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

Appendix VII
FSEP/QMP Audit for Multi-Commodity Establishments Policy

Canada

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1 Scope

This document outlines the policy and procedures for integrating audits of the Food Safety Enhancement Program (FSEP) and the Quality Management Program (QMP). This policy is intended to be applied in an establishment which is 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 reference manual
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 identifying and assessing hazards and risks associated with a food operation, and defining the means of their control.

"FSEP": means 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.

"Non-conformity" : A non-conformity is a deviation identified during an audit that impacts on the integrity of the HACCP system and necessitates a written corrective action plan.

“Major non-conformity”: An incident putting food safety at risk, where the establishment has not taken effective corrective action and the CFIA takes regulatory compliance action on the product **or** failed to implement effective corrective action from a previously-identified non-conformity..

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 FSEP and QMP. This policy seeks to be consistent with the existing audit criteria that are currently 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 (FSEP) and the Department of Fisheries and Oceans (QMP).

When the CFIA was created, FSEP continued to be utilized in the recognition and auditing of HACCP systems, with the exception of the Fish Inspection Program which utilized the QMP. This resulted in two separate audit evaluations being conducted by CFIA staff in the same establishment despite the similarities of the two programs.

FSEP and QMP share similar requirements for prerequisite programs and HACCP plans. The criteria evaluated for the FSEP prerequisite programs were found to have met all of the needs associated with the QMP prerequisite programs. Both programs are based on the 7 principles of HACCP and use the Codex *alimentarious* decision tree to determine Critical Control Points (CCPs). Regulatory Action Points (RAPs) have been added to the Scope of the Audit in order to meet program and QMP requirements.

The policy will serve to satisfy five purposes:

- Eliminate duplication of audit activities
- improve utilization of CFIA resources
- provide a uniform approach to auditing HACCP systems
- Complete recognition and the regulatory system audits for FSEP
- Complete the compliance verification for QMP

6 Policy

6.1 General

This policy will satisfy the requirements of FSEP and QMP while achieving the goal of auditing the two food safety systems simultaneously. The audit policy will provide the establishment with a consistent and uniform approach to auditing and to the reporting of results and expectations of corrective actions.

This policy will be applied to the following scenarios:

- An establishment that has been FSEP recognized **or** licensed under the *Meat Inspection Regulations* sand is operating under QMP.
- 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.
- An establishment which has been FSEP recognized recognized **or** licensed under the *Meat Inspection Regulations* and has now applied for registration under the Fish Inspection Regulations (QMP). In this case, the QMP Auditor will evaluate the RAP's and the fish HACCP plan(s).
- An establishment that is registered under the Fish Inspection Regulations (QMP) and has now applied for FSEP recognition recognized **or** licensed under the *Meat Inspection Regulations* **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). For RAPs within the QMP, records by exception are permitted. When records by exception are permitted, records are only required when a deficiency is identified during the monitoring procedures. In these cases, the processor is required to record the deficiency and document on a corrective action record.

7 Procedures

The FSEP regulatory system audits and QMP regulatory verification policies and procedures are to be applied to evaluate the establishment's food safety and quality systems. Audit criteria and documentation that are similar in nature have been combined and those that are specific to each program have been added to the scope of the audit. Every effort should be made to share results in programs and to avoid duplication of tasks (i.e. Plant profile completed by responsible inspector should be shared with QMP auditors).

7.1 Documentation

Only the following documents are to be completed for the audit (Appendices A-H):

- FSEP/QMP Audit Scope Worksheet
- Opening Meeting Checklist for FSEP/QMP Audits
- FSEP/QMP Prerequisite Programs Checklist
- FSEP/QMP HACCP Plan Review Checklist
- FSEP/QMP Audit Worksheet
- FSEP/QMP Corrective Action Request
- FSEP/QMP Audit Exit Report
- Exit Meeting Checklist for FSEP/QMP Audits

7.2 Audit Team

The auditor(s) must have the appropriate FSEP and/or QMP training and be designated under the relevant regulations. If the audit team members include a QMP representative and an FSEP representative, a pre-audit meeting will be held to plan the audit (e.g., scope of the audit, checklist, time frames etc.).

7.3 Audit Scope

The audit 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 (CAR's)
- Log book entries
- CCP's from selected HACCP plans
- Random selection of prerequisite programs with a possibility of targeting
- Regulatory Action Points (RAPs)

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 and reassessment of the HACCP system review tasks, background product and process information, Verification/Validation, Record Keeping.
Auditing techniques and methodology are 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 FSEP Manual (chapter 4).

7.4 Non conformities

For the purpose of this policy, non conformities and major non conformities will be identified to the establishment as per FSEP Manual Chapter 4. Generally, the critical non-conformity from the QMP is equivalent to a major non-conformity.

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 Non-conformity Flow Diagram outlined in Figure 1. of the FSEP Manual, Chapter 4. Repetitive non-conformities related to the *Fish Inspection Regulations* may result in enforcement action as described in Chapter 3, Subject 3 and Chapter 7 of the Facilities Inspection Manual.

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

Should a non-conformity be identified in one program by an auditor, this information must be shared with the other auditor in order to determine if it impacts on the other program.

