



Canadian Food
Inspection Agency

Agence canadienne
d'inspection des aliments

Canada Organic Regime Quality Management System Manual

Canada

COR Quality Management System

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1.0 COO QUALITY MANAGEMENT SYSTEM MANUAL

1.1 Preface

This Quality Management System (QMS) Manual contains policies and procedures for the Canada Organic Regime. The manual describes the procedures that shall be followed by: Canadian Food Inspection Agency (CFIA) staff in the day to day operations of the CFIA's Organic Office; Accreditation Advisory Bodies in their oversight of Certification Bodies; and Certification Bodies in their oversight of organic operators. The goal in producing a Manual is to provide a structure so that services are delivered in a consistent and efficient manner.

This QMS Manual outlines requirements of the *Organic Products Regulations* (the Regulations). Therefore, the procedures contained within must be followed by Accreditation Advisory Bodies and Certification Bodies.

The *Organic Products Regulations* were made pursuant to section 32 of the *Canada Agricultural Products Act*. The purpose of the Regulations is to establish a system by which the CFIA, as competent authority, shall regulate the use of the "Canada Organic" agricultural product legend (Legend). This national organic regime (Regime) shall facilitate international market access, provide protection to consumers against deceptive and misleading labelling practices and support further development of the domestic market. The need for a federal regulatory regime has been identified and supported by the Canadian organic industry.

Should there be any discrepancy between the COR Organic QMS Manual and the Regulations, the Regulations shall take precedence.

1.2 Overview of the Canada Organic Regime (COR)

Food, feed and seed traded in Canada must comply with food safety, animal health and plant protection regulations. A percentage of this food, feed and seed is produced under the Canada Organic Regime (COR), a mandatory system to federally regulate the organic integrity of products.

The COR is a non-traditional regime for the Canadian Food Inspection Agency (CFIA). The COR uses an alternative service delivery system for organic certification services. Within the COR, the CFIA is the competent authority that oversees the organic regime. The CFIA enters into agreements with Accreditation Advisory Bodies provided these bodies meet the criteria established by the Government of Canada. The Accreditation Advisory Bodies have then the authority to recommend the accreditation of Certification Bodies meeting the accreditation criteria of the COR.

This means that certification of the organic integrity of products at the farm; processor, manufacturer, import and export level is performed by Certification Bodies. Certification Bodies employ third party inspectors to assess the practices of organic operators. These third party inspectors are to be referred to as Certification Body Inspectors (or, CB Inspectors). The CB Inspectors provide the results of their assessments to their Certification Body for evaluation. The Certification Body, in turn, certifies only the organic integrity of processes and products.

In order to facilitate the import/export activities and to ensure that importing country requirements are equivalent or in compliance with the COR, an Equivalency Determination between Canada and another country will be performed. Such agreement may result in reducing the importing country's rate of verification and avoid additional certification in the country of origin but is not generally intended as a condition for trade. Foreign accreditation body is eligible for recognition under COR and foreign Certification Body is eligible to be accredited under COR by a recognized AB only if there is no equivalency agreement between Canada and this country.

The CFIA carries out enforcement activities of the COR that include label inspections in the marketplace, and audits of domestic and international Accreditation Advisory Bodies.

There are three main players in this alternative service delivery system for organic products. These players are:

- **Domestic and International Certification Body** – a body that is accredited as a Certification Body in accordance with section 5 of the *Organic Products Regulations*. The Certification Bodies possess the required ability and reliability to operate a system for certifying

products under the COR. Certification Bodies provide a written guarantee (*in the form of a license*) that a product, process or service conforms to stipulated requirements.

- **Domestic and International Accreditation Advisory Body** – a body that has entered into an agreement with the CFIA under subsection 14(1) of the Canadian Food Inspection Agency Act to administer certain tasks, including: assessing Certification Bodies; recommending the accreditation of Certification Bodies and monitoring the accreditation of Certification Bodies.
- **The CFIA** – The competent authority of the COR. The COR integrates existing private and public sector organic Accreditation Advisory Bodies and Certification Bodies inside this new regime provided they meet criteria established by the Government of Canada. The CFIA shall accredit Certification Bodies, based upon the recommendation of Accreditation Advisory Bodies that it has entered into agreements with. The CFIA shall also provide a level of oversight and a level of compliance assurance (integration with existing CFIA compliance programs).

