CHAPTER 3, SUBJECT 5
FSEP/QMP AUDIT POLICY FOR MULTI-COMMODITY ESTABLISHMENTS

1.   **SCOPE**

This policy outlines the procedures for integrating audits
of the Food Safety Enhancement Program (FSEP) and the
Quality Management Program (QMP). It is intended to be
applied in establishments which are federally registered
under the *Fish Inspection Regulations* and the authority of
another Act or Regulation administered by the Canadian Food
Inspection Agency (CFIA).

2.   **REFERENCES**

Canada Agricultural Products Act
Dairy Products Regulations
Processed Products Regulations
Processed Egg Regulations
Fish Inspection Act
Fish Inspection Regulations
Meat Inspection Act
Meat Inspection Regulations
FSEP Verification Policy
FSEP reference manuals
Facilities Inspection Manual (Fish Inspection Program)
Manual of Procedures (Meat, Dairy, Processed Products,
Processed Eggs)

3.   **DEFINITIONS**

"HACCP": means Hazard Analysis Critical Control Point - a
systematic approach to the identification and assessment of
the hazards and risks associated with a food operation and
to the identification of the means for their control.

"FSEP": means the Food Safety Enhancement Program -
described as a CFIA approach to encourage the development,
implementation and maintenance of HACCP systems in all
federally registered establishments excluding federally
registered fish establishments.

"QMP": means the Quality Management Program - a fish
inspection and control system which includes procedures,
inspections and records, for the purpose of verifying and
documenting the processing of fish and the safety and

quality of fish processed in Canada for export.

"Minor non-conformity": An isolated non-conformity within the sub-element of the prerequisite program, Regulatory Action Point, a CCP of the HACCP plan or other regulatory requirements being audited.

"Major non-conformity": A non-conformity that compromises the integrity of the HACCP system or may result in a fraudulent product.

4.   PREFACE

The intent of this policy is to provide the scope and procedures for conducting audits in multi-commodity establishments which are operating under the FSEP and the QMP. This policy seeks to be consistent with the existing audit criteria that are being applied to establishments operating with FSEP or QMP systems.

5.   BACKGROUND

During the early 1990's, HACCP systems were developed by two federal departments: Agriculture and Agri-Food Canada developed the Food Safety Enhancement Program (FSEP) and the Department of Fisheries and Oceans developed the Quality Management Program (QMP)

The creation of the CFIA merged the departments; however the two HACCP systems remain. FSEP continues to be utilised in the recognition and auditing of HACCP systems for agricultural commodities, and the Fish Inspection Program continues to implement the QMP. This resulted in two separate system evaluations being conducted by CFIA staff in an establishment registered under the Fish Inspection Regulations with a QMP, that also had FSEP for other products such as meat, dairy or processed fruits and vegetables.

FSEP and QMP share similar requirements for prerequisite programs and HACCP plans. The requirements of the FSEP prerequisite program meet the requirements of the QMP prerequisite program. Both programs require the implementation of regulatory action points (RAP) (note that RAPs are dependent on program requirements as described in their respective manuals). Also, both programs use the 7 principles of HACCP.

The policy will serve to satisfy five purposes:

- ▸ eliminate duplication of audit activities;
- ▸ improve utilisation of CFIA resources;
- ▸ provide a uniform approach to auditing HACCP systems;
- ▸ complete recognition and the partial audit for FSEP; and
- ▸ complete the compliance verification for QMP.

6.   POLICY

6.1   General

The goal of this policy is to provide procedures for auditing the FSEP and the QMP simultaneously, while maintaining the requirements for both programs. The audit policy will provide the establishment with a consistent and uniform approach toward auditing, reporting of results, and expectations of corrective actions.

