TABLE OF CONTENTS

H.1 Introduction

The generic protocol is a tool to facilitate the acceptance by regulatory agencies and the incorporation by establishments registered under the Meat Inspection Act and Regulations of new technology or procedures. It specifies the basic tests and the resulting data which are required to permit an evaluation based on science. The generic protocol may need to be customized for specific plant situations. Examples of procedures which may be tested under the protocol; on-line or off-line reprocessing, reuse of chiller overflow water, reconfiguration of evisceration line(s) potentially affecting defect detection or carcass bacteria counts.

H.2 Prerequisites

The proposed test and control operation(s) must operate under a HACCP (Hazard Analysis Critical Control Point) system (prerequisite programs and HACCP plan), acceptable to the Canadian Food Inspection Agency (CFIA), and demonstrate continuous process control, e.g. meet Finished Products Standards (FPS), for the associated establishment to be eligible to participate as a pilot plant under the generic protocol.

H.3 Scope

Proposed changes with potential to have a negative impact on one or more of the following areas must be evaluated by the protocol;

- pathogen count and faecal contamination,
- defect detection relating to postmortem judgment,
- defect detection and their removal.

Operations throughout an establishment may be proposed for a pilot project e.g. live hanging, scalding/defeathering, evisceration, chilling, cut-up/boning, packaging, etc.

H.4 Appeal Mechanism

Whenever there is doubt as to whether a proposed change requires evaluation under this protocol, industry or inspection staff may refer the proposal to the Chief, Poultry Inspection Programs, for a decision following consultation with technical specialists.

H.5 Application Procedure

A submission containing the following items is to be provided to the Veterinarian-In-Charge (VIC);

- a detailed protocol fully describing the proposed operation(s) including a complete experimental design for a pilot project including information referenced in the section titled Experimental Design;
- amended blueprints with facilities and equipment in compliance with Ch. 2;
- description of how process control will be demonstrated based on visual observations and the charting of microbiological test results(refer to section titled Pass/Fail Criteria);
- assurances that the company understands it must perform or pay for all laboratory tests as well as the statistical analysis of the data;
- assurances that the company will supply trained, competent personnel (refer to section titled Employee Competence);
- specify the laboratory to be used and give assurances that the bacteriological test methods and media are listed as an Official Method of Analysis by Health Canada (HC) or by the Association of Official Analytical Chemists (AOAC), International. Indicate if the lab is accredited, and if not, include assurances that the company will provide full access to CFIA to the lab to monitor applicable procedures and test results (refer to section titled Laboratory Accreditation).

The Veterinarian-in Charge (VIC) shall review the submission to ensure all required information has been provided. If judged complete, the submission, including a covering letter from the VIC indicating any concerns shall be referred to the Regional Program Manager, Meat Products for his/her input and transmission to the Chief, Poultry Inspection Programs, Meat and Poultry Products Division (MPPD). The pilot project may only commence after the plant receives a letter of authorization from the MPPD. New procedures or processes which may impact on food safety will be copied to Health Canada (HC).

Control tests may commence before receipt of the letter of authorization provided the VIC agrees to monitor the procedures. However, additional tests or procedures may be required to complete the experimental protocol if it is amended by the MPPD.

H.6 Policy Development

Generally, three(3)- five(5) replications should be adequate to provide sufficient information for related policy formulation including any required control procedures and associated standards or operational guidelines to be included in the Meat Hygiene Manual of Procedures (MOP). Published reports and confidential information submitted by industry will be considered when determining the number of pilot projects required by the Chief, Poultry Inspection Programs, prior to amending the MOP.

A draft of the proposed policy will be circulated for comments to all appropriate groups (including HC).

Confidential projects will be treated as information which is plant specific (i.e. not to be published) until it becomes evident that several establishments have conducted similar pilot projects at which time policy formulation will be initiated.

H.7 Experimental Design

The effect of the proposed change must be demonstrated by collecting control and treatment samples according to an experimental design approved by MPPD and conducted as a pilot project under the oversight of CFIA.

