilised:

dsBPW Diluent	Amount
Peptone	20.0g
Sodium chloride (NaCl)	10.0g
Disodium phosphate (Na_2HPO_4)	7.0g
Potassium phosphate (KH_2PO_4)	3.0g
Distilled water	1000ml
Final pH 7.2±0.2 at 25ºC	

3.7.1.3 Antibacterial agents

(1) The operator must inform the laboratory if antibacterial agents, such as chlorinated compounds, are used during processing so that the laboratory can prepare the appropriate diluent.

(2) If antibacterial agents are used, the laboratory must:

a) determine suitable non-antimicrobial neutralising additives; and
b) add them to the diluent; and
c) label the mixture accordingly.

Guidance

- For example, if a chlorinated compound, such as acidified sodium chlorite (ASC) has been applied prior to sampling, the laboratory must ensure that a peptone diluent with the addition of 1.0ml of a 3% sodium thiosulphate ($Na_2S_2O_3$) solution to 1 litre of diluent is used for sampling.

3.8 Sample collection

(1) The operator must ensure that the following template sizes, swabs, and diluents are used for APC and generic *E. coli* sampling for the species listed below:

Species	Ovine, caprine	Bobby calf, cervine, porcine, and ratite	Bovine
Template size	5cm^2	25cm^2	100cm^2
Number of swabs per carcass site or primal cut site	2 swabs: 1 wet,1 dry	4 swabs: 2 wet, 2 dry	6 swabs: 3 wet, 3 dry
Volume of peptone diluent	10ml	15ml	15ml

(2) For *Salmonella* sampling for carcasses, the operator must ensure a separate set of sites is swabbed from the opposite side of the carcass from APC/generic *E. coli* samples.

Guidance

- A separate set of primal cut swabs is not required for *Salmonella*. The laboratory will use remaining sample diluent after APC/generic *E. coli* analysis.

(3) The following template sizes, swabs (which may be placed into single volume vials or composited into a single bottle), and diluents must be used for *Salmonella* sampling the species listed below:

Species	Bovine	Bobby calf	Caprine	Ratite
5 carcass composite	3 sites per carcass	3 sites per carcass	3 sites per carcass	1 site per carcass
Template (1 per site)	100cm^2	25cm^2	5cm^2	25cm^2
Total number of swabs	6 swabs x 3 sites x 5 carcasses = 90 swabs	4 swabs x 3 sites x 5 carcasses = 60 swabs	2 swabs x 3 sites x 5 carcasses= 30 swabs	4 swabs x 1 site x 5 carcasses = 20 swabs
ssBPW diluent sample volume	250ml	150ml	75ml	75 ml
Scott bottle size	500ml	250ml	250ml	250ml

3.9 Carcass sample sites

(1) The operator must ensure that carcasses are sampled as per all the provisions of this clause.

3.9.1 Bovine

(1) The following 3 sites must be swabbed on bovine:

a) Rump: The site is centred on the fascia overlying the semitendinosis muscle (the 'eye round'). The centre of the sampling site is halfway along the muscle on its superficial lateral margin. Lateral to semimembranosis is the gluteobiceps muscle (the 'outside flat') and the 100cm^2 template may overlap both muscles; and

b) Flank: The site is centred on the fascia overlying the cutaneous trunci muscle. The centre of the site is 10cm lateral to the umbilicus on a line drawn along the ninth rib from the spine and continued on to cut edge of the abdominal wall; and

c) Brisket: The site is centred 10cm off the central midline. The lower edge of the sampling site is an imaginary line drawn transversely along the thoracic wall at the level of the point of the elbow. The margins of the sampling site may overlap onto the fascia overlying the caudal margin of the pectoral profundis muscle.

3.9.2 Ovine

(1) The following carcass site must be swabbed on ovine:

a) Forequarter opening Y-cut: The Y-cut site is centred on the anterior aspect of the humero-radial (elbow) joint close to the brachial vein, which is clearly visible at the site (a little erratic in its course).

3.9.3 Caprine

(1) The following 3 carcass sites must be swabbed on caprine:

a) Outside hindleg: The outside hindleg site is centred one third up on a vertical line originating at the midpoint of a line between the ischial crest and stifle, and extending to a line horizontal to the cut end of the hock; and

b) Flap: The flap site is centred ~50mm from the flap edge, midway between the flap joint and the xiphoid cartilage; and

c) Forequarter opening Y-cut: The Y-cut site is centred on the anterior aspect of the humero-radial (elbow) joint close to the brachial vein, which is clearly visible at the site (a little erratic in its course).

3.9.4 Bobby calf

(1) The following 3 carcass sites must be swabbed on bobby calves:

a) Fore rump: Centred on a horizontal line dissecting the forward (lower) edge of the rectal canal, in line with a cut tail, and no greater than 50mm horizontally from the edge of the rectal canal; and

b) Flank: The site is centred ~50mmm from the flank edge, midway between the flank joint and the xyphoid cartilage; and

c) Foreleg: Centred on the outside surface of the foreleg, on the lateral head of the triceps brachii.

(2) The side (left or right of the animal) of the carcass that APC/generic *E. coli* swabs are collected from must be recorded.

3.9.5 Cervine

3.9.5.1 Cervine – traditional dressing

(1) The following 3 carcass sites must be swabbed on traditionally dressed cervine:

a) Posterior hindleg: The hindleg sample site is centred longitudinally and laterally on an imaginary line drawn between the posterior aspect of the aitch bone and the Achilles tendon; and
b) Sternum: The sternum site is centred immediately adjacent to the intersect of the abdominal cavity opening and brisket, but outside the area of "standard brisket trim" (by <10mm at its closest edge). Note: Tissue exposed by the standard trim must not be sampled; and
c) Foreleg: The foreleg site is centred on the anterior (forward) aspect of the humero-radial (elbow) joint close to the brachial vein, which is clearly visible at the site (a little erratic in its course).

3.9.5.2 Cervine – inverted dressing

(1) The following 3 sites must be swabbed on inverted dressed cervine:

a) Inside hindleg: The sample site is centred on the medial proximal of the hindleg immediately adjacent to the pelvic symphysis (midline); and
b) Brisket: The brisket sample site is centred longitudinally on the brisket, immediately outside the area of "standard brisket trim" (by <10mm at its closest edge). Note: Tissue exposed by the standard trim must not be sampled; and
c) Foreleg: The foreleg site is centred on the anterior (forward) aspect of the humero-radial (elbow) joint close to the brachial vein, which is clearly visible at the site (a little erratic in its course).

3.9.6 Porcine

(1) The following 3 carcass sites must be swabbed on porcine:

a) Outside hindleg: Is centred midway between the stifle and hip joint; and
b) Lower flap: Is centred midway between the 2 lower nipples, 50mm from the abdominal incision; and
c) Outside shoulder: Is centred above the anterior (forward) top end of the shoulder blade.

3.9.7 Ratite (leg hung)

(1) The following carcass site must be swabbed on ratite:

a) Inside leg: Is centred longitudinally on the opening cut line and laterally where the edge of the remaining flap contacts the leg. It is recommended that this site be alternated between left and right legs.

3.10 Sampling method

(1) The operator must ensure that samples are taken as per all provisions of this clause.

3.10.1 Wet/dry swabbing technique

(1) Wet swab sampling must be done by:

a) placing the template in the correct position and ensuring the template does not move; and
b) moistening swabs for 5 seconds in the diluent; and
c) rubbing the wet cotton portion of the swabs vertically, horizontally and diagonally across the entire surface bounded by the template, using as much force as possible without breaking the shaft of the swab; and
d) rotating the swabs to ensure the entire bud is in contact with the surface for:
e) 10 seconds swabbing time for ovine, caprine 5cm^2 templates; and
f) 20 seconds swabbing time for bobby calf, cervine, porcine, and ratite 25cm^2 templates and bovine 100cm^2 templates.

(2) Dry swab sampling must be done immediately after wet swabbing in the same manner as described in (1) c) - d) by rubbing the same area with dry swab/s until the area being sampled is dry.

(3) Once wet/dry swabbing is completed:

a) insert all swabs together into a transport vial, which may or may not contain the diluent; and
b) place the sample in an insulated container, avoiding direct contact with the ice pack.

(4) If any contamination event occurs during sampling, the sample must be discarded and a new sample taken from a new item.

Guidance

- If 1 of the 3 carcass site samples is contaminated, all 3 samples must be replaced so that they are all from the same carcass.

3.10.2 Whole tissue composite sampling technique for bulk meat

(1) Whole tissue composite sampling must be conducted aseptically and according to the following procedures:

a) collect 5 whole tissue samples by trimming a thin layer from the surface; and
b) ensure each sample is approximately 10 grams in weight to result in at least 50 grams collected per carton; and
c) collect samples from the 4 diametrically opposite corners of the carton and one from the centre of the carton; and
d) deposit each of the 5 samples per carton into a sterile sample bag; and
e) seal the sample bag.

(2) Collect samples from an original external carcass surface if possible. If not available, then a cut surface may be sampled.

(3) If any contamination event occurs during sampling, the sample must be discarded and a new sample taken.

Guidance

- A new sample should be taken either from the same piece of meat, provided there is sufficient external surface available, or from a different piece of meat from within the same quadrant from the same carton. If this cannot be achieved, all samples from that carton should be discarded and a new carton should be selected and a full set of samples collected from the new carton.

3.11 Sample description information

(1) The operator must ensure that the following sample description information is recorded directly into the NMD database prior to transport of the sample to the laboratory or, by prior arrangement with the laboratory, recorded on a sample submission form and sent to the laboratory with the samples:

a) sample taker's name; and
b) premises from which samples were taken; and
c) sampling date; and
d) time (24 hour clock) that sampling began, which is the time of sampling of the first item in the sample set; and
e) run, shift, species, and class; and
f) for primal cuts and bulk meat product, descriptors of the boning process (cold, warm, hot).

3.12 Storing and transporting samples

(1) The operator must ensure that samples are stored and transported as follows:

(2) Samples awaiting transport to the laboratory must be stored in a refrigerator operating in the calibrated temperature range of 0°C to 5°C.

(3) Hot/warm boned whole tissue samples must be rapidly cooled to <5°C but not frozen.

Guidance

- Premises may choose to have samples transported to an on-site laboratory for some analyses and off-site for others according to schedules, laboratory scope of testing and other factors.

3.13 Laboratory functions

3.13.1 Receipt of samples

(1) The laboratory must ensure that the NMD testing of samples is initiated within 30 hours after collection of the first sample of the 5 sample set.

(2) The laboratory must deem a sample is unsuitable for NMD testing, reject that sample, and seek replacement samples in that processing week from the operator if:

a) samples arrive too late for testing to commence within 30 hours of time the first sample of the set of 5 was taken; or
b) samples are received frozen; or
c) samples received exceed 10°C; or
d) samples were not taken by a currently listed sample taker.

