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

QSM-07

Quality Management System Manual for Facilities Registered in the Emerald Ash Borer Approved Facility Compliance Program (EABAFCP)

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Contact

For further information and clarification, please contact the Canadian Food Inspection Agency.

Review

This QSM procedure will be reviewed every 5 years.

Endorsement

Approved by:

Joanne Rousson, Project Coordinator Date

Greg Stubbings, Chief Plant Health Officer Date

Amendment Record

Number of amendment:	Amended by:	Date of submission for approval of amendment:	Summary of amendment and number of amended page(s):

Distribution

1. CFIA Directive mailing list (Areas, Regions, PHRA, USDA, other federal government departments)
2. Provincial Government (via Regions)
3. National Industry Organizations (Canadian Nursery and Landscape Association, The Hardwood Lumber Bureau, Canadian Lumber Standard Accreditation Board, other industry representatives)
4. CFIA website
5. North American transport industry representatives
6. Facilities applying to EABAFCP and registered facilities.

Introduction

The Quality Management System Manual for Facilities supplements CFIA Directive D-03-08 "Phytosanitary requirements to prevent the introduction into and spread within Canada of the Emerald Ash Borer, *Agrilus planipennis* Fairmaire". It outlines the requirements that facilities must meet to register as an approved Emerald Ash Borer Approved Facility Compliance Program (EABAFCP) facility. The EABAFCP enables facilities in good standing to receive regulated articles in non-regulated areas and ship regulated articles out of regulated areas without a pre-shipment CFIA inspection. The EABAFCP is a systems based risk mitigation program, which is audited by the CFIA.

1.0 Scope

The Quality Management System Manual for Facilities in the EABAFCP outlines the requirements to comply with the EABAFCP. Facilities not registered in the EABAFCP should refer to Directive D-03-08 for regulatory guidelines.

2.0 References

CFIA Directive D-01-05, The Canadian Wood Packaging Certification Program (CWPCP) for Export

CFIA Directive D-03-02, The Canadian Heat Treated Wood Products Certification Program (CHTWPCP).

CFIA Directive D-03-08, Phytosanitary requirements to prevent the introduction into and spread within Canada of the Emerald Ash Borer, *Agrilus planipennis* Fairmaire.

QSM-08 – CFIA Quality Management System Manual for Auditors for the Emerald Ash Borer Approved Facility Compliance Program (EABAFCP)

CFIA PI-07, Technical Heat Treatment Guidelines and Operating Conditions Management Plan

ISPM No. 5, Glossary of Phytosanitary Terms, FAO (updated annually)

ISPM No. 15, Guidelines for Regulating Wood Packaging in International Trade, Publication, FAO.

ISO Guide 8402, Quality Systems Terminology.

3.0 Definitions, abbreviations and acronyms

Definitions for terms used in this document can be found in the Plant Health Glossary of Terms, http://www.inspection.gc.ca/english/plaveg/protect/dir/glosterme.shtml

4.0 EABAFCP Registration

To apply to the EABAFCP the facility must submit a completed application form (Appendix 1) and a copy of the facility's Quality Management System Manual (referred to herein as the Manual) to the local CFIA office for review and approval. Contact information for local CFIA offices is available at;
http://www.inspection.gc.ca/english/directory/offbure.shtml

The CFIA will review and compare the Manual to the requirements specified in D-03-08 and this QSM. Once the Manual is approved, an evaluation audit of the facility will be conducted. A facility that is granted good standing in the evaluation audit will be a registered facility and CFIA will issue the facility a registration number.

Registered facilities must re-submit an EABAFCP application every year to remain registered in the program and to be eligible to receive import permits for the import of regulated articles.

5.0 EABAFCP Quality Management System Manual

The Manual must outline the procedures and processes implemented by a facility to mitigate the phytosanitary risk of EAB spread associated with the movement of regulated articles. These procedures and processes represent a facility’s phytosanitary management system (PSMS).

The Manual must include all of the elements of a facility’s operations that relate to EAB risk mitigation. Details of these requirements are described below.

A quality management system that follows International Organization for Standardization (ISO) guidelines or a similar management system and is amended to include the required elements of the EABAFCP can be used as a Manual.