The following are suggested options:

- complete all control sampling, then collect all the treatment samples;
- split each test lot in half, collect the control samples, affect the change, and then collect the treatment samples (repeat for the required number of lots);
- randomly split carcasses from the same lot between two similar processing (e.g. evisceration) lines (one line changed to function as treatment line) operating simultaneously in the same plant.

The proposed experimental design must include the following information:

- current and proposed flow chart of affected and related operations including sampling locations;
- description of how control and treatment phases will be accomplished (see listed options above).

H.8 Employee Competence

Applicable employees must be trained to facilitate the proposed change. Personnel must be accredited where required for specified functions e.g. pre-selection, presenter/detectors, reprocessing, FPS testing. A written training program and employee training records must be on-site and readily accessible for auditing by the CFIA.

H.9 Sampling Location

For microbiology tests, carcasses shall be collected as specified in the USDA's Pathogen Reduction/HACCP regulations i.e. minimum of 1/22,000 chickens, 1/3,000 turkeys, although the sampling location may be changed to suit the needs of the experiment.

Sampling should be conducted such that the test results can also be credited towards fulfilling export requirements for the U.S. The experimental protocol shall define a precise location for collection of the sample(s) for each test.

The sample location for prevalence testing for carcass defects (if required) and tests for monitoring the detection of internal cavity defects shall be determined in consultation with the Chief, Poultry Inspection Programs, for pilot projects which involve reconfiguration of the evisceration line. Otherwise, carcasses will be selected:

- downstream from team of establishment carcass/cavity/viscera detectors; and
- before or after establishment helper/trimmer; and
- before viscera is harvested (or discarded) or the carcass is trimmed (other than by the helper/trimmer) and before the carcass is vacuumed.

H.10 Microbiology Tests

NOTE: refer to Chapter 11, export requirements for the United States, for full details on sample selection and processing for bacteriology (E. coli) testing.

Samples are to be randomly selected and handled using sterile technique.

Bacteria counts shall be determined using the carcass rinse technique (Butterfield's phosphate diluent (BPD), 400 ml for chickens, 600 ml for turkeys or by other procedures mandated by CFIA (e.g. swabbing for Turkey carcasses). Rinsing with the diluent may occur in a compatible area of the plant or alternatively, the carcass may be transported to the lab for the rinsing.

Samples (carcasses or rinse fluid) must be refrigerated to 40C or lower (but not frozen) until analyzed (on-site) or packaged for shipping. Shipped samples shall be packed in insulated containers containing ice packs so as to maintain a carcass surface temperature of between 0 and 7oC during (overnight) transport to the lab.

Microbiology tests must commence within 24 h of sample collection and with approximately the same time interval between collection and laboratory processing for all samples.

Total E. coli count per ml or cm2 shall be determined to serve as an indicator of faecal contamination.

Total Plate Count (TPC) should also be determined for each carcass to serve as a confirmatory test for the effect of the proposed change on process hygiene and to provide an indicator of shelf-life.

Domestic policy and international trade considerations may require federal establishments to demonstrate a pathogen reduction (program) based at least on Salmonella sp.

Testing for specified pathogens such as Salmonella sp and/or Campylobacter sp. will be a requirement after development and international acceptance of economical enumeration tests.

Presence or absence for specified pathogens shall be performed whenever it is determined by the Chief, Poultry Inspection Programs, in consultation with technical experts (including HC), that the proposed procedure may favour the growth of, or selective survival of, particular pathogen(s), or when deemed necessary to facilitate international acceptance of new or novel inspection methods, processes, or technology.

H.11 Laboratory Accreditation

Pilot projects for processes/procedures which have been published in peer reviewed journals will usually not require an accredited laboratory as determined by the Chief, Poultry Inspection Programs. However, new, unpublished procedures, may require the use of an accredited lab if required to facilitate international acceptance (and favourable export markets) as determined by MPPD or if requested by HC or CFIA to resolve food safety concerns, particularly for any required bacterial tests for foodborne pathogens.