This policy will be applied to the following scenarios:

a)   An establishment that has been FSEP recognized and is operating under QMP.

b)   An establishment that is undergoing FSEP recognition and systems verification of the QMP at the same time. *Note: the systems verification will be completed independently by the QMP Auditor if the recognition process is not progressing in a timely manner. The certificate of registration issued under the authority of the Fish Inspection Regulations will not be issued until the systems verification has been completed.*

c)   An establishment which has been FSEP recognized and has now applied for registration under the Fish Inspection Regulations (QMP). In this case, the QMP Auditor will evaluate the RAPs and the fish HACCP plan(s).

d)   An establishment that is registered under the Fish Inspection Regulations (QMP) and has now applied for FSEP recognition. *Note: the compliance verification will be completed independently by the QMP Auditor if the recognition process is not progressing in a timely manner.*

6.2   Record Keeping

Establishments must comply with the most stringent record-keeping requirements as outlined in FSEP and QMP (i.e., records must be kept for all monitoring activities in prerequisite programs as required by the FSEP). For RAPs within the QMP, records by exception are permitted (i.e., when a deficiency is identified, the establishment is required to record the deficiency and the corrective action taken).

7.   PROCEDURES

The existing FSEP and QMP policies and procedures are to be applied during the audit. Audit criteria and documentation that are similar in nature have been combined. Requirements that are specific to each program have been added to the scope of the audit. Every effort should be made to share results between programs and to avoid duplication of tasks (i.e., plant profile completed by responsible inspector should be shared with QMP auditors).

7.1   Documentation

1.   When an FSEP recognition is conducted in conjunction with a QMP Compliance Verification (CV), the following forms (see Appendices) are to be used:

   ▸   FSEP/QMP Audit Scope Worksheet
   ▸   Opening Meeting Checklist for FSEP/QMP Audits
   ▸   FSEP/QMP Prerequisite Program and RAP Worksheet
   ▸   FSEP/QMP HACCP Plan Worksheet
   ▸   FSEP/QMP Corrective Action Request
   ▸   FSEP/QMP Audit Exit Report
   ▸   Exit Meeting Checklist for FSEP/QMP Audits

2.   When an FSEP partial audit is conducted in conjunction with a QMP CV the following forms (see Appendices) are to be used:

   ▸   FSEP/QMP Audit Scope Worksheet
   ▸   Opening Meeting Checklist for FSEP/QMP Audits
   ▸   FSEP/QMP Prerequisite Program and RAP Worksheet
   ▸   FSEP/QMP HACCP Plan Worksheet
   ▸   FSEP/QMP Corrective Action Request
   ▸   FSEP/QMP Audit Exit Report
   ▸   Exit Meeting Checklist for FSEP/QMP Audits

3.   When an FSEP verification is conducted in conjunction
      with a QMP CV, the following forms (see Appendices)
      are to be used:

      ▸   FSEP/QMP Audit Scope Worksheet
      ▸   Opening Meeting Checklist for FSEP/QMP Audits
      ▸   FSEP/QMP Prerequisite Program and RAP Worksheet
      ▸   FSEP/QMP HACCP Plan Worksheet
      ▸   FSEP/QMP Corrective Action Request
      ▸   FSEP/QMP Audit Exit Report
      ▸   Exit Meeting Checklist for FSEP/QMP Audits
      ▸   RAP Worksheet of the FSEP Manual, (to be
           used by FSEP auditor)(not included in
           Appendices)

7.2   Audit Team

The auditor(s) must have the appropriate FSEP and/or QMP
training and be designated under the relevant regulations.
The audit team should hold a pre-audit meeting to plan the
audit (e.g., scope of the audit, checklist, time frames
etc.). This could be done in person, by telephone or
through e-mail.

7.3   Audit Scope

The scope for each audit will be comprised of the following
items to ensure that all required elements are covered as
per QMP and FSEP requirements:

▸   Open Corrective Action Requests (CARs)
▸   Log book entries
▸   CCPs from selected HACCP plans
▸   Random selection of pre-requisite programs with a
     possibility of targeting

The audit scope will also include those FSEP and QMP tasks
that are not audited on every visit but must be completed
within a series of audits (i.e., Regulatory Action Points,
HACCP plan review tasks, Background Product and Process
information, Verification/Validation, and Record Keeping
requirements).