Establishments can appeal audit results to the Area FSEP/HACCP Coordinator and/or 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. 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 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, Chapter 4 and QMP audits will be conducted as per the Facilities Inspection Manual. The FSEP/QMP Audit for Multi-Commodity Establishments Policy will be implemented when a compliance verification coincides with an FSEP regulatory system 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.

FSEP/QMP Audit Scope Worksheet

Est. Name and # ___
Auditor:_____

Date:_____

Selected Task	Type of Task

Reference Type of Task: OC = Outstanding CAR; LB = Log Book; HP= HACCP Plan; PPS=Prerequisite Program Sub-element; HSR = HACCP System Review ; RAP = Regulatory Action Point, QMP RAP = Quality Management Program Regulatory Action Point; QMP PP = Background product and process information; QMPV - QMP Verification; QMP R = Record Keeping; QMP MR = Management Roles and Responsibilities

Appendix B

OPENING MEETING CHECKLIST FOR FSEP/QMP AUDITS

Date: _____ **Audit Reference # :** _____

Registered Establishment: _____

Registration # (s): _____

Introduce CFIA Team		**Record meeting attendance**	
Explain objective and scope		**Explain the audit procedures (methods/questioning/sampling)**	
Explain schedule		**Define non-conformities/classifications**	
Confirm establishment shift and break schedules		**Confirm meeting facilities, etc.**	
Check on confidentiality requirements		**Ask if there are any special safety requirements**	
Ask for the company logbook		**Ask establishment representatives if they would like to meet & discuss results each day**	
Confirm establishment representatives to accompany team		**Explain nature of reporting & follow-up**	
Agree on tentative time/date for closing meeting		**Invite senior establishment management to attend closing meeting**	
Comments/Notes: _____ _____ _____			
Signature of Lead Auditor(s) : _____			

Appendices C & D

- FSEP/QMP Prerequisite Programs Checklist - **Appendix C**
- FSEP/QMP HACCP Plan Review Checklist - **Appendix D**

Reference FSEP Manual; Appendix II (**Appendix C**) and Appendix IV (**Appendix D**).

FSEP/QMP Audit Worksheet

AUDIT TASKS (list in order of Audit Scope) • Outs. CARs • Log Book • CCPs • PP Sub-elements • HACCP system Review • RAPS	**INCOMPLETES** Note incompletes identified in the written program (“nil” if none identified)	**MONITORING/DEVIATION/VERIFICATION** **(Comments for HACCP Review Tasks, if applicable)** Note non conforming objective evidence identified during: - Past record(s) review; - Interviews; - On site observations. (“nil” if none identified)	**AUDIT FINDINGS** - Conformity - Audit observation - N/C - Major N/C (note CAR # if applicable)	**DATE/INITIAL** **(if applicable)** when: - amended written procedures were reviewed and found to be complete - CAR is closed

Date of Audit: _____ Lead Auditor _____ Establishment #: _____

Annexe F

FSEP Corrective Action Request

Establishment audited (Name, adresse & No.):	**Audit date:** **CAR#:** **Major ❑ N/C ❑ Amended ❑**

Part A: Non-conformity
Description of non-conformity:

Area of reference (applicable legislation):
Area of reference (Establishment's written program):

Auditor*: Date CAR is issued:

Date for submission of action plan (Part B):

Establishment representative*: **Date:**

Part B: Action Plan
B.1: Corrective actions:

Date for completion of corrective actions:

B.2: Preventative Measures:

Date for completion of preventative measures:

Establishment representative*: **Date:**

Part C: Follow-up
C.1: Written action plan assessment (Part B): Acceptable ❑ Not acceptable ❑

Auditor*: Date:

C.2: Follow-up comments:

CAR closed: Yes ❑ No ❑

Auditor*: Date:

* Print name below signature

FSEP/QMP AUDIT EXIT REPORT

Audit Reference # : _____

Registered Establishment:	**Report Date:**
Address:	**Registration # (s) :** **Exit Meeting Date:**
<u>Audit Scope</u>:	
Audit Team members: _____ _____ _____ _____	**(Signatures)** _____ _____ _____ _____
Corrective Action Requests Attached (numbers):	
Establishment Representatives (Print name and title) _____ _____ _____	**(Signatures)** _____ _____ _____
The signature(s) of the establishment's representative(s) above indicates their acknowledgement and understanding of the audit results.	
General Comments (Audit Findings and Conclusions):	

FSEP/QMP AUDIT EXIT MEETING CHECKLIST

Date: _____ **Audit Reference # :** _____

Registered Establishment: _____
Registration # (s) : _____

Chaired by Lead Auditor		**Record meeting attendance**	
		Restate scope & indicate if any changes	
		Review audit results	
Identify non-conformities and outline the objective evidence to support			
Explain that all non-conformities must be corrected		**Ask for any questions or concerns from establishment representatives/management**	
Negotiate reasonable time frame for establishment to submit Corrective Action Request, if applicable		**Explain follow-up procedures to assess Corrective Action Request**	
Establishment representatives to sign FSEP/QMP Audit Exit Report		**Copies of FSEP/QMP Audit Exit Report given to all present**	
Comments/Notes:			
Signature of Lead Auditor(s) : _____			