

The role of the Canadian government agency in assessing HACCP

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Abstract

In Canada, two food inspection programs have developed to embody internationally recognized principles of safe food processing. The Food Safety Enhancement Program (FSEP) is for establishments registered under the Meat Inspection Act and the Canada Agricultural Products Act, while the Quality Management Program (QMP) is for federally registered fish processing establishments. Both FSEP and QMP are fully compatible with the international HACCP guidelines adopted by Codex alimentarius. Under both QMP and FSEP initiatives, food manufacturers are responsible for the development, implementation and maintenance of HACCP food safety systems. The CFIA is responsible for verifying or auditing that industry operates acceptable systems. © 2000 Elsevier Science Ltd. All rights reserved.

1. Introduction

HACCP is becoming the “food passport” to the international market place. Recently, the United States Food and Drug Administration and the United States Department of Agriculture both published regulations requiring meat, poultry or fishery products offered for sale in the USA to be processed under an HACCP system. A timetable for implementation is established for each commodity. Similar requirements for some commodities already exist in other countries or are expected to be adopted in the future.

In Canada, two food inspection programs have developed to embody these internationally recognized principles of safe food processing. The Quality Management Program (QMP) is mandatory for federally registered fish processing establishments, and the Food Safety Enhancement Program (FSEP) is voluntary for establishments registered under the Meat Inspection Act and the Canada Agricultural Products Act. Both FSEP and QMP are fully compatible with the international HACCP guidelines adopted by Codex alimentarius, and are recognized by our trading partners to meet their requirements for food safety.

2. Food inspection systems

2.1. Food safety enhancement program

The Food Safety Enhancement Program (FSEP) is the Canadian Food Inspection Agency’s (CFIA) program designed to encourage the development and maintenance of HACCP systems in federally registered agri-food processing establishments. These establishments are involved in processing the following commodities: dairy, meat and poultry (including slaughter), processed fruits and vegetables, shell egg and processed egg. The development of FSEP has been done through a strong partnership with the Canadian agri-food industry.

In order to qualify for the regulatory system audit under FSEP, the operator must develop and maintain an acceptable and effective HACCP system. The system must be fully documented and readily accessible for review and audit by the CFIA.

2.2. Quality management program

The Quality Management Program (QMP) was successfully implemented in over 1200 fish processing plants in February 1992 and was the first mandatory food inspection program in the world based on HACCP principles. QMP is recognized internationally as an effective system for controlling the production of fish products

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and has facilitated the exportation of Canadian fish products around the world.

Although QMP is based on HACCP principles, since its implementation, there have been significant advances in the application of these principles. Several internal and external analyses have been carried out to measure the effectiveness of QMP. These analyses have identified the strengths and weaknesses of QMP and provided a strong foundation to evolve QMP into a more effective, efficient and focused fish inspection system that fully incorporates the advances made in the HACCP application. The re-engineering of the QMP began in June 1996 and re-engineered QMP will become mandatory in 1998. The re-engineering initiative has been done with the full consultation of the Canadian fish processing industry.

3. CFIA recognition of industry food safety systems

The development of an HACCP system is the responsibility of the operator. The commitment of senior management is essential for the successful implementation of the HACCP system.

3.1. FSEP criteria for eligibility

It is the company's responsibility to develop, implement and maintain adequate prerequisite programs and HACCP plans. Prerequisite programs are an important step which must be done prior to the development of product/process-specific HACCP plans. Prerequisite programs are the foundation of HACCP plans and need to be in place for HACCP plans to be functional.

Many tools have been developed as an aid for HACCP system development, implementation and maintenance. The operators are encouraged to use these tools.

- Volumes I, II, III and IV of FSEP implementation manual.
- Generic models.
- Reference Database for Hazard Identification.
- Technical HACCP video.
- HACCP curriculum guidelines.

Many of the above tools are available on the FSEP Internet Homepage at the following address: <http://www.cfia-acia.agr.ca/english/food/haccp/haccp.html>.

3.2. The QMP reference standard

The QMP Plan must meet the requirements as outlined in the QMP Reference Standard. The reference standard is based on the Fish Inspection Regulations and consists of seven sections.

- Management roles and responsibilities.
- Background product and process information.
- The prerequisite plan.

- The regulatory action points plan.
- The HACCP plan.
- Verification requirements.
- Record-keeping requirements.

CFIA has developed various tools to support Industry in developing re-engineered QMP Plans, including: the Re-engineering QMP Newsletter series, QMP workshops, Example QMP Plans, the "How to Re-engineer your QMP" Guide and facilitation of training through various Industry trainers (Canadian Food Inspection Agency, 1997).

4. Industry documentation

4.1. FSEP documentation package

When the HACCP system is developed and implemented as described, a complete, comprehensive documentation package is submitted to CFIA in order to begin the HACCP recognition process.