There are four main documents that provide a mandate and policies for the Canada Organic Regime. These are:

- The Organic Products Regulations – new regulations under the authority of the Canadian Agricultural Products Act;
- The Organic Production Systems General Principles and Management Standards, CAN/CGSB-32.310 – developed by the organic industry and the Canadian General Standards Board;
- The Organic Production Systems Permitted Substances List, CAN/CGSB-32.311 - developed by the organic industry and the Canadian General Standards Board;
- The COO QMS Manual.

1.3 Canada Organic Office (COO) Structure

The COO Structure is determined by the COO Organisation Chart and the job descriptions for its personnel. The Organization Chart is administered by the Director's Office. The job descriptions are administered by the COO National Manager.

1.3.1 COO Personnel

The COO shall deliver a range of services necessary for a national regulatory system. The COO shall consist of 6 full time employees at CFIA Headquarters. References include Job Descriptions for all 6 positions, and the COO Organisation Chart.

1.3.1.1 National Manager

The National Manager coordinates day to day activities, and liaises with other CFIA Programs. Also, the National Manager is responsible for approving agreements with Accreditation Advisory Bodies, and the accreditation of Certification Bodies on the recommendation of the Accreditation Advisory Bodies (see Section 5 of the Regulations).

1.3.1.2 Administrative Assistant

The Administrative Assistant performs administrative tasks for the COO Manager and staff, such as: Staffing Actions, Authority Requests, Travel and Expense Claims, Correspondence ...etc.

1.3.1.3 Regulations and Standards Officer

The Regulations and Standards Officer administers: the Regulations, which refer to The Organic Production Systems General Principles and Management Standards, CAN/CGSB-32.310 and The Organic Production Systems Permitted Substances List, CAN/CGSB-32.311 - developed by the organic industry and the Canadian General Standards Board. The Officer also answers inquiries relating to regulations, Standards and the QMS Manual.

1.3.1.4 Lead Auditor

The Lead Auditor develops procedures/guidelines in consultation with stakeholders for the audit and evaluation of

Accreditation Advisory Bodies, Certification Bodies, and Operators. Also, leads the evaluation process of domestic and foreign Accreditation Advisory Bodies through application review and assessment and by conducting audits of Accreditation Advisory Bodies. Lead Auditor is responsible for maintaining and administering the COO Quality Management System Manual.

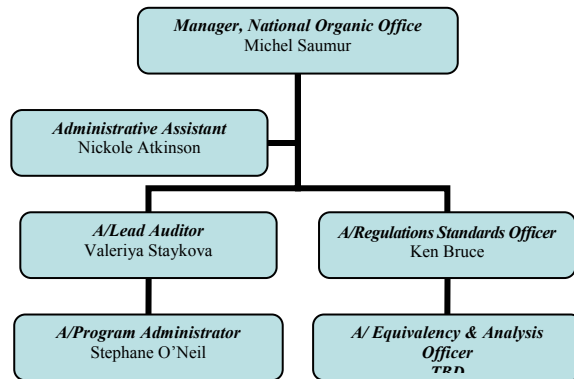
1.3.1.5 Equivalency and Analysis Officer

This Officer evaluates and assesses applications from foreign Competent Authorities. The Officer also develops procedures/guidelines in consultation with stakeholders for organic imports, exports, and international issues.

1.3.1.6 Program Administrator

The Program Administrator develops and implements the communications plan, provides advice & services related to: communications, web site, record keeping, on-line forms, information gathering, reporting, and web-based enforcement tools.

1.3.1.6.1 Organisation Chart



1.3.2 External Stakeholders

The COO has relationships with several stakeholders, both external and internal. External Stakeholders include other Federal government departments, provinces, territories, Accreditation Advisory Bodies, Certification Bodies, industry advisory bodies, trade associations, international standards organizations, trading partners, processors, producers and consumers. Below is a description of the COO's interaction and/or relationship with several key external stakeholders.

1.3.2.1 Agriculture and Agri-Food Canada (AAFC)

The COO shall support AAFC's public awareness activities, round-table advisory group, and in their efforts for gathering statistics related to the trade of organic products.

1.3.2.2 Canada Border Services Agency (CBSA)

The COO shall work with the Canada Border Services Agency (CBSA) to develop import control activities for organic products.

