



Canadian Food
Inspection Agency

Agence canadienne
d'inspection des aliments

Appendix VIII

Mandatory FSEP/HACCP

Canada

Appendix VIII - MANDATORY FSEP/HACCP

For Establishments requesting a licence:

These establishments must submit a complete documentation package, as defined in the FSEP Manual, prior to beginning operations.

The “FSEP/HACCP Checklist for Establishment requesting a licence” must be used to ensure that the establishment has fully developed written prerequisite programs which can be implemented at start-up of operations. This must include a written review **of the following sub-elements:**

- A 4.1 - Water, Ice & Steam
- B 1.2 - Temperature Control
- C 1.2 - Equipment Maintenance & Calibration
- D 1.2 - Technical Training
- D 2.1 - Cleanliness & Conduct
- E 1.1 - Sanitation Program
- E 2.1 - Pest Control Program
- F 1.1 - Recall Program

This sub element review must ensure that the Meat Program requirements are met and are in accordance with Appendix VI of the FSEP Manual “Complete Written Program”.

The “FSEP/HACCP Checklist for Establishment requesting a licence” will also be used to ensure that the establishment has fully developed written HACCP Plan(s) which can be implemented at start-up of operations. This must include a written review **of the following:**

The HACCP Plan Form 10 or equivalent:

1. lists all CCPs identified on CCP determination form (Form 8 or equivalent)
2. includes critical limits for each CCP
3. includes monitoring procedures for each CCP
4. includes deviations procedures for each CCP
5. includes verification procedures for each CCP to demonstrate that the HACCP plan is implemented as designed
6. indicates records for each CCP for monitoring, deviation and verification procedures

Following the initial completion of the checklist, the auditors will take a copy of the following for review by the CFIA: establishment's HACCP plan(s); supporting validation studies; HACCP system reassessment procedures; and any reference material related to the HACCP plan(s).

The HACCP plan(s) must be fully developed and ready to be implemented at the time the establishment starts to operate. This requirement is part of the establishment's registration process as per the Meat Inspection Act and Regulations.

For an establishment that doesn't meet the requirements listed on the "FSEP/HACCP Checklist for Establishment requesting a licence" :

- A notification letter identifying deficiencies will be sent by the Area FSEP/HACCP Coordinator to the establishment management (Hand delivered or registered mail). The Area Program Network Director and the Regional Supervisor will be copied on this letter to add to the file of Program concerns for the establishment.
- Appropriate modifications must be corrected prior to receiving their license.

CFIA Office review of the HACCP plan(s).

- A notification letter identifying deficiencies will be sent by the Area FSEP/HACCP Coordinator, to the establishment management (hand delivered or registered mail).
 - The establishment will have 60 days from the date of issue of the notification letter to make appropriate modifications to its HACCP plan(s).
 - A follow-up visit will be conducted after the 60 day deadline to review amendments to the HACCP plans. A separate follow-up visit may be performed or the review of the amendments may be incorporated into the scope of the first regulatory system audit.

A regulatory system audit should be performed as soon as possible once the CFIA Office review of the HACCP plan(s) has been completed, however must not occur prior to the 60 day deadline.

New HACCP Plans:

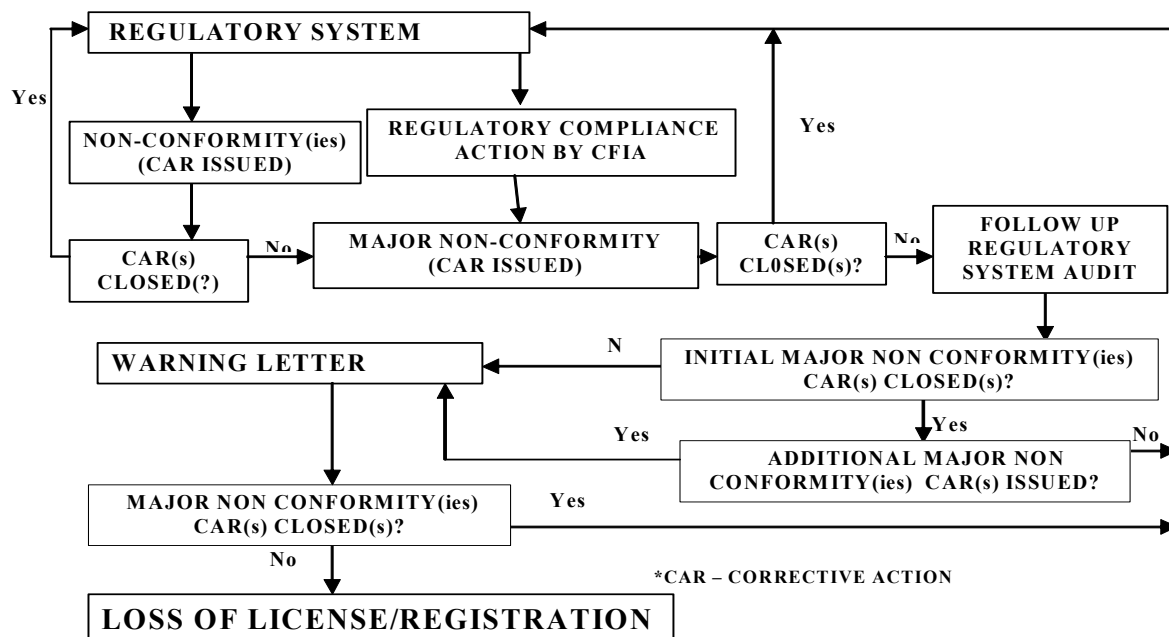
When an establishment develops a new HACCP Plan or product line, the actual review process of the new HACCP plan will follow the rules described in the FSEP Manual, Chapter 3.

Regulatory System Audit - Non-Conformity Flow Diagram:

The *Non-Conformity Flow Diagram* (see Figure 1) illustrates steps the Agency will take when a non-conformity is identified during a Regulatory System Audit. The steps include:

- A follow-up evaluation of corrective actions to close the CAR associated with the non-conformity(ies).
- A follow-up Regulatory System Audit if the major non-conformity(ies) cannot be closed. This audit is performed as soon as possible.
- A warning letter if the initial major non-conformity(ies) cannot be closed during the follow-up Regulatory System Audit or if another CAR is issued for a major non-conformity. This letter must be completed and signed by the Regional Director and copied to Area Program Network Chief and the Area FSEP/HACCP Coordinator.

FIGURE 1. NON-CONFORMITY FLOW DIAGRAM



The follow-up Regulatory System Audit is an additional audit conducted when the integrity of the HACCP System is in question. Its scope resembles that of a planned Regulatory System Audit, but the audit team may target specific CAPS, prerequisite program sub-elements, or HACCP reassessment procedures.