The documentation package must include the following components.

1. The letter of endorsement from senior management.
2. The name of HACCP coordinator (or on-site liaison person) and team members (if applicable).
3. The company's self-evaluation of its prerequisite programs.
4. The list of products and their grouping in their respective HACCP plans.
5. For each HACCP plan:
 - Product/Process type description, incoming materials, process flow diagram, plant schematic diagram, hazard analysis, critical control point determination, critical limits, monitoring procedures, deviation procedures, verification procedures, and record-keeping procedures and samples of records.

6. The maintenance procedures for the HACCP system.

The review and update procedures include what is reviewed, the specified frequency of the review and who is responsible for the review and making of changes to the HACCP system.

4.2. QMP documentation package

Prior to submission to the CFIA, the processor is responsible for verifying the written QMP Plan to ensure that all elements of the QMP Reference Standard are addressed. The CFIA provides a self-verification checklist for this process.

After the processor's self-verification is completed, the processor prepares a submission to the CFIA which includes.

1. Plant background information.
2. Self-verification checklist.

3. Identification of operation(s) and product(s) included under the re-engineered QMP Plan.
4. The QMP Plan.

5. CFIA review of industry systems

5.1. FSEP recognition

The purpose of this review is to challenge and thoroughly assess whether prerequisite programs and HACCP plans are complete (i.e. meet FSEP and regulatory requirements), and are implemented as described and effective.

The review is divided into three steps as follows.

(1) *Documentation package screening for completeness.* The first step in the local review of the FSEP documentation package is a screening by the reviewer to confirm that all required components are included and that they are acceptable.

(2) *Prerequisite programs' review.* Following the FSEP documentation package screening, the reviewer(s) will proceed with the prerequisite programs' review to determine if they are complete, implemented as described and effective.

(3) *HACCP plan review.* The written HACCP plan review will verify that the following has been done:

- (a) product/processes adequately grouped into respective HACCP plans and appropriate generic model(s) were used;
- (b) proper application of HACCP principles;
- (c) proper identification of hazards;
- (d) proper selection of CCPs, and if hazards listed in the applicable generic model have not been identified in the HACCP plan, information should be made available to support this;
- (e) appropriate critical limits, monitoring deviation and verification procedures for *each* identified hazard within a CCP;
- (f) appropriate record keeping;
- (g) all regulatory requirements relating to health and safety are being addressed by the HACCP plan.

The written review is followed up by an on-site recognition audit to make sure the program is implemented as described.

Following a successful review, the establishment will be HACCP recognized by CFIA. The inspection regime will then change to a regulatory system audit.

5.2. QMP systems verification

The systems verification is the audit of the company's documented QMP Plan against the QMP Reference Standard which specifies the following criteria.

(1) *Management roles and responsibilities:* Processors are recommended to describe how the re-engineered

QMP was developed, how it will be implemented and identify the position responsible for the maintenance of the QMP plan.

(2) *The product and process information:* Processors are required to identify product and process information in the form of a Product Description, Process Flow Diagram and a Plant Floor Plan where necessary.

- The Product Description must identify those product attributes and characteristics that are important in ensure a safe and acceptable fish product.
- The Process Flow Diagram must outline all the production steps and assist in identifying those steps that are important in processing a safe fish product meeting all regulatory requirements.
- The Plant Floor Plan identifies cases where hazards are controlled through the application of sanitary or restricted access zones.

(3) *The prerequisite plan:* Processors are required to identify the in-plant controls that provide assurances that:

- the physical plant facilities are designed, constructed and maintained in a condition to allow for the sanitary production of food,
- all potential sources of significant contamination are controlled, and
- product can be rapidly recalled from first shipping destinations.

(4) *The regulatory action point (RAP) plan:* Processors are required to establish, document and apply controls that ensure the final product meets the requirements of the Fish Inspection Regulations.

(5) *The hazard analysis critical control point (HACCP) plan:* Processors must develop, document and implement an HACCP Plan to address any health and safety hazards related to the product or process. The processor must apply the principles of HACCP¹ to identify any significant hazards and for those significant hazards identified, develop an HACCP plan to prevent, eliminate or reduce the hazard to an acceptable level.

The HACCP Plan must include the following.

- Hazard analysis.
- Critical Control Points (CCPs).
- Critical limits.
- Monitoring procedures.
- Corrective action system.
- Verification procedures and record-keeping system.

(6) *Verification requirements:* Processors will be required to perform the following verification activities to ensure that their QMP plan is functioning correctly:

¹ Consistency with the CODEX Food Hygiene Committee document, Alinorm 97/13 and the Hazard Analysis and Critical Control Point System by the National Advisory Committee on the Microbiological Criteria for Foods, 1992.