Laboratories accredited by a federal, provincial or US government agency for the specific bacteriology test(s) or by an internationally recognized registrar e.g. Canadian Standards Council (CSC), will be considered as accredited for the GENERIC PROTOCOL. Laboratories of the federal or provincial governments and Universities will be recognized as having equivalent to accredited status for this protocol. Establishments wishing recognition of their in-plant laboratory require a Quality Management System (QMS) for the lab, equivalent to that required for government (HC/CFIA) accreditation. A submission should be made to the Chief, Foodborne Pathogens, CFIA, for his/her evaluation. One or more on-site review(s) by the Chief or his/her delegated representative(s), at the plants' expense, will be required for recognition as equivalent to accreditation status for the purposes of this protocol.

Non accredited laboratories must be included within the plants' prerequisite programs, as part of their HACCP system, and be accessible to CFIA staff (for auditing the applicable test procedures, records and equipment) to qualify for use under this protocol. If remotely located from the plant, the company must provide assurances of unrestricted access to CFIA staff and to pay for CFIA audit expenses on a fully cost recovered basis.

NOTE: Upon completion of the pilot project under the GENERIC PROTOCOL, an accredited lab is no longer required. Ongoing microbiological testing is to be performed in the laboratory specified by the plant's HACCP system.

H.12 Sample Size

NOTE: this section describes test requirements for pilot projects which consistently remain in compliance with all program requirements and standards including monitoring tests for the detection of internal cavity defects and pre-chill FPS tests as described in Annex D of this chapter. Refer to section titled Pass/Fail Criteria for corrective action, including additional test requirements, whenever ongoing testing fails to indicate that the tested process is still under control.

Whenever a Canadian national standard does not exist, then a plant specific standard must first be established by collecting samples during a control period conducted over the same period of time as planned for the treatment phase of the pilot project.

Various studies have found that the greatest source of experimental variation is commonly between carcasses from the same lot processed under what appears to be similar conditions. However, a significant source of variation may be between the producers or lots. Therefore, sampling for tests should be spread over at least 30 lots and 20 producers for control samples and again for treatment samples or over a minimum of 20 lots or producers if collected as paired samples. Testing for defects shall continue throughout the control and treatment phases of the pilot project.

H.12.1 Microbiology tests; (Total E. coli counts)

100 control and 100 treatment carcasses if collected as before and after samples (design option i.);

50 paired samples if control and treatment samples collected from same lot in same time period (design option ii.), if experimental design and process controls considered valid by consulted technical experts, and for option iii..

Using a 95% confidence limit and 80% power, and assuming a pooled variance of 0.58, a sample size of 100 carcasses was calculated as sufficient to detect a 0.3 log10 mean E.coli count difference between the control and treatment groups.

H.12.2 Defect detection and removal

FPS pre-chill tests and postchill tests

H.12.3 Defect non detection rate

Monitoring tests for internal cavity defects are described in section 19.6.2 of this chapter.

If a process is not covered by this GENERIC PROTOCOL or Chapter 19, sample selection and frequency shall be specified by the Chief, Poultry Inspection Programs.

H.12.4 Prevalence of defective carcasses requiring veterinary judgment

Only required for proposed changes which have potential to affect evidence of generalized disease of a public health significance in carcasses prior to postmortem detection/inspection.

Required tests are to be performed by the government inspection staff. The Veterinarian-in-Charge (VIC) shall ensure that postmortem detection/inspection is not compromised. Unusual situations which might affect Veterinary disposition are to be referred to the VIC throughout the prevalence testing. The Operations Director must agree to provide the staff to perform the tests. The evaluator and scribe require training to correlate their judgment for the test with national policy/interpretation. The need for the test will be determined by the Chief, Poultry Inspection Programs, in consultation with technical experts, in particular, the Chief, Epidemiology Risk Analysis. If applicable, they will provide the sample size and a detailed sampling protocol for each prevalence test.