5.1 Administration

5.1.1 Facility Identification

The Manual must provide the address and contact information of all facility locations where regulated ash articles are received and processed.

5.1.2 Certification Manager

The Manual must identify a Certification Manager (CM) and an alternate to the CM. The CM is the official contact with CFIA and is responsible for developing the Manual, enacting changes and updates, providing training to employees with roles and responsibilities under the EABAFCP and conducting optional internal audits. The CM will also be responsible to meet with CFIA and assign staff to accompany and assist during audits.

5.1.3 Manual Modifications

The CM must have a CFIA-approved and up-to-date copy of the Manual with an assigned version number and date of revision. Subsequent changes must have a new version number and replace previous versions. When the Manual is altered, the updated version must be sent to the CFIA for approval prior to implementation. Where repeated updates are required, an amendment log must be kept to document changes. A copy of the amendment log must be attached to the Manual. Facility employees must be informed of the procedure changes and the changes made to the Manual once they have been approved by CFIA. This notification should be recorded in a training log.

5.1.4 Organization of Manual

A table of contents page must be included to improve the organization of the Manual.

5.2 Staff Responsibilities

The facility must identify the staff members responsible for ensuring that the facility meets the EABAFCP requirements. Position titles and a description of responsibilities in relation to the EABAFCP must be documented.

5.3 Staff Training

The facility must describe the training procedures of staff responsible for procedures that mitigate the spread of EAB in accordance with the EABAFCP. This includes the specific training elements and the intervals between training sessions. The training records must include the names of the employees trained.

Information on the signs and symptoms of EAB, a copy of the facility's Manual, and D-03-08 must be accessible to all facility staff that contribute to meeting the EABAFCP requirements.

5.4 Phytosanitary Control Points

Phytosanitary control points are critical processing steps where regulated articles must be processed in accordance with EABAFCP and D-03-08 in order to mitigate the spread of EAB. These may include stages where regulated articles are segregated, regulated articles enter a different stream of production, employees are responsible for regulated article transfer, or an article changes from non-compliant to a compliant state.

In the Manual, the facility must identify all phytosanitary control points and outline how it will conduct mandatory internal inspections of the points to verify that regulated articles are processed in accordance with EABAFCP. The facility could develop a flow diagram to identify control points. Inspection and audit records at these control points must be current and complete, as specified in Section 5.5. Staff must fully understand their roles and responsibilities regarding phytosanitary control points.

5.4.1 Receiving Regulated Articles

The Manual must document how incoming regulated articles are identified upon receipt. Procedures may include signing off on incoming shipping documents, verifying the Compliance Form for the Transport of Regulated Articles, and unique markings for loads of regulated articles. The facility must record incoming regulated articles and inspect the incoming shipments for signs of EAB. An inspection record must be maintained for every lot.

5.4.2 Segregation

Facilities in non-regulated areas must develop and document procedures to ensure regulated articles are segregated from non-regulated articles for the entire chain of production. This includes arrival of articles at the facility to distribution or disposal of waste material and by-products. The Manual must specify a system that addresses the facility's unique chain of custody and processing to segregate regulated articles. Segregation methods may include physical barriers such as signage, fencing, colour specification, or designated areas separated by buffer zones of a size approved by CFIA. A site plan must be included with the Manual to identify the location of these specific areas. For facilities in non-regulated areas, products (lumber, firewood, etc.) originating from regulated logs must be segregated from products originating from unregulated logs.

5.4.3 Processing Procedures

The Manual must indicate the processing procedures used to generate compliant regulated articles and the procedures used to confirm that the processing conditions are met. For example, inspection procedures to confirm bark chips are less than 2.5 cm in two (2) dimensions, inspection procedures for lumber to ensure bark and sapwood have been removed to a depth of 2.5 cm past the cambial layer, and verification of charge reports to ensure heat treatment has been attained to the prescribed treatment schedules.

Treatment measures to generate compliant products are outlined in Appendix 8 of D-03-08.