Before implementation the processor will be required to:

- validate the critical limits of CCPs, where appropriate, and
- verify the QMP Plan to ensure that all of the necessary controls are in place and that it meets the requirements of the QMP Standard.

Once the QMP Plan is implemented the processor is required to:

- perform routine verification of the HACCP Plan to ensure it is functioning effectively (e.g. Record reviews, Corrective Action reviews, review of calibration of equipment),
- verify or validate any changes to QMP controls or CCP critical limits that may occur in the ongoing development of the QMP Plan, and
- verify the QMP Plan at least once per calendar year.

(7) *Record keeping requirements:* The record keeping requirements for the QMP plan are:

- Record keeping requirements for the Prerequisite Plan and the Regulatory Action Point Plan (RAPs) will be “records by exception”. Records will only be required when a deficiency is identified during the monitoring procedures. In these cases, the processor is required to record the deficiency and document the corrective action that was taken.
- Record keeping requirements for the HACCP Plan require that all testing, measurements and monitoring procedures at CCPs are recorded and corrective actions are recorded when the critical limits are exceeded.
- Records must be maintained of all verification actions.
- To ensure that the QMP Plan is accurately documented, processors are also required to maintain records of the amendments to the QMP Plan.

6. CFIA assessment of industry system implementation

6.1. FSEP regulatory system audit

The regulatory system audit is used to verify that prerequisite programs and HACCP plans are in fact being implemented as described and are effective on a continuous basis.

The regulatory system audit under FSEP has both a full and partial audit component, each with its own frequency. The full system audit consists of an evaluation of all prerequisite programs and all HACCP plans. The partial audits consist of a partial review of the HACCP system. It will provide a snapshot relative to the conformity and effectiveness of the prerequisite programs and operating HACCP plans.

The focus of the partial audit could vary according to CFIA needs. It may focus on the following:

- randomly selected components of the HACCP system;
- follow-up to previous full or partial audits (outstanding Corrective Action Requests);
- concerns developed through consumer complaints;
- changes in the company's HACCP system (company's log book);
- targeted areas of interest on an industry-wide sector. The intent of the regulatory system audit is threefold:
 1. to confirm that the written procedures (prerequisite programs and HACCP plans) are up-to-date;
 2. to review the HACCP system for its conformity with the written procedures (i.e. implemented as described); and
 3. to measure the effectiveness of the HACCP system in meeting the objectives set in the written procedures.

6.2. QMP compliance verification

The compliance verification is an audit of the operating QMP to verify that the industry is implementing the QMP as designed and that the system is effective in meeting the requirements as set out in the QMP Reference Standard.

The scope of the compliance verification and the Inspector activities in the facility are planned based on the CFIA policy, plant compliance history, risk factors and Inspector knowledge of the operations.

A compliance verification checklist is prepared during a pre-audit review of the QMP and in advance of the compliance verification. The checklist may be expanded during the course of the compliance verification if required in order to determine compliance to the reference standard. Checklist questions are devised by the Inspector to determine if the QMP Reference Standard criteria are met.

The Inspector will verify that criteria are met by using a combination of activities which may include inspection, interview, observation, measurement, sampling for laboratory analyses and document review.

During the compliance verification at the plant, the Inspector will collect objective evidence in support of the inquiry and record the findings accordingly.

7. Determination of non-compliance

7.1. FSEP assessment

The regulatory system audit under FSEP is based on the assumption that a sound HACCP system is in operation and capable of controlling hazards in a preventative mode. Non-conformity with the HACCP system leads to questions and concerns with the integrity of the operator's HACCP system and the ability to effectively control hazards.

7.1.1. Judging the immediate impact on health and safety

For each audit finding, the auditor first assesses if it has an immediate impact on health and safety and if immediate corrective action is required. If immediate corrective action is necessary (e.g., hold products, initiate recall procedures) it should be initiated by the company. If the company does not initiate the appropriate corrective action immediately, then the auditor must take compliance action. When CFIA staff are left to initiate immediate compliance action to protect the safety of a product, this is automatically a major non-conformity.

7.1.2. Judging the integrity of the HACCP system

Once an audit finding has been assessed to establish if there is an immediate concern regarding the safety of the product, the auditor then assesses if it is a non-conformity. If it is, the auditor will establish whether it is major or minor.

An audit finding is not always a non-conformity. If the company can prove through records that it has already identified this problem and is taking the appropriate steps to address it, the audit finding should not be a non-conformity.

A minor non-conformity is defined as an isolated non-conformity within the sub-element of the prerequisite program or CCP of the HACCP plan being audited.

An isolated non-conformity is one that does not compromise the integrity of the sub-element or CCP (i.e. overall the written program is still effective in controlling the sub-element or CCP).