1.3.2.3 Department of Foreign Affairs and International Trade

COO shall align its efforts and liaise with the Department of Foreign Affairs and International Trade Canada (DFAIT) when engaging in foreign recognition activities.

1.3.2.4 Organic Sector (ABs, CBs, Operators, Importers, Exporters, Trade Associations)

The COO is responsible for:

- administering the Canada Organic Regime
- consulting with the organic sector so that the COR is responsive to the needs of stakeholders; and
- working with certifiers, processors, importers, exporters and training institutions to improve the competence of CB inspectors delivering verification activities for certified organic operators.
- communicating the intent of the regulations and meaning of the logo to stakeholders

1.3.3 Internal Stakeholders

The COO is responsible for developing and maintaining relationships with the other various branches within CFIA. Engaging in these relationships is crucial for integrating existing programs for food sampling and testing, recalls imports, labelling, enforcement and investigation into the COR. Below is a description of the COO's relationship or interaction with several key internal stakeholders.

1.3.3.1 Food Recall and Emergency Response (FRER)

Food Recalls are emergencies initiated and overseen by CFIA's Office for Food Recall and Emergency Response (FRER). Organic food products shall be integrated into the regular activities of FRER. Should an organic product be subject to recall, it shall be handled by FRER. Serious cases related to health and safety shall be investigated by the Enforcement and Investigation Services (EIS).

1.3.3.2 Import Coordination

Imports of organic products shall be subject to the same quality inspections, residue testing, label review and documentation requirements as all products imported into Canada. The COO shall work with the CFIA's Import Coordination Section to track organic imports.

1.3.3.3 Fair Labelling Practices Program (FLPP)

The CFIA has a Fair Labelling Practices Program (FLPP) that verifies the accuracy of a label's advertising claims, and declarations for product composition, quantity, best before date, country of origin, and responsible party.

The COO shall work with the FLPP and stakeholders to establish labelling and advertising guidelines organic products. These guidelines shall be published in Canada's Guide to Food Labelling and Advertising.

1.3.3.4 Operations and Programs (Integration of Organic Program Delivery)

The Operations Branch of the CFIA is responsible for the delivery of field inspection activities. While, the Programs Branch is responsible for developing the policies and procedures used by Operations to deliver inspection activities.

The COO is an Office within CFIA's Programs Branch. It is responsible for the development of various policies and procedures for the compliance verification of organic products. These policies and procedures are to be used by the various other sections within Programs Branch, so that they may integrate them into their respective compliance verification activities. Finally, Operations shall deliver these compliance verification activities.

1.4 COO Resource Management

1.4.1 Resource Management

This section describes the procedures in place for maintaining records concerning the educational, technical, and managerial experience of all personnel and describes the manner in which competence in the organization is ensured and enhanced. These procedures are set up to comply with CFIA human resource policies for the purposes of the Acts and Regulations enforced by the CFIA.

1.4.1.1 Personnel Records

Work descriptions, organization charts, and performance feedback and reviews define authority and responsibility of tasks. Work descriptions and performance feedback are kept in personnel files for each employee. These files are maintained by the Administrative Assistant. Although employees may view or obtain copies of file documents, only the Supervisor, the Manager or the Quality Coordinator may sign out files. These files are kept solely for the convenience of the COO and for specific purposes identified in the QMS Manual or SOPs. Official personnel files, both by position and by individual staff member are maintained by Human Resources Division.

The COO's personnel files include:

- Administrative Records;
- Work Description;
- Statement of Qualifications;
- Performance feedback and Reviews;
- Notice of Staffing;
- Letter of Offer;
- Training Records;
- Career Plan;
- Quality Management System Records;
- Curriculum Vitae (CV); and
- Familiarization Training Records, *COO-F -004 QMS Familiarization Record*.

1.4.1.2 Statement of Qualifications

Qualifications are segregated into basic and rated requirements. Basic requirements include education,

language requirements, and experience. The rated requirements include knowledge, ability, and personal suitability.

1.4.1.3 Work Description

Work description details the duties and responsibilities inherent with each position in the Program.

1.4.1.4 Performance Feedback and Review

Appraisals relate accomplishments achieved during the review period to pre-established goals, provide constructive comments on specific aspects of employee performance, establish goals for the upcoming period, and provide an opportunity for either party to identify training or developmental requirements.