3.13.2 Entry to NMD and records

(1) The laboratory must enter the sample descriptors under clause 3.11 supplied by the sample taker on the sample submission form into the NMD database if not already entered by the sample taker.

(2) The laboratory must record the following sample receipt details:

a) confirmation sample taker is currently listed; and
b) sample temperature; and
c) time from sampling to initiation of analysis; and
d) confirmation that sample is suitable for testing.

3.13.3 Preparing dilutions and dilutions required

(1) The swab suspension (swab immersed in the initial volume of 10ml or 15ml diluent) is an undiluted sample referred to as the zero dilution, and must be entered into the calculations as the 10^0 dilution.

(2) The laboratory must ensure that:

a) the volume of diluent used is sufficient to enable inoculation of duplicate agar plate count plates, half plates or Petrifilm™, and if applicable, sufficient volume remaining for the composite *Salmonella* pre-enrichment broth; and
b) the bacteria are evenly distributed within the diluent, such as by shaking the sample.

(3) To avoid having a "too numerous to count" (TNTC) result, the laboratory must ensure that sufficient dilutions are undertaken to obtain plate counts below the maximum allowable counts on at least 1, or 1 set of, plates as follows:

Analyses	Red meat
APC^{30}	10^0 to 10^{-4} plus higher dilutions if required
Generic *E. coli*	10^0 to 10^{-3} plus higher dilutions if required

3.13.4 Allowable counts

(1) The laboratory must ensure that only plates with colonies that fall in the acceptable counting range as specified below are counted:

Plate dilution	Spreadplate APC	Spreadplate APC ½ plate	Petrifilm™ APC	Petrifilm™ *E. coli*
10^0	1-300	1-150	1-250	1-150
All other dilutions	30-300	15-150	25-250	15-150

3.13.5 High end dilutions and TNTC results

(1) If a count exceeds the maximum allowable count, as specified in subclause 3.13.4 (1), on the highest dilution, TNTC must be recorded.

(2) The test does not need to be repeated for the sample with a TNTC result.

(3) If a TNTC result occurs, the laboratory must extend the dilution series to ensure results are within the acceptable counting range for subsequent samples.

3.13.6 Low end dilutions

(1) Plates or Petrifilm™ plates that contain less than the lowest acceptable counting range for the 10^0 sample as per subclause 3.13.4 (1) must be counted and reported.

3.13.7 Duplicate plating/analytical precision

(1) Duplicate plating must be done for all dilutions for APC[30] and generic *E. coli* to give statistical confidence to the results obtained. Use the Analytical Precision calculation (for each operator) in chapter 5 Appendix 1.7 of the Meat Industry Microbiological Methods (MIMM) to determine a Z score which is then compared to a limit of 1.96.

(2) If a laboratory demonstrates that it meets the Analytical Precision criteria outlined in MIMM, it may use singlet plating for all dilutions other than the 10^0 dilution sample.

(3) Records of the duplicate plate count precision analysis must be kept.

3.14 Sample preparation

3.14.1 Preparing swabs for APC and generic *E. coli* testing

(1) The laboratory must ensure that:

a) if the swab samples arrive in in vials without beads, 4-9 beads are added to each vial; and
b) if the swab samples arrive in vials with no diluent, the correct volume of diluent is added as follows:
c) for bovine, bobby calf, cervine, porcine, and ratite: 15ml of 0.1% peptone diluent; and
d) for ovine and caprine: 10ml of 0.1% peptone diluent; and
e) the vial is closed and shaken vigorously to loosen the cotton bud of the swab for 2 minutes by either:
f) shaking by hand; or
g) using a combination of initial shaking by hand and a vortex mixer in 3 x 10 second bursts; and
h) the cotton swabs are not removed from the vials at any stage prior to the completion of plating.

3.14.2 Preparing bulk meat (whole tissue) samples for APC and generic *E. coli* testing

(1) The laboratory must ensure that:

a) the whole tissue samples (5 x ~10g) are placed on a sterile chopping board and finely sliced aseptically; and
b) 25g of sliced tissue is aseptically weighed directly into a sample bag; and
c) 225ml of sterile diluent (0.1% peptone + 0.85% NaCl) is added to the bag; and
d) the bag is stomached for 2 minutes.

3.15 Aerobic plate count (APC) test methods

(1) The laboratory must ensure that 1 of the following 3 permitted methods of testing is used:

a) APC[30] by spreadplate (CLT 2.1.2); or
b) APC Petrifilm™ Aerobic Plate Count (CLT 2.1.3); or
c) APC[30] spiral plater (CLT 2.1.4).

(2) The laboratory must ensure that all quality control procedures for the media and methods are carried out using *Pseudomonas aeruginosa* NZRM 981 or *Lactobacillus viridescens* NZRM 3313 as the positive control.

3.15.1 Preparing plate count agar plates

(1) All plate count agar plates must be dried before use by one of the following methods:

a) incubation for 24h at 30-37°C, inverted with lids in place; or
b) inverting with lids ajar in a laminar flow cabinet for 20-30 minutes; or
c) inverting with lids ajar in a still air incubator at 30-37°C for 1½ to 2 hours; or
d) inverting with lids ajar in a forced air incubator at 30-37°C for 30 minutes.

3.15.2 Initiation of analysis

(1) Initiation of analysis for APC is defined as the time when the sample is suspended and ready for serial dilution.

3.15.3 Incubation

(1) The required incubation temperature for the APC is 30°C ± 1°C (ISO 17604:2003).

(2) The required incubation time is 48 hours (h).

(3) If colonies are indeterminate at 48h, estimate a count, re-incubate for a further 18-24h and recount.

(4) If plates cannot be counted at 48h, plates may be:

a) incubated for up to 72h in total; and
b) removed from the incubator and stored for no longer than 48h in a refrigerator at 0°C to 5°C.

(5) The total incubation time must be recorded on the result sheet.

(6) Any additional storage time of the plates following incubation must be recorded on the result sheet.

3.15.4 APC[30] by spread plate method

(1) The following is the APC[30] by spread plate method:

a) dispense 0.1ml (100µl) volumes of each dilution onto 2 count agar plates, or a single ½ plate; and
b) mix the dilutions thoroughly and start plating with the highest dilution; and
c) spread the inoculum over the surface of the agar as evenly and as quickly as possible using a sterile spreader; and
d) allow the inoculum to soak into the agar surface (should occur within15 minutes); and
e) invert the plates so that the agar is on the top and incubate.

Guidance

- The same pipette/tip may be used for all inoculations when plating from the highest to lowest dilution for APC spread plates.
- If liquid does not soak in (i.e. the plates were not dried sufficiently), the viable bacteria present in the inoculum may start to replicate and spread, possibly resulting in an inaccurate count.
- Inversion prevents condensation dropping onto the surface of the agar, reducing contamination and preventing the spread of motile micro-organisms.

3.15.5 APC Petrifilm™ Aerobic Count Plate method

(1) The following is the APC Petrifilm™ Aerobic Count Plate method:

a) process each Petrifilm™ plate individually; and
b) place the Petrifilm™ Aerobic Count plate onto a flat surface, label and lift the top film; and
c) dispense 1ml of each dilution onto the agar; and
d) slowly roll the top clear plastic film down onto the inoculum to prevent entrapment of air bubbles; and
e) distribute the sample evenly using the spreader provided (ridge side down as the plates do not have a foam dam), by applying gentle even pressure; and
f) move the completed Petrifilm™ plate to one side and leave for 1 minute for the agar to set; and
g) incubate all Petrifilm™ plates clear side up in stacks of no more than 20.

3.15.6 APC[30]: Spiral plater method

(1) Plates must be prepared according to the manufacturer's guidelines supplied with the spiral plater.

(2) The plate surface must be smooth.

(3) The following is the spiral plater method:

a) follow all manufacturer's instructions for use; and
b) after inoculation, leave the plates on the bench right-way-up for 10 minutes to allow the inoculum to soak into the agar; and
c) invert the plates and incubate.

3.15.7 APC results

(1) Count only plates within the acceptable counting range defined in clause 3.13.4.

(2) Record the result as the number of colony forming units (CFU)/cm^2 or /g of sample.

(3) If there are no colonies present on both of the duplicate 10^0 dilution plates, record the result as "not detected".

3.16 *Escherichia coli* Petrifilm™ test method

(1) The laboratory must use the *E. coli* Petrifilm™ method, which is the only method approved for the NMD red meat programme CLT 2.2.2.

(2) Carry out all quality control procedures for the media and methods using *Escherichia coli* NZRM 916 as the positive control and *Klebsiella pneumoniae* NZRM 482 or *Enterobacter aerogenes* NZRM 798, as the negative control.

3.16.1 Initiation of analysis

(1) Initiation of analysis is defined as when the sample has been suspended and is ready for serial dilution.

3.16.2 Method

(1) Place a Petrifilm™ *E. coli* plate on a flat surface and hold the plate flat.

(2) Mix the dilutions thoroughly before dispensing.

(3) Lift the top film and dispense 1ml of each dilution into the agar.

> Guidance
> - Do not inoculate several at the same time. It is imperative to inoculate and lower the top film before proceeding to the next.

(4) Slowly roll the top clear plastic film down on to the inoculum to prevent entrapment of air bubbles.

(5) If necessary use the spreader provided flat side down, as Petrifilm™ *E. coli* plates have a rim around the well to distribute the sample evenly by applying gentle even pressure to the spreader.

(6) Move the completed Petrifilm to one side and leave for 1 minute for the agar to set.

(7) Incubate all plates for 18-24h at 35 ± 1°C or 37 ± 1°C clear side up and in stacks of no more than 20.

(8) If plates cannot be counted at 24h, the plates may be removed from the incubator and stored for no longer the 72h in a refrigerator at 0° - 5°C, or freezer. Record the storage time and temperature on the result sheet.

(9) If colonies are indeterminate at 24h, count as best as possible, re-incubate for a further 18-24h and recount. Record the total incubation time on the result sheet.

(10) Count as generic *E. coli* all blue colonies with or without gas bubbles.

(11) Count only plates with between 15 to 150 colonies for Petrifilm™ *E. coli* plates. Do not count colonies that have grown on the foam dam.

(12) High numbers of generic *E. coli* will turn the medium blue and high numbers of Enterobacteriaceae will turn the medium red. Both situations make accurate enumeration impossible. Should this occur for the highest dilution plated, record results as TNTC and immediately notify the operator.

3.16.3 Generic *E. coli* results

(1) Express the results as the number of generic *E. coli* CFU/cm^2 or /g or /ml of sample.

(2) If blue colonies with or without gas are not detected, record the results as “not detected”.

3.17 *Salmonella* test method

(1) The laboratory must ensure that the following method for CLT 2.4.3 is used for *Salmonella* detection.

(2) All quality control procedures for the media and methods must be carried out using *Salmonella* M*enston* NZRM 383 as the positive control and *E. coli* NZRM 916 as the negative control.

3.17.1 Initiation of analysis

(1) Initiation of *Salmonella* analysis is defined as the time the BPW suspension is placed in the incubator.