A major non-conformity is one that compromises the integrity of the HACCP system. There are many types of major non-conformity and they are defined as follows:

1. *Absence or failure*: The absence or failure of the sub-element of the prerequisite program or CCP being audited. *Absence* means that the sub-element or CCP of the written program being audited is not being performed at all. *Failure* means that the written program being audited is not effective to the point where the overall integrity of the sub-element or CCP is compromised (i.e. it is not working).
2. *Cumulative*: Cumulative minor non-conformities can become a major non-conformity. Cumulative means that within *one* sub-element or CCP being audited there are a number of minor non-conformities that compromise the integrity of the sub-element or CCP.
3. *Repetitive*: Repetitive minor non-conformities can become a major non-conformity. Repetitive means that there are similar types of minor non-conformities:
 - (a) within a number of different sub-elements and/or CCPs being audited; or
 - (b) occurring over consecutive audits.

4. *Inappropriate corrective action taken by company in the case of an immediate health risk*: In the case of an immediate health risk, if the company does not initiate immediate corrective action and CFIA must initiate the compliance action to dispose properly the product, the non-conformity must be major.
5. *Falsification of records*: If the auditor has objective evidence that clearly demonstrates without doubt that a record was falsified, a major non-conformity will be issued (e.g., a control sheet has been completed with the next day's results).
6. *Failure to implement effective corrective action for a previously identified minor non-conformity*: When a minor non-conformity is not corrected within the time frame agreed upon ("Date for completion of corrective action" in Part B of CAR) or it is found that the corrective action that was taken is not effective, the minor non-conformity becomes a major non-conformity and a new CAR form will be issued.

7.1.3. Corrective action request (CAR form)

When either a major or minor non-conformity is identified during a partial or full audit, the description of the non-conformity, the company's written corrective action and the subsequent follow-up findings (by CFIA) are all documented on the CAR form.

The CAR form is divided into three parts as follows:

Part A: Description of non-conformity. This first part of the CAR form is completed by the lead auditor to describe the non-conformity and any corrective/compliance action taken and by whom.

Part B: Corrective action. This part of the CAR form is completed during the closing meeting by the HACCP coordinator or designated establishment representative, detailing what corrective action will be taken to address the non-conformity identified.

Part C: Follow-up. This part is completed by the auditor/responsible inspector when reviewing what the company has written for corrective action (Part B). The auditor checks off the appropriate box if found acceptable/unacceptable and signs and dates this part.

7.2. QMP assessment

As stated above, the operating QMP will be assessed through the compliance verification process. Variations from the QMP Plan will be referred to as non-conformities. A non-conformity is a deficiency in the processor's QMP by virtue of a deviation from the QMP Plan, the QMP Reference Standard or the applicable regulations. Each non-conformity will be evaluated based on objective evidence, such as qualitative or quantitative information, records, or statement of fact which is based on observation, measurement or test.

Minor non-conformities are those deficiencies where procedures specified in the processor's QMP are not followed, but there is no violation of specific product or process regulations.

Major non-conformities are those deficiencies that violate the QMP Reference Standard but do not present a health or safety risk.

Critical non-conformities are those deficiencies in the processor's QMP that may have resulted in unsafe or fraudulent product.

The results of the compliance verification shall be documented in a report and provided to the processor. The processor will be required to provide a Corrective Action Plan addressing all non-conformities indicated on the Compliance Verification Report.

The processor must take immediate corrective action on critical non-conformities. For major and minor non-conformities, the company is responsible for initiating and implementing corrective actions to correct the non-conformity and the cause of the non-conformity. Corrective action should be implemented as soon as practicable.

The compliance verification will be closed when all corrective actions have been implemented by the processor and verified by CFIA.

8. Conclusion

Under both QMP and FSEP initiatives, food manufacturers are responsible for the development, imple-

mentation and maintenance of HACCP food safety management systems to ensure compliance with the health and safety regulations and trade agreements. These food safety management systems must include a hazard analysis, written procedures for control of hazards and written procedures for verification of the system's effectiveness. The Canadian Food Inspection Agency (1998) continues to be responsible for developing the regulations, standards, policies and procedures which are the guidelines for industry compliance. The CFIA is also responsible for verifying or auditing that industry operates acceptable systems, and when required, the CFIA takes appropriate enforcement action. As food manufacturers demonstrate reliability of their HACCP system, the CFIA responds by conducting less frequent, but more comprehensive audit-type activities. In comparison with the traditional inspection approach, which is a "snapshot in time" of compliance, regulatory audits or verifications are an assessment of the manufacturer's capability to maintain control consistently over time. In the HACCP environment, the CFIA can better direct resources based upon industry compliance and product risk.

References

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