Performance Feedback and Reviews are completed in conjunction with the employee by the immediate supervisor.

The Performance Feedback and Review process applies to all group classifications. The performance is formally assessed at the established schedule or at the request of the employee. If there is no current appraisal in the employee's administrative file, then the employee is considered to be performing at a fully satisfactory level.

1.4.1.5 Employee Work Résumés

Employee work related experience and qualification résumés are filed in the administrative files. Access to this information is limited to the employee, responsible Administrative Assistant, Manager, Supervisor and the Quality Coordinator.

Employee work related experience and qualification résumés are updated as necessary by the addition of expanded educational credentials, special training, new skills, or experience gained subsequent to appointment to a position. The employee is responsible to ensure that their file is up to date.

1.4.2 Personnel Orientation and Training

Qualified and well-trained personnel are essential for producing high quality work. The COO is committed in providing each employee with the training necessary for each position.

1.4.2.1 New Employees

The Agency uses the employee Orientation Site on its Intranet “Merlin” web page to introduce new personnel to the Agency to serve as a guide for their orientation.

The process shall vary depending on the trainee's experience and the nature of the position.

1.4.2.2 Current Employees

Manager of COO is responsible for identifying training needs through performance appraisal and/or other means. The Manager submits an annual Training & Development Plan and Conference Plan to the Food Safety Directorate Executive Director. In order to ensure that the employee is able to meet the job requirements, training is offered through:

- On-the-job training;
- Software training;
- Workshops;
- Short courses such as ISO awareness;
- Conferences;
- University or college courses;
- Public Service Commission courses; and
- Departmental/Agency courses.

A record of training is maintained for each employee in the employee's Administrative file.

1.4.3 Retraining

The retraining of an existing employee is initiated in the event that: considerable time has passed since a particular task was performed by that employee, or upgrading of skills is required as recommended in an audit report.

1.4.4 Work Environment

COO provides, manages and maintains a proper work environment free from harassment to achieve conformity to services requirements.

Employees shall follow the access and visitor security policies applicable to their work location.

Filing cabinets which contain sensitive and/or confidential documents are locked when the rooms are unattended by authorized personnel.

1.5 Scope of the Manual – Introduction to the Canada Organic Office QMS Manual

This manual describes the Quality system for the COO.

1.5.1 Quality Policy

The COO Quality Management System is developed and implemented by the COO team to enhance, promote and support the COR in Canada and abroad and is based on internationally recognized practices. We endeavour to provide timely, high quality and professional services that meet our clients' needs.

This policy is achieved through management and personnel commitment to apply good practices and provide quality services. This effort is aided by the distribution of a Quality Management System Manual that is maintained and administered under the direction and authority of the Quality Coordinator.

1.5.2 Objectives

The main objectives of the COO QMS are:

- To develop, implement and maintain Canada Organic Regime
- To continually improve overall quality of COO work performance by assuring personnel are adequately trained for procedures performed

1.5.3 Quality Responsibilities

All COO personnel are responsible for adhering to the QMS Manual and are encouraged to participate in the preparation and revision of the QMS Manual and operating procedures.

The QMS responsibilities of each position within the COO are summarized in the following sections.

1.5.3.1 COO Manager

The COO Manager's responsibilities are to:

- approve and assign time and resources to the QMS;
- establish and authorize QMS policy and direction;
- review and audit QMS (quality reports);
- provide qualified and adequate management and management structure;

- appoint the Quality Coordinator; and
- implement and maintain QMS.

1.5.3.2 Quality Coordinator

The role of the Quality Coordinator will be taken by the COO Lead Auditor. The Quality Coordinator's responsibilities are to:

- write, or assign other personnel to write maintain and implement the QMS Manual;
- seek participation from COO personnel in the writing, maintenance and implementation of the QMS;
- authorize or obtain the authorization of the Manager for justifiable deviation from QMS Manual;
- authorize all changes to the QMS Manual submitted with the Deviation Observation Form (to be developed);
- coordinate internal audits and reports on findings (including deficiencies and corrective action plan); and
- maintain a filing system for all quality records.

1.5.3.3 COO Team Members

The COO Team Members' responsibilities are to:

- implement and follow the QMS (e.g., QMS Manual, Operational Procedures (OPs));
- ensure quality of the final product or any other services provided to COO clients;
- participate in technical training, where appropriate;
- identify, investigate and report deficiencies/nonconformities;
- suggest/propose and implement solutions/improvements;
- participate in the preparation of the SOP Manual and QMS Manual; and
- comment on QMS policies and procedures.