3.17.2 Preparing carcass composite samples for *Salmonella* testing

(1) The laboratory must ensure that all swabs used for *Salmonella* sampling of NMD carcass sites are placed into a single bottle allowing sufficient volume for diluent and mixing.

(2) The laboratory must ensure that the listed amount of diluent is added for each species below:

Species	Bovine	Bobby calf	Caprine	Ratite
Sites per carcass	3 sites per carcass	3 sites per carcass	3 sites per carcass	1 site per carcass
Total number of swabs	6 swabs x 3 sites x 5 carcasses = 90 swabs	4 swabs x 3 sites x 5 carcasses = 60 swabs	2 swabs x 3 sites x 5 carcasses= 30 swabs	4 swabs x 1 site x 5 carcasses = 20 swabs
Volume of ssBPW diluent	250ml	150ml	75ml	75ml
Scott bottle size	500ml	250ml	250ml	250ml

(3) Add an appropriate number of glass beads to aid suspension of the microbes in the diluent, close the bottle and mix vigorously for 2 minutes.

3.17.3 Samples

(1) Following receipt of samples, the laboratory must ensure cooling of these original suspensions during APC and generic *E. coli* testing and use of pre-chilled dsBPW to <5°C to make up the final *Salmonella* sample suspension.

3.17.4 Pre-enrichment step

(1) dsBPW must be used to constitute a BPW pre-enrichment broth for:

a) primal cut swab suspensions remaining after generic *E. coli* and APC plating has been completed; and
b) bulk meat sample composite *Salmonella* samples by adding an equal volume of dsBPW to the remaining peptone diluent.

(2) Immediately after preparing the dsBPW suspension, incubate the pre-enrichment samples at 35±1ºC or 37±1ºC for 18-24 hours.

(3) Once the *Salmonella* analysis has been initiated testing must be completed within the time and temperature requirements, and the pre-enrichment broth and/or the Rappaport-Vassiliadis Salmonella (RVS) selective enrichment broth must not be refrigerated at any time.

3.17.5 Enrichment

(1) Following incubation transfer 0.1ml of the dsBPW enrichment culture to 10ml of RVS selective enrichment broth pre-warmed to 42°C.

(2) Incubate the RVS selective enrichment broth for 24 hours ± 2 hours at 42±0.2°C in a water bath or incubator.

3.17.6 Plating

(1) Following incubation transfer a loop-full (10µl) of the RVS enrichment culture to one plate of Brilliant Green Modified (BGM) agar and to a plate of Xylose Lysine Desoxycholate (XLD) agar selective plating media and streak to obtain single, well isolated colonies. Label plates with the agar type (BGM or XLD) as the agar colour can change during incubation making it hard to distinguish between the 2 types of media.

(2) Incubate both agar plates for 18-24 hours at 35±1°C or 37±1°C.

(3) Examine the agar plates for the presence of typical *Salmonella* colonies:

a) BGM agar: pink colonies surrounded by bright red medium; and
b) XLD agar: red colonies with a black centre (H_2S negative serotypes have red colonies without a black centre).

3.17.7 Confirming presumptive positive *Salmonella*

(1) Select 5 or more single, typical *Salmonella* colonies from the XLD and/or BGM selective plating media for confirmation.

(2) Use biochemical tests and/or commercial kits as listed in MIMM, "Identification of *Salmonella* Colonies", including serotyping; and

(3) Test each of the 5 colonies sequentially; and

a) if any one of these colonies is positive, the sample is deemed positive; and
b) upon detection of a positive colony, any remaining colonies need not be tested.

3.17.8 Final confirmation and serological typing

(1) Streak colonies from either selective media onto MacConkey agar (without salt and crystal violet).

(2) Incubate for 24h at 35±1°C or 37±1°C.

(3) Subculture typical colourless colonies to plate count agar and incubate overnight at 35±1°C or 37±1°C.

(4) Following overnight incubation, colonies may be confirmed using Poly-O and Poly-H anti-sera. If either is positive, submit purified colonies to Institute of Environmental Science and Research Limited (ESR) Enteric and *Leptospira* Reference Laboratory, Wallaceville for confirmation and serotyping.

3.17.9 *Salmonella* results

(1) If samples are composited for *Salmonella* testing, express the result as *Salmonella* "detected in a composite sample" or "not detected in a composite sample".

3.18 Reporting and recording of results

(1) Laboratories must report NMD results using 1 of the following methods:

a) automated result calculation (NMD web-based data entry); or
b) manual result calculation followed by entry into NMD.

Guidance

- The web-based data entry takes raw counts and dilution data and automatically performs all calculations, providing descriptive statistics, and graphical profiles. It acts as an ongoing repository of data derived from the NMD sampling programmes. It will also accept partially calculated CFU/ml, CFU/g or fully calculated log CFU/ml, log CFU/g results.

3.18.1 Automated result calculation

(1) Laboratories that use the NMD web-based data entry to enter results of APC or *E. coli*, or the presence/absence results in the case of *Salmonella,* must do so as per subclauses (2) and (3).

(2) Data must be entered into the web-based NMD portal as follows:

a) test results must be entered by the laboratory; and
b) confirmation results for *Salmonella* must be entered by ESR.

(3) Prior to submitting results to NMD, results must be authorised as follows:

a) samples: the type of sample, the run, shift, and time of day (24 hour clock) must be authorised by a data submitter who must be able to confirm that a currently listed sample taker took the samples; and

b) laboratory test results must be entered by a data submitter who must authorise the report upon confirming that a currently listed sample taker took the samples and that a KTP for the tests concerned has signed the laboratory report; and
c) confirmed result and serotyping for *Salmonella* are entered by an ESR data submitter who ensures the confirmation report has been signed by a qualified ESR analyst.

3.18.2 Manual result calculation

(1) Laboratories that use manual result calculation of APC or generic *E. coli*, or the presence/absence results in the case of *Salmonella*, must do so as follows.

(2) Calculate the number of CFU per cm2 or per g using the following rationale.

(3) The dilution series values for calculations below are to be mathematically expressed as 10^0, 10^{-1}, 10^{-2}….

Guidance

- The swab suspension is not a dilution and is entered into calculations as the 100 dilution.
- Although the whole tissue suspension is a 1:10 dilution, in order to maintain consistency in plate labelling it is entered into calculations as the 100 dilution or zero dilution.

Aerobic plate count (spread plate)

Swab samples – 100cm^2 area and 15ml suspension volume

$$\text{CFU / cm} = \frac{\text{Count 1 + Count 2}}{2} \times \frac{1}{\text{Dilution}} \times \frac{1}{0.1\text{ml}} \times \frac{15\text{ml}}{100\text{cm}^2}$$

Swab samples – 25cm^2 area and 15ml suspension volume

$$\text{CFU / cm} = \frac{\text{Count 1 + Count 2}}{2} \times \frac{1}{\text{Dilution}} \times \frac{1}{0.1\text{ml}} \times \frac{15\text{ml}}{25\text{cm}^2}$$

Swab samples – 5cm^2 area and 10ml suspension volume

$$\text{CFU / cm} = \frac{\text{Count 1 + Count 2}}{2} \times \frac{1}{\text{Dilution}} \times \frac{1}{0.1\text{ml}} \times \frac{10\text{ml}}{5\text{cm}^2}$$

Whole tissue samples – 25g sample + 225ml diluent = 250ml total volume

$$\text{CFU / g} = \frac{\text{Count 1 + Count 2}}{2} \times \frac{1}{\text{Dilution}} \times \frac{1}{0.1\text{ml}} \times \frac{250\text{ml}}{25\text{g}}$$

Aerobic plate count (Petrifilm™)

Swab samples – 100cm^2 area and 15ml suspension volume

$$\text{CFU / cm} = \frac{\text{Count 1 + Count 2}}{2} \times \frac{1}{\text{Dilution}} \times \frac{1}{1\text{ml}} \times \frac{15\text{ml}}{100\text{cm}^2}$$

Swab samples – 25cm^2 area and 15ml suspension volume

$$\text{CFU / cm} = \frac{\text{Count 1 + Count 2}}{2} \times \frac{1}{\text{Dilution}} \times \frac{1}{1\text{ml}} \times \frac{15\text{ml}}{25\text{cm}^2}$$

Swab samples – 5cm^2 area and 10ml suspension volume

$$\text{CFU / cm} = \frac{\text{Count 1 + Count 2}}{2} \times \frac{1}{\text{Dilution}} \times \frac{1}{1\text{ml}} \times \frac{10\text{ml}}{5\text{cm}^2}$$

Whole tissue samples – 25g sample + 225ml diluent + 250ml total volume

$$\text{CFU / g} = \frac{\text{Count 1 + Count 2}}{2} \times \frac{1}{\text{Dilution}} \times \frac{1}{1\text{ml}} \times \frac{250\text{ml}}{25\text{g}}$$

Aerobic plate count (spiral plater)

Calculate the number colony forming units per cm^2 or per g using the procedures outlined in the spiral plater's operating instructions. The typical volume for the inoculum is 50µl = 0.05ml or 100µl = 0.1ml.

Swab samples – 100cm^2 area and 15ml suspension volume

$$\text{CFU / cm} = \frac{\text{Count 1 + Count 2}}{2} \times \frac{1}{\text{Dilution}} \times \frac{1}{\text{Inoculum ml}} \times \frac{15\text{ml}}{100\text{cm}^2}$$

Swab samples – 25cm^2 area and 15ml suspension volume

$$\text{CFU / cm} = \frac{\text{Count 1 + Count 2}}{2} \times \frac{1}{\text{Dilution}} \times \frac{1}{\text{Inoculum ml}} \times \frac{15\text{ml}}{25\text{cm}^2}$$

Swab samples – 5cm^2 area and 10ml suspension volume

$$\text{CFU / cm} = \frac{\text{Count 1 + Count 2}}{2} \times \frac{1}{\text{Dilution}} \times \frac{1}{\text{Inoculum ml}} \times \frac{10\text{ml}}{5\text{cm}^2}$$

Whole tissue samples – 25g sample + 225ml diluent = 250ml total volume

$$\text{CFU / g} = \frac{\text{Count 1 + Count 2}}{2} \times \frac{1}{\text{Dilution}} \times \frac{1}{\text{Inoculum ml}} \times \frac{250\text{ml}}{25\text{g}}$$

Escherichia coli (Petrifilm™)

Swab samples – 100cm^2 area and 15ml suspension volume

$$\text{CFU / cm} = \frac{\text{Count 1 + Count 2}}{2} \times \frac{1}{\text{Dilution}} \times \frac{1}{1\text{ml}} \times \frac{15\text{ml}}{100\text{cm}^2}$$

Swab samples – 25cm^2 area and 15ml suspension volume

$$\text{CFU / cm} = \frac{\text{Count 1 + Count 2}}{2} \times \frac{1}{\text{Dilution}} \times \frac{1}{1\text{ml}} \times \frac{15\text{ml}}{25\text{cm}^2}$$

Swab samples – 5cm^2 area and 10ml suspension volume

$$\text{CFU / cm} = \frac{\text{Count 1 + Count 2}}{2} \times \frac{1}{\text{Dilution}} \times \frac{1}{1\text{ml}} \times \frac{10\text{ml}}{5\text{cm}^2}$$

Whole tissue samples – 25g sample + 225ml diluent = 25ml total volume

$$\text{CFU / g} = \frac{\text{Count 1 + Count 2}}{2} \times \frac{1}{\text{Dilution}} \times \frac{1}{1\text{ml}} \times \frac{250\text{ml}}{25\text{g}}$$

3.18.3 Reporting exceptions

3.18.3.1 Periods of not operating

(1) The operator must notify the laboratory in writing if they are not operating within an NMD sampling period.