5.4.4 Traceability of Regulated Articles

Non-compliant regulated articles must be clearly identified or segregated using clear markings that are applied prior to transport. This enables verification of the identity and traceability to the origin of the regulated articles. When the identity of a regulated article is ambiguous it will be assumed to originate in a regulated area. Ash lumber and logs for export that requires a certification for origin from areas where EAB is not known to occur must establish a traceability system confirming the origin of ash lumber or logs. Please note that this requirement applies to facilities in non-regulated areas only. The details of this traceability system must be outlined in the Manual. Please contact the CFIA for further details.

5.4.5 Other Control Activities

Other control activities implemented by the facility that may impact the integrity of the EABAFCP must be included in the Manual.

5.5 Records and Documentation

Facilities are required to maintain records that track all activities or procedures related to the EABAFCP for a minimum of three (3) years. Examples of these records include incoming shipping documents, movement certificates and log journals, inspection records for incoming regulated articles, training records, Compliance Forms for the Transport of Regulated Articles, sales records for regulated articles sold, and internal audit reports.

5.6 Supplier List

The facility must maintain a list of suppliers from which it will source regulated articles in the Manual. Changes made to the suppliers list must be communicated to the CFIA. Contact your local CFIA office for more information.

5.7 Transportation of Regulated Articles

Regulated articles must be transported under the conditions outlined in D-03-08, Section 2 for domestic movement and Section 3 for imports. The Manual must outline how the facility will meet the requirements for transport of regulated articles.

All regulated articles originating in a regulated area moving to a non-regulated area or transiting a non-regulated area must be delivered directly to the approved processing facility. The regulated articles may not be diverted to any other destination without written permission from the CFIA. Regulated materials must be secured during transport. Any spillage must be documented and reported to the CFIA immediately.

Facilities using their own vehicles to transport regulated articles must outline the procedures used to mitigate the risk of EAB spread. Facilities that employ contract vehicles to ship regulated articles and facilities that import regulated articles are responsible for ensuring that the vehicles transporting regulated articles carry a completed Compliance Form for Transportation of Regulated Articles (Appendix 6 of D-03-08). The receiving facility must have a copy of this form and retain these records for three (3) years.

5.8 Movement Certificates

Facilities registered in EABAFCP will be issued a Movement Certificate to allow the movement of regulated articles. The Manual must indicate the specific procedures and employees responsible for the care and control of the Movement Certificates. Specific information such as the movement certificate number, commodity, quantity, date of shipment, origin of shipment, must be maintained for each shipment transported under the authority of the movement certificate. This information should be recorded in the EABAFCP Movement Certificate Log (see Appendix 2).

5.9 Heat Treatment

Facilities not registered under the Canadian Heat Treated Wood Products Certification Program (CHTWPCP) but intending to use heat treatment to generate compliant articles must meet the treatment requirements outlined in *The Technical Heat Treatment Guidelines and Operating Manual* (PI-07), http://www.inspection.gc.ca/english/plaveg/for/cwpc/htreate.shtml

Alternately, the CFIA will recognize specific treatment schedules developed by a recognized CFIA heat treatment evaluator. In this instance, the Manual must describe the kiln layout, including dimensions, direction of air flow, and location of all sensors. An example of the charge report, showing calculations used to confirm that heat treatment requirements are met must also be included in the Manual.

A list of CFIA recognized heat treatment evaluators is available at; http://www.inspection.gc.ca/english/plaveg/for/cwpc/chtwpcpbe.shtml

5.10 Facility Non-Conformance

The facility must specify an internal system for addressing and recording non-conformances.
A non-conformance record must include the following information;

- Description of the non-conformance
- Date of occurrence
- Employees involved
- Corrective actions taken
- Signature of approval by the Certification Manager

Examples of non- conformances are listed in Appendix 9 of D-03-08.

An example of the facilities' non-conformance record must be included in the Manual. The CFIA must be notified within 24 hours of a non-conformance that affects the ability of the facility to meet the requirements of EABAFCP.

5.11 Clean-Up and Disposal of By-Products

Facilities in non-regulated areas must specify that processing, treatment, clean-up and disposal of regulated articles will be completed by March 31, which is the end of the low-risk period. Procedures to contact CFIA once the final clean-up is completed must be outlined in the Manual. Clean-up and disposal activities will be verified by CFIA.