Auditing techniques and methodology will be implemented
using the existing FSEP and QMP requirements (based on ISO
standards). The FSEP/QMP Audit Scope Worksheet will be
utilized to record the scope of the audit as described in
the policies and procedures of the *Facilities Inspection
Manual* and *the FSEP Manual.*

7.4   Non conformities

For the purpose of this policy, non-conformities will be
identified to the establishment as either minor or major as
per the FSEP Manual. Generally, the critical non-conformity
from the QMP will be equivalent to a major non-conformity,
and a non-conformity from the QMP will be equivalent to a
minor non-conformity from the FSEP.

To provide clarification on classifying non-conformities,
fraud related non-conformities within the authority of the
Fish Inspection Regulations will be rated as major but will
not have an affect on the Partial Audit Flow Diagram outlined
in the FSEP Manual. Repetitive non-conformities related to
the *Fish Inspection Regulations* may result in enforcement
action as described in Chapter 3, Subject 3 of the *Facilities
Inspection Manual* and the FIP Compliance Management Process.

Deficiencies identified in an establishment's written
program may result in a non-conformity (QMP) or an
incomplete (FSEP). In either case, the establishment would
be responsible for amending their written program.

Non-conformities identified in one program must be shared
with the auditor from the other program due to possible
implications they may have on the other program. This
includes non-conformities identified during FSEP
Verification when the QMP auditor may not be present.

Establishments may appeal audit results to the Regional
Director within 30 days of the decision that is being
appealed.

7.5   Data Entry

For the purposes of tracking in CFIA information systems
(i.e., Multi-commodity Activity Program (MCAP)), FSEP/QMP
joint audits will be considered as two separate and
distinct audits that will be captured in MCAP Audit for
both the FSEP and QMP, when available.

When a non-conformity is identified, the CAR will reference
the affected program (QMP, FSEP or both programs). Those
non conformities identified with QMP or both programs will
be recorded in the MCAP - Fish Component as either a non-
conformity or a critical non-conformity as defined by the
Facilities Inspection Manual.

8.   **FREQUENCIES OF AUDITING**

In multi-commodity establishments, FSEP audits will be conducted at a frequency outlined in the FSEP Manual and QMP audits will be conducted as outlined in the Facilities Inspection Manual. The FSEP/QMP Audit for Multi-Commodity Establishments Policy will be implemented when a compliance verification coincides with an FSEP partial audit.

The coordination of audits will be the responsibility of Area/Regional Operations and should consider the schedule of the plant, products being processed and the availability of CFIA personnel.

8.1   **FSEP Verification**

FSEP verification will be applied as per the FSEP Verification Policy. Based on trade requirements for meat, the responsible inspector is required to be present in the establishment for two to three days per week. The audit scope, as outlined in the FSEP Manual, will be delivered over the course of a month instead of a consecutive two to three day period as per the Regulatory System Partial Audit procedures.

FSEP Verification presents a new challenge for the scheduling process in that QMP Compliance Verifications have been traditionally conducted over a 2-3 day period. It will be the responsibility of the FSEP contact person to communicate to the QMP Auditor in each of the Areas as each multi-commodity registered establishment initiates FSEP Verification. Communication between the FSEP and QMP Auditors is essential.

The seven elements of the QMP must be evaluated during a two or three year planning cycle through a series of audits. The scope of these audits may vary from one task to many tasks. Due to this flexibility in delivery, CVs can easily be coordinated with FSEP Verification audits by conducting many CVs, focusing on specific sections or elements of the Reference Standard.

The QMP Auditor and the FSEP Auditor will determine the audit scope. This will allow the QMP Auditor to decide if they will participate in any of the visits that are planned for the month, based on scheduling, production of fish products, and audit tasks that need to be covered in the QMP CV.

9.   **FORMS/DOCUMENTS**

Appendix A - FSEP/QMP Audit Scope Worksheet
Appendix B - Opening Meeting Checklist for FSEP/QMP Audits
Appendix C - FSEP/QMP HACCP Plan Worksheet
Appendix D - FSEP/QMP Prerequisite Program and RAP
              Worksheet
Appendix E - FSEP/QMP Corrective Action Request
Appendix F - FSEP/QMP Audit Exit Report
Appendix G - Exit Meeting Checklist for FSEP/QMP Audits

APPENDIX A

APPENDIX B

APPENDIX C

APPENDIX D

APPENDIX E

APPENDIX F

APPENDIX G