(2) The laboratory must record "not operating" (NO) in the NMD web database.

3.18.3.2 Missed samples

(1) The operator must notify the laboratory in writing if any samples are missed.

(2) The laboratory must enter a "missed" sample result in the NMD web database.

3.18.3.3 Technical failures

(1) If a sample was taken, but a technical failure occurs at the laboratory, the laboratory must enter the details of the sample and the nature of the technical failure. This does not generate an M-alert.

3.19 Limits of detection

(1) The laboratory must ensure results are entered in accordance with subclause (2). If there is not a count within the acceptable range as per clause 3.13.4, then:

a) if colonies are not present, enter results as "not detected"; or
b) if colonies are too numerous to count, enter results as "TNTC".

(2) Not detected results are results less than the lowest limit of detection (LLD). The values used to represent LLD and "not detected" results in the NMD database are as follows:

Volume, Area of Site, Weight of Sample	Lowest Limit of Detection Value				"Not Detected"
	APC CFU/cm^2 or /g	APC Log_{10} value	*E. coli* CFU/cm^2 or /g or /ml	*E. coli* Log_{10} value	Log_{10} value
Spreadplate 0.1ml					
$5cm^2$	10	1.00			-0.31
$25cm^2$	3	0.48	Not applicable	Not applicable	-0.53
$100cm^2$	0.75	-0.12			-1.13
Bulk Meat (25g)	50	1.70			-0.31
Petrifilm™ 1ml					
$5cm^2$	1	0.00	1	0.00	-0.31
$25cm^2$	0.3	-0.52	0.3	-0.52	-0.53
$100cm^2$	0.075	-0.12	0.075	-1.12	-1.13
Bulk Meat (25g)	5	0.70	5	0.70	-0.31
Spiral plater 50µl					
$5cm^2$	20	1.30			-0.31
$25cm^2$	6	0.75	Not applicable	Not applicable	-0.53
$100cm^2$	1.5	0.18			-1.13
Bulk Meat (25g)	100	2.00			-0.31

Guidance

- When CFU/cm^2 results (arithmetic) are transformed to log CFU/cm^2 results (logarithmic) for NMD reporting all results above the LLD, even though they may be negative logarithmic values, they represent detections/counts if greater than the values in the above table.

3.20 National Microbiological Criteria

3.20.1 M-limits

(1) The National Microbiological Criteria (NMC) is the maximum allowable regulatory limit (M-limit) for red meat processing. The limits for APC and for generic *E. coli* are listed for each species below:

Species	M-limit (APC log_{10})	M-limit (generic *E. coli* log_{10})
Bovine	4.00	2.00
Bobby calf	5.00	4.00
Ovine	5.00	
Caprine	5.00	4.00
Cervine	4.00	2.00
Porcine	4.00	2.00
Ratite	4.00	2.00

3.20.2 M-alerts

(1) The M-alert is determined from both a single processing week's results and a 5 moving window of 5 sets of samples. Each new set of sample results displace the oldest set of results from the window.

(2) An M-alert for a product type will be generated if:

a) 2 or more samples in a processing week exceed the M-limit; or
b) 3 or more samples above the M-limit are recorded within a moving window of 5 sets of samples.

(3) Any missed samples count as exceeding the M-limit.

(4) Any APC or *E. coli* TNTC results count as exceeding the M-limit.

(5) The moving window is reset after an M-alert is raised.

Guidance

- If the moving window M-alert is breached, this will be expressed automatically in each premises' NMD ledger. For standard throughput premises a moving window will be 5 weeks. For VLT premises a moving window will be 5 months.
- Product types include carcasses, cuts and bulk as applicable to the species. If multiple carcass sites are sampled, results from all sites are combined in a single moving window. For example, a bovine operator would have moving windows for carcasses, primal cuts, and bulk (i.e. 3 moving windows).

3.20.3 M-alert responses

(1) On the first M-alert from the start of processing under this notice or after 5 weeks or more of processing without an M-alert, when an M-alert occurs, an operator must:

a) within 1 working day, begin a review of the process to identify and document factors that may have compromised hygienic processing; and
b) take corrective and preventative action if factors that have compromised hygienic processing have been identified.

(2) Should a second occurrence of an M-alert occur in the next 5 processing weeks, the operator must also:

a) within 1 working day, notify the premises verifier that an M-alert was triggered; and

b) within 1 working day, begin a review of the process to identify and document factors that may have compromised hygienic processing; and
c) take corrective and preventative action if factors that have compromised hygienic processing have been identified.

(3) Should a third occurrence of an M-alert occur in the next 5 processing weeks, the operator must also:

a) within 1 working day, notify the premises verifier that an M-alert was triggered; and
b) within 1 working day, begin a review of the process to identify and document factors that may have compromised hygienic processing; and
c) take corrective and preventative action if factors that have compromised hygienic processing have been identified.

(4) Should a fourth (or subsequent) occurrence of an M-alert occur in the next 5 processing weeks, the operator must also:

a) within 1 working day, notify the premises verifier that an M-alert was triggered and the premises verifier must be involved in the review; and
b) within 1 working day, begin a review of the process to identify and document factors that may have compromised hygienic processing; and
c) take corrective and preventative action if factors that have compromised hygienic processing have been identified.

Guidance as to MPI's response

MPI may intervene directly in the process. This may involve:

- products dispositions (e.g. market restrictions, downgrading); and
- slowing the chain speed, or stopping the chain; and
- any other action that is considered appropriate by MPI, such as enhanced Regulatory Oversight.

3.21 *Salmonella* Performance Standard (SPS)

(1) The *Salmonella* Performance Standard (SPS) applies to operators of standard throughput premises processing bobby calf, bovine, caprine, or ratite species when *Salmonella* is detected by the laboratory in samples from any of the following product types from the species listed:

a) carcasses of bobby calf, bovine, caprine, or ratite species; and
b) primal cut product of bobby calf, bovine, or caprine species; and
c) bulk product of bobby calf, bovine or caprine species.

3.21.1 Detection

(1) When notified by the laboratory of any detection of *Salmonella*, the operator must:

a) determine if any personnel handling either animals or product have any symptoms of salmonellosis; and
b) consult the laboratory(s) providing an animal health service in the stock catchment area as to any increase in reported cases of animal salmonellosis; and
c) undertake the following process responses, which escalate according to the frequency of *Salmonella* detections in the season.

3.21.2 Process responses

(1) After being notified by the laboratory of any detection of *Salmonella*, the operator must commence a SW in the next sampling week or, if the detection occurs within the PSW, reset the PSW.

(2) On the first detection of *Salmonella*, the operator must:

a) within 1 working day, begin a review of the process to identify and document factors that may have compromised hygienic processing; and
b) take corrective and preventative action if factors that have compromised hygienic processing have been identified.

(3) On the second detection in the 6 week moving window following the first detection, the operator must:

a) within 1 working day, notify the premises verifier that an M-alert was triggered; and
b) within 1 working day, begin a review of the process to identify and document factors that may have compromised hygienic processing; and
c) take corrective and preventative action if factors that have compromised hygienic processing have been identified.

(4) On the third detection in the 6 week moving window following the first detection, the operator must:

a) within 1 working day, notify the premises verifier that an M-alert was triggered and the premises verifier must be involved in the review; and
b) within 1 working day, begin a review of the process to identify and document factors that may have compromised hygienic processing; and
c) take corrective and preventative action if factors that have compromised hygienic processing have been identified.

(5) On the fourth (or subsequent) detection in the 6 week moving window, the operator must:

a) within 1 working day, notify the premises verifier that an M-alert was triggered and the premises verifier must be involved in the review; and
b) within 1 working day, begin a review of the process to identify and document factors that may have compromised hygienic processing; and
c) take corrective and preventative action if factors that have compromised hygienic processing have been identified.

Guidance as to MPI's response

MPI may intervene directly in the process. This may involve:

- products dispositions (e.g. market restrictions, downgrading)
- slowing the chain speed, or stopping the chain
- any other action that is considered appropriate by MPI, such as enhanced Regulatory Oversight.

Part 4: NMD Poultry Programme

4.1 Interpretation

(1) In this Part, unless the context otherwise requires:

'alert' response means an immediate review of the process by an operator to identify and document factors that may have compromised hygienic processing, and if appropriate, take corrective and preventative action

breeder chicken means a spent parent or grandparent bird from poultry farms that produce fertile eggs for the broiler poultry companies' hatcheries for chick production or breeder laying operations

broiler chicken means a chicken commonly produced primarily for meat

chicken means a bird of the species *Gallus gallus* that is processed for human consumption, categorised as young chicken (broiler, poussin, small breed) and old chicken (breeder chicken, and end-of-lay hen)

cut number means the number of times you have been into a shed to partially or fully depopulate that shed

duck means a bird of the species *Anas platyrhynchos* domestica or *Anas pekin* (Peking ducks) or of the species *Cairina moschata* (Muscovy ducks) or a hybrid of these known as mulard or moulard ducks that is processed for human consumption

end-of-lay chicken means a spent hen culled from an egg layer flock at an egg production farm

farm means the location at which the poultry sheds are situated

initiation of analysis means:

a) in relation to a *Campylobacter* analysis as per subclause 4.10.2 (2) from the time the sample is direct plated to mCCDA; and
b) in relation to *Salmonella* analysis as per subclause 4.11.2 (3), the commencement of incubation of the BPW pre-enrichment broth

new start-up premises means a premises processing young chickens for the first time after gaining MPI approval of its risk management programme (RMP) until the premises achieves a clear CPT moving window

old chicken means a breeder chicken or end-of-lay chicken

poussin means a young meat chicken processed for human consumption and includes spring chickens

primary chilling means the initial chilling of a poultry carcass by immersion chilling or air chilling

processing day means a day when the primary processing of poultry as defined in Part 1 of this notice occurs

shed means a shelter for poultry with facilities for the delivery of feed and water, and may define a poultry flock for traceability purposes

small breed of chickens means a small breed of chicken processed for human consumption and includes Silkie (Silky)

ssBPW means single strength buffered peptone water

standard throughput premises means a poultry premises at which, at the beginning of a season, it can reasonably be expected that more than 1 million (1,000,000) birds will be processed in that season

turkey means a bird of the species *Meleagris gallopavo* processed for human consumption

VLT premises means a very low throughput poultry premises at which, at the beginning of a season, it can reasonably be expected that fewer than 1 million (1,000,000) birds will be processed in that season

Whole Flock Health Scheme means, in relation to a flock of farmed poultry, a documented programme of health surveillance and includes measures taken to reduce infection of flocks by *Campylobacter* or *Salmonella*

Young chicken means a broiler chicken, small breed or poussin.