5.12 Pest Notification

Live EAB or signs of EAB damage, may be encountered by facility staff during the processing of regulated articles. The Manuals of facilities located in non-regulated areas must clearly specify a commitment to notify the CFIA immediately if EAB in any life stage or signs of EAB are found on regulated articles sourced from a non-regulated area.

5.13 Internal Audits

Facilities are encouraged to conduct internal audits. These audits should occur at the same frequency as surveillance audits, but at a different date. The internal audits should include an audit of all the phytosanitary critical control points. The facility should document internal audits using a log that can be audited by CFIA. Facilities are responsible for creating and maintaining this log.

6.0 Movement Requirements

6.1 Domestic Movement Requirements

Domestic shipment of regulated articles received or sent by the facility must meet the requirements for domestic transport, as outlined in Section 2 of D-03-08. Facilities must obtain a movement certificate to ship or receive regulated articles, which are issued in accordance with conditions outlined in Appendices 2 and 3 of D-03-08. CFIA issued movement certificates cannot be altered. Movement Certificates that are altered are considered void. The facility can mark a copy of the document as needed to maintain the EABAFCP Movement Certificate Log. Movement certificates must accompany the shipment of all regulated articles moving out of a regulated area. Copies of all movement certificates as well as Bill of Landing or invoices must be maintained for a minimum of three (3) years.

6.2 Import Movement Requirements

Each shipment of regulated articles received from the United States must meet the import requirements as outlined in Section 3 and Appendix 5 of D-03-08. Facilities must obtain a permit to import or a phytosanitary certificate to receive regulated articles.

7.0 Domestic Firewood Movement

The interim firewood module of EABAFCP permits the domestic movement of non-ash firewood from regulated to non-regulated areas. The firewood supplier must implement a verifiable ash exclusion process. The facility must provide assurance that the Certification Manager or alternate has expertise in tree species identification. This expertise could be obtained from experience or education. Movement of firewood that cannot be verified as ash-free is prohibited. The exclusion process includes identifying non-ash firewood source trees and segregating ash from non-ash commodities during harvest. Details of these procedures must be clearly outlined in the facility's Manual according to section 5.4.

The domestic movement of firewood of all tree species is permitted within a regulated area.

8.0 Audits and Reviews

Audit frequency may be modified based on the discretion of CFIA.

8.1 Manual Review

The CFIA will review the Manual. If the Manual does not meet the requirements of EABAFCP, CFIA will identify the improvements required to meet the Manual requirements as outlined above. Upon approval of the Manual, the CFIA will conduct an Evaluation Audit.

8.2 Evaluation Audit

An Evaluation Audit is a systemic examination conducted by CFIA, to verify that a facility is capable of meeting the EABAFCP requirements as outlined in the facility's Manual. Once CFIA approves the Manual and a facility receives good standing in the Evaluation Audit, the facility will become an approved EABAFCP facility.

8.3 Surveillance Audit

Surveillance Audits are continual verifications that the processes and procedures described in the facility's Manual are implemented to effectively mitigate the phytosanitary risks of EAB spread. Newly approved facilities are subject to a surveillance audit every month for three (3) months. Facilities that demonstrate conformance will have their audit frequency reduced to once every three (3) months.

Facilities located in non-regulated areas operate under the EABAFCP during the low risk season only (Oct. 1 – March 31). One (1) of the several surveillance audits for facilities in non-regulated areas is a Clean Up Surveillance Audit dedicated to verifying that the facility is completely free of regulated articles by March 31. The deadline for the Clean-Up Surveillance Audit will be reviewed by CFIA on a case by case basis to accommodate facilities located in areas that continue to experience winter climatic conditions associated with low-risk periods after March 31.

Facilities in regulated areas are subject to surveillance audits throughout the year.

8.4 Systems Audit

The Systems Audit is a comprehensive review audit of the organization structure, processes, and resources of the facility used to adhere to the requirements of the EABAFCP. The Systems Audit focuses on the phytosanitary control points. System audits occur once a year.