In general, for a plant with two similar evisceration lines and permitting paired sampling (e.g. inspector rotates to the other line every "X" min. and spends approximately the same amount of time on each line for each lot), a total of 14,000 carcasses should be evaluated i.e. 700 carcasses/day X 20 days and 7,000 carcasses/line. However, if the testing can be replicated in a second plant, (also with two lines) to facilitate statistical analysis, then 7,000 carcasses should be collected from each plant over 10 working days i.e. 700 carcasses/day X 10 days and 3,500 carcasses/line X 4 lines, again for a total of 14,000 carcasses.

Using a 95% confidence level, an 80% power, a one (sided) tailed test, and an estimated national prevalence rate of 1.2%, a sample size of 14,224 was calculated as sufficient to detect a 0.3% difference (drop) in the number of carcasses with visible evidence of disease or conditions (at the postmortem detection/inspection stations) and which require removal from the line for veterinary disposition.

H.13 Pass/Fail Criteria:

H.13.1 Testing while in Compliance:

H.13.1.1 Microbiology tests

If a plant specific standard is required, the results from control samples shall be analyzed to calculate required values for the control chart as selected for use during the treatment phase. Bacteriology counts for treatment carcasses shall be plotted on a control chart e.g. Shewart, Cusum or as illustrated in the USDA's Pathogen Reduction/HACCP regulations as outlined in Chapter 11, section on export requirements for the United States.

Treated carcasses may be sold as "edible" if the plant provides evidence satisfactory to the CFIA that product complies with all regulatory requirements. Treatment carcasses will be deemed to be in compliance whenever test results comply with the predetermined acceptance/rejection limits as specified in the application for the pilot project (see section titled Application Procedure) e.g. if using the Shewart Control Chart, then no bacteria count from a treatment carcass may exceed the Upper Control Limit (UCL) or if using the chart from the USDA's Pathogen Reduction/HACCP regulations (1996), a moving window of the last 13 tested carcasses must indicate that no more than 3 exceeded the marginal value (little m) and none exceeded the fail value (large M).

H.13.1.2 Defect detection and removal

Shall be deemed to be in compliance whenever product rework is not required e.g. under FPS pre- chill tests.

Defective carcass detection and removal-shall be deemed to be in compliance whenever line speed reductions are not required as a result of the tests performed to monitor the detection and handling of defective carcasses by plant employees.

H.13.2 Corrective Action:

Whenever a bacteria count exceeds the fail/rejection limit and/or treated carcasses must be reworked under the FPS program and/or the linespeed must be reduced due to ineffective carcass detection by plant employees, then the cause must be determined, corrective action taken (including possibly amending the treatment protocol or implementing a CCP to improve process control). The treatment period counter must then be reset to zero i.e. start all over again. The Chief, Poultry Inspection Programs shall be copied all relevant information and may terminate a pilot project for repeated failure i.e. 2 or more resets to zero.

H.13.3 Acceptance By CFIA:

Statistical analysis of the data must indicate that the proposed change (treatment) either exceeds or at least maintains the then current CFIA standard(s) for whichever of the following items were included in the pilot project:

- pathogen count (if specified by CFIA) and total E. coli counts as an indicator of faecal contamination,
- defect detection relating to postmortem judgment,
- defect detection and their removal (e.g. FPS testing including compliance with "zero tolerance" for visible evidence of faecal contamination).

H.14. Records, ATIP and Auditing:

Data and associated statistics analysis will be considered as confidential and is only to be released under ATIP (Access to Information Procedures) in a summarized generic format (e.g. plant A, plant B, etc.) such that test results cannot be identified to a specific originating establishment.

Upon completion of analysis and review by MPPD, all copies of raw data are to be returned by the CFIA to the plant(s) of origin.

The following records shall be stored on-site by plant management and be readily accessible for review by the VIC and government auditors:

- complete submission and corresponding letter of authorization from MPPD;
- all raw data (e.g. completed forms, test results);
- records of ongoing monitoring and verification tests and other procedures for the retention period specified in the associated policy section of the appropriate CFIA manual (e.g. MOP, FSEP (Food Safety & Enhancement program)).