4.2 NMD poultry sampling and testing requirements

(1) The NMD poultry programme monitors *Salmonella* and *Campylobacter* contamination of poultry through 5 independent sampling programmes as follows:

a) ducks; and
b) old chickens; and
c) turkeys; and
d) young chickens; and
e) new start-up premises.

4.2.1 Poultry to be sampled

(1) A standard throughput premises operator must ensure that the number of carcasses for each type of poultry he/she processes are sampled as follows:

a) ducks: 3 carcasses each processing day
b) old chickens: 3 carcasses each processing day
c) turkeys: 3 carcasses each processing day
d) young chickens: 3 carcasses each processing day.

(2) A VLT premises operator must ensure that the number of carcasses for each type of poultry he/she processes are sampled as follows:

a) ducks: 3 carcasses on 1 processing day each processing week
b) old chickens: 3 carcasses on 1 processing day each processing week
c) turkeys: 3 carcasses on 1 processing day each processing week
d) young chickens: 3 carcasses on 1 processing day each processing week.

(3) A new start-up premises operator must ensure that 3 carcasses are sampled each processing day until there is a clear *Campylobacter* Performance Target (CPT) moving window. Following this, the operator must sample 3 carcasses on 1 processing day each processing week.

4.2.1.1 Sampling for VLT premises processing multiple poultry types

(1) VLT premises processing multiple poultry types are only required to sample 3 poultry carcasses per processing week.

(2) VLT premises that process 2 or more of the types of poultry covered by this notice and under the scope of their RMP during any processing week are only required to sample 1 type of poultry during that processing week.

(3) The operator must randomly select the type of poultry sampled each processing week.

4.3 Sample selection

4.3.1 Sample selection plan

(1) The operator must ensure that a plan covering the sample selection requirements in clause 4.2.1 is in place for each type of poultry processed.

(2) The operator must keep all records relating to sample selection criteria for 4 years.

4.3.2 Standard throughput premises: Random selection of sampling times

(1) The operator of a standard throughput premises must ensure that for each product type to be sampled under clause 4.2.1, the 3 discrete sample times are randomly selected prior to processing based on:

a) 3 unique carcass identification numbers across the entire processing day; or
b) 3 discrete times (in minutes) that processing is reasonably likely to be underway that processing day.

(2) The randomly selected times (reported in minutes) must be recorded prior to sampling.

4.3.3 VLT premises: Random selection of sampling day, time and carcasses

(1) The operator of a VLT premises must ensure that all 3 carcasses are selected from 1 randomly selected processing day and time during any processing week as follows:

a) if processing occurs on only 1 processing day of the processing week, then this is the sampling day; or
b) if processing occurs on more than 1 day in any processing week, then the sampling day must be randomly selected from the known processing days; or
c) if there is doubt about when processing will occur, samples must be taken on the first processing day of that processing week.

(2) The operator must ensure that the initial carcass is randomly selected from all times that processing is reasonably likely to occur on that processing day as per clause 4.3.2.

(3) The remaining 2 carcasses must be collected at time intervals equivalent to the time required to bag or rinse each carcass.

4.3.4 Departure from the original sample selection

(1) If a problem occurs during the collection of a sample, the operator must ensure that sample is discarded and the next available carcass must be selected for sampling.

(2) If a sample is missed or if the processing schedules change in a manner that means that the original random sampling plan cannot be followed, the operator must ensure that every reasonable effort is made to randomly sample carcasses from within the remaining processing time available to meet requirements under this notice.

(3) The operator must ensure that any variation to the random selection of sampling days or times is recorded in the operator's random sample selection records.

(4) If the required samples are not collected, each missed sample will be considered a "missed sample".

4.4 Sampling equipment

(1) The operator must ensure that the sample taker has appropriate sampling gear and equipment ready for undertaking whole carcass rinse sampling.

(2) Sampling equipment includes:

a) plastic sample bags with twist ties or equivalent, such as poultry rinse bags with a tear tie; and
b) insulated container and pre-cooled sterile BPW diluent; and
c) a means to record sampling details and label vials; and
d) the appropriate number of vials to collect a 70ml sample of whole carcass rinse sample if this occurs in the processing area, and a vial containing liquid to verify temperature of the sample on receipt by the laboratory; and
e) alcohol wipes; and
f) a means to time the 2 minute carcass rinse procedure.

4.5 Diluents for sampling and testing

4.5.1 Diluents

(1) An operator must ensure that:

a) the laboratory provides to sample takers:

i) sterile diluents that are correctly prepared as per clause 4.9.5 and labelled; and
ii) sterile diluents used for sampling and testing that are not cloudy, loose lidded, odorous, or have passed their expiry dates; and

b) the sample taker uses the appropriate diluent according to whether antibacterial agents were applied to the carcass during processing.

4.5.2 Single strength buffered peptone water (ssBPW)

(1) An operator must ensure that the appropriate volumes of sterile ssBPW diluent are used for sampling of the poultry carcasses using the whole carcass rinse method:

a) 400ml of ssBPW per carcass is required for all chicken and duck rinses; and
b) 600ml of ssBPW per carcass is required for turkey rinses.

(2) The laboratory must use the appropriate volumes of sterile ssBPW diluent for performing the laboratory analysis for *Campylobacter* when undertaking a 10 fold dilution series whole carcass rinsate samples.

4.5.3 Antibacterial agents

(1) Prior to sampling, an operator must inform the laboratory if antibacterial agents are used during processing.

(2) If antibacterial agents are used during processing, the laboratory must prepare the appropriate ssBPW diluent for sampling (not testing) by:

a) determining suitable non-antimicrobial neutralising additives; and
b) adding these to the diluent if required; and
c) labelling the mixture accordingly.

Guidance

- For example, if a chlorinated compound, such as acidified sodium chlorite (ASC) has been used during processing, the laboratory must ensure that a peptone diluent with the addition of 1.0ml of a 3% sodium thiosulphate ($Na_2S_2O_3$) solution to 1 litre of diluent is used for sampling.

4.6 Sample collection

(1) An operator must ensure that samples are collected as per all the provisions of this clause.

4.6.1 Poultry carcass selection criteria

(1) A whole poultry carcass must be selected for sampling from the line after primary chilling at the last readily accessible point prior to the carcass entering any packing bins, being bagged, cut up or sent for further processing.

(2) If the carcasses are mixed in bins at manual grading, the carcasses must be selected immediately prior to grading (for example, off the drain-table, after draining).

(3) If the carcasses are re-hung on the chain after primary chilling, the carcass must be selected immediately prior to the first drop point, or similar, at which the carcasses enter secondary processing or are bagged for retail.

(4) If the position of the first drop point is not readily accessible, the operator must:

a) determine the time the carcass would normally take to move from the point it will be selected from the line to the first drop point (known as T°); and
b) communicate this information to the laboratory and the sample taker.

4.6.2 Taking samples

(1) The carcasses must be sampled no more than 10 minutes either side of the originally selected random sampling time.

(2) If the carcass is selected prior to the drop point, the selected carcass must be hung for time T^0 determined in clause 4.6.1 (4). If the carcass is selected directly from grading bins, this is not required.

(3) The sampling time must be recorded using a format that can be translated to 24 hour clock units when the sample descriptors and results are entered into the NMD database:

a) for standard throughput premises, record the time for each of the 3 poultry carcasses selected during that processing day; or
b) for VLT premises, record the time for the first carcass selected.

(4) Carcasses must be handled aseptically during sampling and the carcass rinse procedure.

(5) Each carcass must be placed in a sterile sampling bag.

(6) Any whole carcass rinse must be undertaken according to the procedure in clause 4.6.3:

a) in the processing area of the poultry premises; or
b) in a laboratory.

(7) Carcasses for the day must not be collected all at once from the line and then bagged or rinsed unless there are no other opportunities to complete collection of the 3 carcasses.

4.6.3 Carcass rinse procedure

(1) The carcass rinse procedure must be performed as follows:

a) pour the required volume of the chilled sterile ssBPW diluent over the carcass within the bag. Expel most of the air from the bag and then secure the bag tightly by hand or with a twist tie to prevent losing any of the diluent; and
b) commence the whole carcass rinse procedure and begin timing. This must continue for 2 minutes to ensure complete coverage of both the external and internal surfaces of the carcass with the diluent, which becomes the 'rinsate' when the rinse procedure begins; and
c) rinse the carcass -- begin by rocking the carcass in the bag in an arching motion to rinse the outside of the carcass, including the wings and legs. Transfer the weight of the carcass from one hand to the other while simultaneously massaging the carcass surface, particularly around the wings and the legs. When the rinsate becomes yellowy in colour (with suspended fats), proceed to the next step; and
d) ensure that the cavity of the carcass is rinsed by periodically positioning the carcass so that the rinsate can enter. Any fat or skin covering the vent may need to be cleared to enable the rinsate to enter the cavity; and
e) swirl the rinsate so that the entire internal cavity is rinsed and the rinsate on exiting from the cavity is a pink to red colour; and
f) continue rocking the carcass to pass the rinsate over the external and internal surfaces for the remainder of the 2 minutes. There should be at least 2 complete internal cavity rinses during the 2 minutes. On completion of the whole carcass rinse, check that the rinsate has a reddish tint and is thicker than the starting diluent due to the presence of suspended fats and visible cells.

4.6.4 Collecting the carcass rinsate

(1) Collect the carcass rinsate by either of these 2 methods:

a) whole sample bag:
b) Place the sample bag and carcass on a flat surface. Open the bag and remove the carcass aseptically using a gloved hand. Expel the air from the sample bag (for ease of packaging) and secure the top to prevent contamination and/or spillage of the rinse sample; or
c) sample of rinsate:
d) Before removing the carcass, aseptically transfer at least 70ml of the rinse sample to a sterile vial.

4.6.5 Carcasses

(1) If carcasses that have been rinsed in the processing area of the poultry premises are intended for human consumption, they must be returned to a point in the chain where subsequent processing will ensure that the carcass meets requirements for human consumption.

(2) Carcasses sent to the laboratory must not be supplied for human consumption by any person.