8.5 Internal Audits

Facilities are encouraged to conduct optional internal audits. Internal audits are essentially internal checks to ensure that the facility is abiding by the requirements outlined in the Manual. These audits should occur at the same frequency as Surveillance Audits conducted by CFIA, but at a different date. The internal audits should include an audit of the phytosanitary critical control points. The facility should document internal

audits in a log that may be audited by CFIA. Alternatively, the facility may administer an internal quality audit conducted on a routine basis to ensure quality control. A copy of the internal audit record should be included in the Manual.

9.0 EABAFCP Non-Conformance

When CFIA audits identify that a registered EABAFCP facility is not in conformance with their Manual, QSM-07 or D-03-08, the facility must implement corrective actions. CFIA will provide a Corrective Action Request to the registered facility identifying the details of the non-conformance. Examples of non-conformances are listed in Appendix 9 of D-03-08.

10.0 Cancellation and Reinstatement

Facilities that are unable to address the necessary corrective actions, have a total failure of their quality management system, or voluntarily withdraw will be immediately cancelled from the EABAFCP. Cancelled EABAFCP facilities will have their Movement Certificates cancelled immediately and the facility will be removed from the CFIA list of approved EABAFCP facilities.

To be reinstated as EABAFCP approved facility status, cancelled facilities must submit a new application and a revised Manual. The facility must also receive a good standing on a Systems Audit. Once the facility has demonstrated to the CFIA on-going compliance with the requirements of D-03-08 and QSM-07, the CFIA may reduce the audit frequency.

Individuals or companies that are non-compliant with the *Plant Protection Act* may be subject to additional penalties including prosecution.

Facilities in non-regulated areas may become reinstated in the EABAFCP as approved facilities during the low risk season. The facility must contact the local CFIA office to request reinstatement. It is strongly recommended that the facility make a reinstatement request a month before the desired reinstatement date. An audit to verify suitability for reinstatement in the EABAFCP will be conducted and include a review of the Manual and the phytosanitary critical control points to mitigate the risk of EAB spread.

Appendix 1 - Application to Register in the EAB Approved Facility Compliance Program

PART A – APPLICANT/PERMIT HOLDER INFORMATION

Facility name & address :		
Location of the receiving facility:		
Contact name / Certification Manager :		
Telephone(s) :	**e-mail :**	**Fax :**
Anticipated sources (counties and states/provinces from which the ash may be sourced):		

PART B – FACILITY CONSENT

The facility must agree to permit the inclusion of its name on the public List of EABAFCP Approved Facilities, which will be posted on the CFIA website.

Signature: _____

PART C – DECLARATION

I,_____ the owner/ authorized signatory of the above named facility have read and understood all the conditions and obligations stated herein and have read and hereby agree to comply with the requirements of the EAB Approved Facility Compliance Program.

Further, I am and shall be responsible for and shall indemnify and save harmless and defend at its own costs Her Majesty the Queen in right of Canada, including the CFIA and its employees and agents, Her Heirs, Successors and Assigns from and against all claims, demands, losses, damages, costs, including solicitor and own-client costs, expenses, actions suits or other proceedings whatsoever, brought or prosecuted in any manner which heretofore or hereafter may be made by whomever; however and whenever caused by, arising out of, attributed to or with respect to any failure, inadvertent or otherwise, by act or omission, to fully comply with the said conditions and requirements.

Name and title of Certification Manager:	
Signature :	**Date :**

PART D – APPROVAL [TO BE COMPLETED BY CFIA]

Approved as :	☐ **Sawmill**	☐ **Firewood Producer (domestic only)**
	☐ **Disposal**	☐ **Other :** _____
Comments :		
Names of Auditors:		
Manual Approval		
Signatures:		**Date:**
Evaluation Audit Approval		
Signatures:		**Date:**
Final Approval		
Name of CFIA RPO (responsible for EABAFCP):		
Signature:		**Date:**
Name CFIA Area Program Specialist (responsible for EABAFCP):		
Signature:		**Date:**
EABAFCP registration number:		

Appendix 2 – EABAFCP Movement Certificate Log

Entry	Date	Commodity	Source	Destination	Authorization (Initials)	Movement Certificate Number
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						

Appendix 3: EABAFCP Audit and Facility Status Flow Chart