4.7 Sample description information

(1) An operator must ensure that the following sample description information is recorded directly into the NMD database prior to transport of the sample to the laboratory or, by prior arrangement with the laboratory, on a sample submission form sent to the laboratory with the samples:

a) name of the sample taker; and
b) poultry premises from which samples were taken; and
c) specific information associated with the poultry provided to the premises:
    i) cut number; and
    ii) average age of birds; and
    iii) farm reference number and shed number; and
    iv) free range or not free range; and
    v) poultry species: young chicken, old chicken, duck, or turkey; and
d) classes of young chicken (broiler, poussin, and small breeds); and
e) classes of old chicken (end-of-lays and broilers); and
f) sampling date; and
g) time (24 hour clock) first sample in the set was taken; and
h) the method of drainage and, if required, the drainage time; and
i) the location where the carcass rinse procedure was conducted (poultry premises or laboratory).

4.8 Storing and transporting samples to the laboratory

(1) An operator must ensure that samples are transported to the laboratory as per all the provisions of this clause.

4.8.1 Preparing samples for transport

(1) The sample bag containing the carcass rinsate with or without the poultry carcass, or the aseptically collected rinsate in a sterile vial, or the unrinsed carcass in the sample bag must be tightly sealed to ensure the contents are secure.

(2) All secured samples must be immediately placed into the pre-cooled insulated container. The samples must not be in direct contact with any frozen coolant used.

(3) Samples awaiting transport to the laboratory must be stored in a refrigerator operating in the calibrated temperature range of 0°C to 5°C.

4.8.2 Delivery of samples to the laboratory

(1) Whole carcasses transported to the laboratory for rinsing must be:

a) transported in insulated containers with sufficient frozen coolant to cool the sample; and
b) delivered to the laboratory no later than 30 minutes after selection of the whole carcass from the processing chain; and
c) rinsed immediately upon receipt by the laboratory and no later than 60 minutes after the carcass was selected from the line.

(2) Carcass rinse samples must be transported to the laboratory so that:

a) the temperature of the rinsate is maintained at a temperature between 0°C and 5°C; and
b) laboratory testing can be initiated within 30 hours from when the first sample was collected.

4.9 Laboratory functions

4.9.1 Receipt of samples

(1) The laboratory receiving the samples must:

a) record in the sample register the sample temperature on receipt (for carcass rinse samples); and
b) reject samples that are frozen, or samples that exceed 10°C; and
c) confirm that the sample is suitable for testing, and
d) confirm that testing will be initiated within 30 hours from time of collection of the first sample; and
e) confirm that the sample taker recorded as collecting the samples is currently listed as a certified trainer or sample taker; and
f) enter the sample descriptors supied by the sample taker on the submission form into the NMD database if not already entered by the sample taker.

(2) If samples submitted by the operator are rejected as above, the laboratory must request replacement samples from the same processing day for standard throughput premises or processing week for VLT premises. If replacement samples are not available, no additional samples are required to be collected in the next processing day (standard throughput premises) or processing week (VLT premises).

(3) The laboratory must record the missed results as a technical failure, with reasons, in the NMD database.

4.9.2 Testing required

(1) The laboratory must:

a) If samples received are whole carcasses, then rinse carcasses as per clauses 4.6.3 - 4.6.5; and
b) test each rinse sample for *Campylobacter*; and
c) randomly designate a rinse sample from the 3 and test it for *Salmonella* in addition to *Campylobacter*.

4.10 *Campylobacter* testing

(1) The laboratory must comply with all provisions under this clause.

4.10.1 Preparing for testing

4.10.1.1 Dilutions required

(1) A 10-fold serial dilution series is required for the analysis of *Campylobacter*.

(2) The dilutions 10^0 and 10^1 are required in addition to sufficient higher dilutions to make sure that the maximum allowable count is obtained on at least 1, or 1 set of, plates. (The undiluted carcass rinsate is the 10^0 dilution for the purposes of calculations.)

(3) The laboratory must ensure that only plates with counts that fall in the acceptable counting range as specified below are counted:

Plate dilution	Allowable count for mCCDA direct plate *Campylobacter*
10^0 dilution	0 - 150 CFU
All other dilutions	15 - 150 CFU

4.10.1.2 High end dilutions and TNTC results

(1) If a count exceeds the maximum allowable count on the highest dilution (above), a TNTC result must be recorded.

(2) The test does not need to be repeated for the sample that has a TNTC result.

(3) If a TNTC result occurs, the laboratory must extend the dilution series, to ensure results are within the acceptable counting range for subsequent samples submitted by the premises in question.

4.10.1.3 Duplicate plating/analytical precision

(1) Duplicate plating must be done for all dilutions to give statistical confidence to the results obtained. Use the Analytical Precision calculation (for each operator) outlined in chapter 5 Appendix 1.7 of the Meat Industry Microbiological Methods (MIMM) to determine a Z score which is then compared to a limit of 1.96.

(2) Record all duplicate plate counts that fall within the acceptable counting ranges as follows:

Dilutions	mCCDA direct plate
10^0	0-150
10^{-1}, 10^{-2},…..10^{-n}	15-150

(3) If a laboratory demonstrates that it meets the Analytical Precision criteria outlined in MIMM, it may use a single plate for each dilution other than the undiluted (zero) dilution sample.

4.10.1.4 Preparing dilution volumes

(1) All serial dilutions for whole poultry carcass rinse samples must be performed using ssBPW and either of the 2 dilution volumes:

a) 9 ml in 25 ml universal bottles or vials, with 1 ml transfer volume; or
b) 4.5ml in microcentrifuge or microdilution tubes, with 0.5 ml transfer volume.

(2) The use of pre-poured dilution volume is allowed only if a laboratory can provide evidence that:

a) they do not lose volume during autoclaving; and
b) they have an appropriate quality assurance programme in place for ongoing verification.

(3) A fresh pipette or pipette tip must be used for each transfer of diluted sample.

(4) The laboratory must ensure that the bacteria in the dilutions are as homogenously distributed as possible at all stages.

4.10.2 *Campylobacter* Direct Plate enumeration method

(1) The laboratory must ensure that the *Campylobacter* Direct Plate enumeration method (CLT 22.1), which is outlined in this clause, is used when undertaking testing for *Campylobacter* for poultry carcass rinsate samples under this notice.

4.10.2.1 Preparing mCCDA plating media

(1) The plating media modified charcoal cefoperazone desoxycholate agar (mCCDA) must be used for *Campylobacter* testing.

(2) Dehydrated mCCDA basal medium (commercially available) must contain the following proportions of ingredients:

Basal medium components	Quantity in grams (g) per 1000ml
Lab-lemco powder	10.0
Peptone	10.0
Sodium chloride	5.0
Bacteriological charcoal	4.0
Casein hydrolysate	3.0
Sodium deoxycholate	1.0
Ferrous sulphate	0.25
Sodium pyruvate	0.25
Agar	12.0

(3) Suspend 22.75g of dehydrated mCCDA basal medium in 500ml of distilled water, mix well and boil to dissolve the agar.

(4) Sterilise by autoclaving at 121°C for 15 minutes.

(5) The final pH of the mCCDA basal medium must be pH 7.4±0.2.

(6) To complete the medium, add mCCDA Selective Supplement (commercially available) containing Cefoperazone 16 mg and Amphotericin B 5 mg to the mCCDA basal medium as follows:

a) cool the autoclaved mCCDA basal medium to about 50°C; and
b) aseptically add each selective supplement to 500ml of the mCCDA base; and
c) mix thoroughly and pour into Petri plates.

(7) mCCDA plates can be stored for up to two weeks in sealed containers at 4°C.

(8) The mCCDA plates must be air dried before use (do NOT use an laminar flow cabinet), either by leaving unopened on the bench overnight, or when plates are used on the day of preparation, in an incubator at 42°C.

4.10.2.2 Direct plating

(1) Carry out all quality control procedures for the media and methods using *Campylobacter jejuni* NZRM 1958 as a positive control and *Escherichia coli* NZRM 916 as a negative control.

(2) Take 2ml of rinsate (10^0 dilution) from the sample bag or sample vial and apply over 6 dried and labelled mCCDA plates. All of the 2ml must be dispensed over the 6 plates using approximately equal volumes. The exact volume dispensed per plate does not need to be recorded.

(3) Spread each individual volume dispensed on the agar surface with the same sterile spreader. Allow the 6 plates to remain upright at room temperature to permit the sample to soak in before inverting.

(4) Also plate 2 further volumes of 0.1ml of the rinsate (10^0 dilution) onto 2 additional mCCDA plates.

(5) If a higher concentration of *Campylobacter* is expected, undertake additional 10 fold serial dilution using sterile ssBPW. Plate 0.1ml of each dilution (in duplicate) onto mCCDA plates.

(6) Incubate all of the plates for 48 hours ± 2 hours at a temperature of 42± 0.5ºC in a microaerobic atmosphere (5% O_2, 10% CO_2, 85% N_2). Maintain the microaerobic atmosphere at all stages of incubation.

Guidance

- An appropriate number of sachets for the jar/container should be used. If too many sachets are used a moist environment and condensate on plates will occur, which could influence colony growth and cause colony spreading. Too many or too few sachets will not create the correct gaseous mixture in the container.

4.10.2.3 Presumptive count

(1) Select a set of plates with not more than 150 colonies per plate from any serial dilution. These may be any of the dilutions, from either the 2ml set of 6 plates, or from the 0.1ml duplicate plates. Plates with counts of over 150 are considered TNTC.

(2) Examine these plates for typical thermotolerant *Campylobacter* spp colonies: flat grey and moistened, variable size for 1mm - 5mm in diameter, from pinpoint colonies to roundish or flattened out colonies with irregular spreading margins.

(3) Count and record the numbers of typical thermotolerant *Campylobacter* spp. colonies on this set of plates for the dilution.

Guidance

- Other organisms that may be present on mCCDA plates include creamy coloured yeast colonies, which can easily be distinguished by 10x magnification, and *Arcobacter* and Pseudomonads.

4.10.2.4 Oxidase/latex confirmation

(1) Oxidase/latex confirmation must be conducted on fresh cultures from mCCDA agar plates immediately following incubation and the presumptive count to confirm the presence of thermotolerant *Campylobacter* spp.

(2) Select 5 typical colonies, or all colonies if there are fewer than 5 colonies.

(3) Screen all 5 colonies for oxidase activity. Record the result.

(4) On the first oxidase positive colony carry out a latex agglutination test to confirm for *Campylobacter*, and:

a) if the latex agglutination test is positive, assume that all of the colonies are *Campylobacter* positive; or
b) if not, conduct the latex test on the remaining oxidase positive colonies.

(5) If there are no typical colonies present, no further confirmation is required.

(6) Record the colony count and associated dilution for purposes of calculating the number of *Campylobacter*. The calculation to enumerate *Campylobacter* is:

a) the total number of colonies that were selected for oxidase testing = n; and
b) the number of those colonies that were latex positive confirmed for thermotolerant *Campylobacter* spp.

Guidance

- Small colonies may not contain enough cells to perform the oxidase and latex tests. To ensure that there are sufficient cells available it is recommended that small colonies are subcultured to blood agar prior to confirmation.
- The latex/oxidase agglutination tests will confirm the presence of 3 thermotolerant *Campylobacter* species: *C. jejuni, C. coli* and *C. lari.* Speciation of the *Campylobacter* is not required.

4.10.2.5 Reporting Campylobacter results (Campylobacter enumeration)

(1) If there are no typical *Campylobacter* colonies present on the mCCDA plates following the incubation, then report the results as "*Campylobacter*: not detected".

(2) If the number of colonies exceeds 150 on any of the mCCDA plates with the highest dilution in the sample set, report the result as "TNTC".

(3) Record presumptive *Campylobacter* spp. colonies as follows:

a) if no thermotolerant *Campylobacter spp.* colonies were confirmed, report as "not detected"; or
b) if thermotolerant *Campylobacter spp.* colonies were confirmed, calculations to determine the number of colony forming units (CFU) per carcass need to be undertaken as per clause 4.12.1.

4.10.2.6 Weekly validation of confirmation method

(1) The laboratory must validate the method of *Campylobacter* confirmation once a week.

(2) Choose a set of 5 characteristic *Campylobacter* colonies from mCCDA agar plates that are oxidase positive and test all 5 with latex to validate the presumption that an oxidase positive test will be latex positive.

Guidance
Example of confirmatory results by Oxidase/Latex

Typical colonies selected	Oxidase	Latex	Result per colony
1	positive	positive	*Campylobacter*
2	positive	presume remaining oxidase positive are latex positive	*Campylobacter*
3	positive		*Campylobacter*
4	positive		*Campylobacter*
5	positive		*Campylobacter*

Example of negative results by Oxidase/Latex if the first oxidase colony of the selected colonies records a latex negative result.

Typical colonies selected	Oxidase	Latex	Result per colony
1	negative	not conducted	negative
2	positive	negative	negative
3	positive	positive	*Campylobacter*
4	positive	positive	*Campylobacter*
5	negative	not conducted	negative

4.11 *Salmonella* test method

(1) The laboratory must ensure that the following method for CLT 2.4.3, which is outlined in this clause, is used for *Salmonella* detection in all poultry tested under this notice.

(2) All quality control procedures for the media and methods must be carried out using *Salmonella* M*enston* NZRM 383 as the positive control and *E. coli* NZRM 916 as the negative control.

4.11.1 Initiation of analysis

(1) Initiation of *Salmonella* analysis is defined as the time the BPW suspension is placed in the incubator.

4.11.2 Carcass rinse sample for *Salmonella* testing

(1) Samples are derived from the whole poultry carcass rinsate.

(2) Randomly select 1 of the 3 samples for *Salmonella* testing.

4.11.3 Pre-enrichment step

(1) Transfer 30ml of the carcass rinsate to a separate sterile vial for use as the ssBPW suspension used for the pre-enrichment.

(2) Immediately after preparing the ssBPW suspension, incubate the pre-enrichment samples at 35±1ºC or 37±1ºC for 18-24 hours.

(3) Once the *Salmonella* analysis has been initiated testing must be completed within the time and temperature requirements and the pre-enrichment broth and/or the Rappaport-Vassiliadis Salmonella (RVS) selective enrichment broth must not be refrigerated at any time.

4.11.4 Enrichment

(1) Following incubation transfer 0.1ml of the ssBPW enrichment culture to 10ml of RVS selective enrichment broth pre-warmed to 42°C.

(2) Incubate the RVS selective enrichment broth for 24 hours ± 2 hours at 42±0.2°C in a water bath or incubator.

4.11.5 Plating

(1) Following incubation transfer a loop-full (10µl) of the RVS enrichment culture to one plate of Brilliant Green Modified (BGM) agar and to a plate of Xylose Lysine Desoxycholate (XLD) agar selective plating media and streak to obtain single, well isolated colonies. Label plates with the agar type (BGM or XLD) as the agar colour can change during incubation making it hard to distinguish between the 2 types of media.

(2) Incubate both agar plates for 18-24 hours at 35±1°C or 37±1°C.

(3) Examine the agar plates for the presence of typical *Salmonella* colonies:

a) BGM agar: pink colonies surrounded by bright red medium; and
b) XLD agar: red colonies with a black centre (H_2S negative serotypes have red colonies without a black centre).

4.11.6 Confirming presumptive positive *Salmonella*

(1) Select 5 or more single, typical *Salmonella* colonies from the XLD and/or BGM selective plating media for confirmation purposes.

(2) Use biochemical tests and/or commercial kits as listed in MIMM, "Identification of *Salmonella* Colonies"; and

a) perform the agglutination reaction as per the manufacturer's instructions, testing each of the 5 colonies sequentially; and
b) if any one of these colonies is positive the sample is deemed positive; and
c) upon detection of a positive colony, any remaining colonies need not be tested.

4.11.7 Final confirmation and serotyping

(1) Streak a colony from either selective media onto MacConkey agar (without salt and crystal violet).

(2) Incubate for 24h at 35±1ºC or 37±1ºC.

(3) Subculture typical colourless colonies onto plate count agar and incubate overnight at 35±1ºC or 37±1ºC.

(4) Following overnight incubation, colonies may be confirmed using Poly O and Poly H anti-sera.

(5) If either is positive, purified colonies must be submitted directly to the Institute of Environmental Science and Research Limited (ESR) Enteric and Leptospira Reference Laboratory, Wallaceville, for final confirmation and serotyping.

4.11.8 Recording *Salmonella* results

(1) For poultry whole carcass rinse samples, record the *Salmonella* results as "not detected/carcass" or "detected/carcass".

4.12 Reporting results

4.12.1 Calculation of the results

(1) The laboratory must report the NMD results using one of the following methods:

a) Automated result calculation (NMD web-based data entry); or
b) Manual result calculation as prescribed in clause 4.12.1.2.

> Guidance
> - The web based data entry takes raw counts and dilution data and automatically performs all calculations, providing descriptive statistics, and graphical profiles. It acts as an ongoing repository of data derived from the NMD sampling programmes.

4.12.1.1 Automated result calculation

(1) The laboratory must use the NMD web-based data entry to enter the colony counts from *Campylobacter* plates or the presence/absence results in the case of *Salmonella*.

(2) Data must be entered into the web-based NMD portal as follows:

a) test results must be entered by the laboratory; and
b) the *Salmonella* serotype and the Enteric Reference Laboratory (ERL) report number, confirmed result and serotyping for *Salmonella* are entered by an ESR data submitter who ensures the confirmation report has been signed an ESR analyst qualified for *Salmonella*.

4.12.1.2 Manual calculation of results

(1) Calculation requires the counts of the total number of presumptive *Campylobacter* spp. colonies on the set of plates, the number of colonies with the characteristic *Campylobacter* morphology selected for confirmation (n), and the number of colonies confirmed as being a thermotolerant *Campylobacter.*

(2) For counts obtained from 2ml of the 10^0 dilution spread over 6 plates the formula is:

a) CFU/carcass = (number of colonies confirmed as *Campylobacter* spp./n) x total count of typical *Campylobacter* morphology colonies (plate 1 + plate 2 + plate 3 + plate 4 + plate 5 + plate 6) x rinsate volume (400ml or 600ml)/2ml = number of *Campylobacter* organisms/poultry carcass sample.

(3) For counts obtained from duplicate plates of higher dilutions the formula is:

a) CFU/carcass = (number of colonies confirmed as *Campylobacter* spp./n) x count of typical *Campylobacter* morphology colonies (plate 1 + plate 2)/2 x + rinsate volume (400ml or 600ml)/0.1ml x 1/dilution = number of *Campylobacter* organisms/poultry carcass sample.

> Guidance
> - The ratio of the '(number of colonies confirmed as *Campylobacter* spp./n)' is usually 5 out of 5 or will be a proportion of 5 if the remaining colonies had to be confirmed, e.g. 3/5

- If fewer than 5 typical colonies were available for oxidase/latex tests, then the ratio will be the number of colonies confirmed as *Campylobacter* spp. divided by the number of typical colonies selected, e.g. 1/3.

4.12.2 Limits of detection

(1) The laboratory must ensure results are entered in accordance with this clause.

(2) "Not detected" are considered to be results less than the limit of detection.

(3) The limit of detection for NMD *Campylobacter* enumeration is where only a single colony on 1 of the 6 zero dilution plates is confirmed as *Campylobacter* spp. such that the *Campylobacter* spp. count of 5 plates of 6 = 0, and the count on only 1 plate of the 6 = 1.

(4) The values used to represent the limit of detection and "not detected" results in the NMD database are as follows:

Test	Lowest Limit of Detection Value	"Not Detected"	
Campylobacter direct plating	CFU/carcass	Log_{10} value per carcass	"Not detected" log_{10} value per carcass
2ml for 400ml	200	2.30	2.00
2ml for 600ml	300	2.47	2.00

(5) A "not detected" *Campylobacter* result will be recorded as 2.00 log_{10}CFU/carcass on the NMD database.

4.12.3 Recording of sample descriptors and default results

(1) The laboratory must ensure sample descriptors as per clause 4.7 are recorded in the NMD database for every sample taken.

(2) If sample descriptors are not entered, a missed sample result will be recorded on the database for that processing day or processing week.

4.12.3.1 Missed samples

(1) Missed samples occur when fewer samples than required are collected during a processing week or processing period.

(2) Each missed sample will default to a *Campylobacter* result of greater than 3.78 log_{10} CFU/carcass result recorded as 3.79 log_{10} CFU/carcass result on the database.

4.12.3.2 Technical failures

(1) If samples have been collected but a technical failure (TF) has not permitted a result, the sample descriptors must be entered as proof of sampling with TF recorded in the result field. Entering the sample descriptors ensures that a *Campylobacter* 3.79 log_{10} CFU/carcass default result is not generated and a figure reflecting current performance will be used instead.

4.12.3.3 Too numerous to count Campylobacter results

(1) TNTC results occur when counts are greater than 150, as per the maximum allowable counts in subclause 4.9.2.1 (3), on any of the plates in the highest dilution plated.

(2) TNTC results must be reported.

(3) Each TNTC result will default to a greater than the 3.78 log_{10} CFU/carcass result; recorded as 3.79 log_{10} CFU/carcass on the database

4.13 *Salmonella* Performance Standard (SPS) for young chickens

(1) The *Salmonella* Performance Standard (SPS) is that *Salmonella* may be detected in no more than 5 carcass rinse samples in a 51 sample moving window.

(2) The SPS applies to an operator processing young chickens.

(3) For the purposes of the Animal Products (Risk Management Specifications) Notice 2008, the SPS is deemed to be a regulatory limit.

4.13.1 Detection of *Salmonella*

(1) Upon detection of *Salmonella*, the operator must:

a) immediately inform the verifier of the detection; and
b) ensure the laboratory has submitted purified cultures of isolates detected to the Institute of Environmental Science and Research Limited (ESR) Enteric and Leptospira Reference Laboratory, Wallaceville, for serotype identification; and
c) ensure records from the original product sampled are traced back to the catchment area of the chicken being processed and review the Whole Flock Health Scheme; and
d) determine if any personnel handling either the birds or the carcasses have any symptoms of salmonellosis; and
e) consult any laboratory providing an animal health service in the stock catchment area, and inquire as to any increase in reported cases of animal and poultry salmonellosis; and
f) review the entire process; and
g) identify contributing factors; and
h) implement corrective and preventative measures.

4.13.2 Process responses

(1) On breaching the moving window, the operator must:

a) immediately review the process, chicken flocks and feed *Salmonella* status to identify and document factors that resulted in breach of the performance standard; and
b) review and consider whether the process control programmes (pre-requisite and HACCP) must be modified; and
c) provide a verifier with a *Salmonella* Management Plan within 7 days of breaching the moving window, describing
d) process/HACCP reviews; and
e) measures implemented to reduce the prevalence of pathogens.

(2) Following review of the operator's corrective and preventative actions and *Salmonella* Management Plan, the Director-General may apply sanctions as per the Act.

Guidance as to MPI's response

- Sanctions under the Act include, but are not limited to, one or more of the following:
  a) increased frequency of verification
  b) full-time supervision of processing
  c) introduction of further interventions
  d) product disposition
  e) further sampling and research initiatives
  f) premises closure.
- If any of the above sanctions are applied they will remain in place until revoked by an Animal Products Officer after the premises has a compliant 51 sample moving window or at the direction of the Director-General.

4.14 *Campylobacter* Performance Target (CPT) for young chickens

(1) The *Campylobacter* Performance Target (CPT) consists of 2 regulatory limits requiring *Campylobacter* testing of chicken carcass rinse samples over set processing periods as follows:

a) Standard throughput premises: 3 samples must be taken per processing day. Each of the 3 samples must be collected at a separate randomly selected sampling time. A processing period is 5 days processing equalling a total of 15 samples; and
b) VLT premises: 3 samples on a single randomly selected processing day of a processing week must be randomly selected. These 3 samples make up the processing period.

(2) The moving window is defined as 3 processing periods. The addition of the samples of the latest processing period displaces the samples of the oldest processing period.

(3) A "not detected" *Campylobacter* result will be recorded as 2.00 $\log_{10}$CFU/carcass on the NMD database.

(4) Two CPT regulatory limits are used to determine compliance over each moving window:

a) number of samples with a *Campylobacter* enumeration (count) of greater than 6000 CFU/carcass, 3.78 $\log_{10}$CFU/carcass; and
b) number of positive samples: those samples with a result of 2.30 $\log_{10}$CFU/carcass or higher representing *Campylobacter* detection.

(5) The Enumeration Target is as follows:

a) Standard throughput premises: for no more than 6 out of 45 individual carcass rinse samples taken from a 3 successive processing periods' moving window to have *Campylobacter* counts greater than 6000 CFU per carcass (3.78 $\log_{10}$CFU/carcass); or
b) VLT premises: for no more than 1 out of 9 individual carcass rinse samples taken from a 3 successive processing periods' moving window to have *Campylobacter* counts greater than 6000 CFU per carcass (3.78 $\log_{10}$CFU/carcass).

(6) The Detection Target is as follows:

a) Standard throughput premises: for no more than 29 out of 45 individual carcass samples taken from a 3 successive processing periods' moving window to have *Campylobacter* counts of 2.30 $\log_{10}$ CFU/carcass or greater; or
b) VLT premises: for no more than 5 out of 9 individual carcass samples taken from a 3 successive processing periods' moving window to have *Campylobacter* counts of 2.30 $\log_{10}$ CFU/carcass or greater.

Guidance Example CPT sampling requirements (routine processing)		
Sampling period	Standard throughput premises	VLT premises
A moving window of 3 processing periods	45 samples over 15 processing days	9 samples over 3 weeks

4.14.1 New start-up premises

(1) New start-up premises operators must collect NMD samples each processing day that young chickens are processed as per standard throughput premises operators until there has been a clear moving window.

(2) New start-up premises operators must maintain this increased frequency of sampling until a complying *Campylobacter* moving window has been achieved. Following this, the operator must commence the VLT sampling programmes as specified in clause 4.2.1.

Guidance as to MPI's response

- If the *Campylobacter* results remain non-compliant and validation of the process conducted under the new RMP remains in question, the Director-General may impose additional measures and, if necessary, sanctions under a Notice of Direction under the Act.

4.14.2 CPT non-compliance

(1) The 2 regulatory limits for CPT non-compliance for young chickens are enumeration failure (EF) and detection failure (DF).

(2) An EF will be generated upon detection of a value greater than 6000 CFU per carcass (3.78 $\log_{10}$CFU/carcass) in:

a) Standard throughput premises: 7 or more out of 45 individual carcass samples taken from a 3 successive processing periods' moving window; or
b) VLT premises: 2 or more out of 9 individual carcass samples taken from a 3 successive processing periods' moving window.

(3) A DF will be generated upon a result of 2.30 $\log_{10}$ CFU/carcass or greater in:

a) Standard throughput premises: 30 or more out of 45 individual carcass samples taken from a 3 successive processing periods' moving window; or
b) VLT premises: 6 or more out of 9 individual carcass samples taken from a 3 successive processing periods' moving window.

(4) If the premises has an EF, a DF, or both for a moving window, it is counted as one non-compliant window. Responses to CPT escalate according to the number of consecutive non-compliant moving windows.

(5) To clear the non-compliance, a moving window without an EF and without a DF is required. The database then resets to zero to show that the premises is compliant.

Guidance

- A non-compliance will be recorded in the database as soon as the non-compliance becomes evident (which may be before the results from all samples for that moving window have been entered). This enables corrective actions to be initiated at the earliest opportunity.

4.14.3 Required responses to CPT non-compliance

(1) The operator must ensure that the NMD results for the premises are checked at least once every processing period to determine whether or not the premises has met the CPT.

(2) The operator must ensure that the verifier is notified within 24 hours of determining each non-compliant moving window.

(3) Responses escalate with each consecutive non-compliant moving window. With each non-compliant moving window the investigations, corrective actions undertaken and further actions planned to restore control must be documented by the operator. With consecutive non-compliant moving windows the following responses must be undertaken:

Number of consecutive CPT non-compliances	Responses required to consecutive CPT non-compliances
1	Within 1 week of non-compliance 1, and any successive consecutive CPT non-compliances reported in the NMD:

	• the NMD controller must notify the operator and the verifier, who will inform MPI nominated managers/technical persons; and • the operator must investigate and initiate corrective actions to restore control.
2	As soon as a 2nd consecutive CPT non-compliance is reported in NMD: • the NMD controller must notify the operator, and within 1 week: • the operator must document the investigations done, corrective actions taken to date and further actions planned to restore control; and • the operator must report this information to the verifier. Guidance If the premises verifier or an MPI manager/technical person is not satisfied that the actions are appropriate they may notify the Director-General who may require an immediate response as per the response required for 7 consecutive CPT non-compliances.
3	As for CPT non-compliance 2
4	As for CPT non-compliance 3
5	As for CPT non-compliance 4
6	As for CPT non-compliance 5; and • the operator must also document any product disposition options they could implement in order to minimise the risk of contaminated product reaching the consumer; and • the product disposition options must be provided to the MPI-assigned premises verifier within 1 week of CPT non-compliance 6 status.
7	Proceed as per CPT non-compliance 6 unless a *Campylobacter* Response Team (CRT) visit is authorised by the Director-General. If a CRT visit is authorised by the Director-General, the CRT Leader must: • notify the operator at least 24 hours before the intended visit; and • visit to investigate suitability of actions being undertaken by the operator to address the non-compliance at the first available opportunity by: a) reviewing all actions to date and recommending to the operator corrective actions necessary to bring the premises into compliance; and b) if the CRT Leader considers appropriate (in his or her discretion), recommend to the Director-General the application of sanctions under section 89 of the Animal Products Act 1999 to protect the consumer. If a CRT recommends corrective actions the operator must: • implement the corrective actions recommended by the CRT Leader; or • implement the corrective actions recommended by the CRT Leader and provide other evidence to the Director General demonstrating compliance; or • provide evidence to the Director General demonstrating compliance. The verifier will review the operator's actions and report to either: • MPI manager/technical person if a CRT visit was not required; or • CRT Leader if a CRT visit took place.
8	The Director-General may apply sanctions under the Act to protect the consumer.

Guidance as to MPI's response

- The sanctions may include, but are not limited to, one or more of the following:
  a) visit(s) by the CRT and implementation of any actions / recommendations of the CRT
  b) increased frequency verification
  c) full-time supervision of processing
  d) introduction of further interventions
  e) product disposition

f) further sampling and research initiatives
g) premises closure.

- If any of the above sanctions are applied they will remain in place until revoked by an Animal Products Officer after the premises has a compliant 51 sample moving window or at the direction of the Director-General.

4.15 Prevalence Performance Target (PPT) for *Campylobacter* in young chickens

(1) The Prevalence Performance Target (PPT) is for *Campylobacter* to be detected in less than 30% of the samples taken from young chickens and tested under this notice for the quarter.

(2) This clause applies to an operator of a standard throughput premises that processes young chickens if, at the close of a quarter, the operator does not meet the PPT for the quarter.

(3) For the purposes of Animal Products (Risk Management Specifications) Notice 2008, the PPT is deemed to be a regulatory limit.

(4) An operator must:

a) provide a verifier with a written initial report within 15 days from the last day of the quarter that identifies the reasons why the operator did not meet the performance prevalence target; and
b) provide a verifier with a plan (the implementation plan) within 30 days from the last day of the quarter that:

i) details actions that address the reasons identified in paragraph (a); and
ii) provides a date by which each action will be completed; and
iii) provides for checks by the operator to test whether the implementation plan will enable the performance prevalence target to be met in the future.

(5) The operator must take the actions mentioned in the implementation plan within 90 days from the last day of the quarter, unless otherwise agreed with the Director-General.

Appendix: Verification and MPI carton seals

This appendix is not part of the Animal Products Notice, but is intended to provide more information.

Verification requirements

The recognised verifier will verify that the operator complies with this notice twice per year.

For each verification, the verifier will:

- observe the sample selection protocol carried out by the operator; and
- observe the collection of samples; and
- observe the handling of samples to ensure temperature control and identity of the samples is maintained; and
- confirm that the operator has a system in place to ensure that all required samples are collected, including *Salmonella* and post-chill sampling, if required; and
- review historical results and actions relating to any alerts.

MPI carton seal or intervention seal

The verifier will apply an MPI carton seal or intervention seal to the set of NMD samples observed as part of verification to permit a check with the receiving laboratory to verify that sample handling and testing comply with NMD requirements.

When samples with an MPI carton seal arrive at the laboratory, in addition to the NMD sample receipt information the laboratory will record the number of the carton seal and whether the carton seal or intervention seal was intact or not.

Samples that arrive with a carton seal or intervention seal that is not intact will be deemed unsuitable for testing. This will be reported by the laboratory to the Director-General.