1.5.4 COO Quality Management System Manual

The purpose of QMS Manual is to provide a description of the quality system to be used by all personnel, to define the requirements for the system's maintenance, documentation and records, and to identify the location of the supporting COO operating procedures. All of this ensures accuracy and reliability and demonstrates our commitment to quality. The COO QMS Manual is prepared and maintained by the Quality Coordinator in conjunction with COO personnel and management.

The COO QMS Manual provides comprehensive procedures and guidelines for the documentation of COR activities.

1.5.4.1 Format

The COO QMS Manual is prepared and maintained in a binder for ease of revision by the Quality Coordinator. Each section is identified with version number. Original copies of all previous versions of each section are kept on file by the Quality Coordinator to provide historical reference.

1.5.4.2 COO QMS Manual distribution

The COO QMS Manual does not contain confidential information and its availability is not limited to COO team. COO shall establish distribution list and updated versions shall be provided annually.

1.5.4.3 Implementation and Revisions

The Quality manual has been developed by COO National Manager in conjunction with COO personnel and in consultation with the industry.

Revisions to the Manual may result from errors found in the manual, changes in procedures to improve the QMS, audits, Reviews, non-conformities, complaints and the addition of new activities. If no revision has been made; the entire manual is reviewed every year. All employees and other stakeholders can make proposals for change (using COO-QMS- 004 Deviation Observation). All proposals are recorded documented and managed through the revision process by the Quality Coordinator with stakeholders' involvement.

Approval of a revision is required from the Quality Coordinator and the Manager prior to its implementation. Upon revision, the Quality Coordinator promptly sends, to responsible staff members, a copy of the revised manual, including an electronic version. All previous versions (except electronic) are returned to the Quality Coordinator. Documents are filed in a central file system for historical purposes by the Quality Coordinator and are kept at COO office.

1.5.5 COO Operating procedures

COO Operating Procedures are an integral part of the QMS, representing prescribed documentation for daily operation of the COO both in terms of directional and technical guidance. Operating procedures help to ensure that all the activities are performed in a consistent manner by all COO staff.

Operating procedures are updated as required to reflect current procedures and must be made readily available to all personnel.

1.5.5.1 Preparation

The operating procedures are prepared by Individuals that are most familiar with the procedures and perform the procedures routinely. However, all personnel can propose and/or prepare new operating procedures or revision to operating procedures

1.5.5.2 Identification

The operating procedures are all under the same category and level. Each procedure is assigned a unique number by the Quality Coordinator as follows **COO – XXX – YYY**.

Where:

XXX represents the subsection such as QMS (Quality Management System OPs), ADM (Administrative OPs), COM (Communication OP), etc.

YYY represents a sequential number such as 001, 002, etc.

1.5.5.3 Format

The operating procedures are consistently formatted to the format outlined below on page 20. A template outlining the current format is available from the Quality Coordinator and from the COO QMS Manual. Sections may vary somewhat to appropriately address the subject of the procedure. The operating procedure may be all-inclusive and/or refer to specific sections or pages of other documents. Following appropriate training, COO staff is expected to follow and perform the tasks covered by the document correctly and consistently.

The typical format includes:

Title of the Operating Procedure

References/ Background Information: References to a book, journal, document, web site, etc. Appendices are listed as well. Information to introduce or enhance the understanding of the concepts can be included in the OP. (e.g. definitions)

Authority: The legal authority (Acts and Regulations) governing this Chapter

Objective (Scope): Identifies the activity or group of activities covered by the OP and the extent to which it applies. It can also identify limitations or restrictions.

Procedures: Lists the steps to be followed. The use of numbers to separate individual procedures and/or to group related activities is advised unless the steps are limited.

Frequency: How often the procedure shall be done.

Person responsible: Title of CFIA personnel responsible for carrying out the procedures.

Records: Description of the records that shall be maintained.

Training: Description of the training the CFIA staff shall need to be able to perform the procedures.

SOP Revision History: The revision of history helps to identify the correct version of OP and the revision. It allows for the tracking of the OP's enhancements and/or refinements as well as the history. A table, as outlined below, is used to track revisions.

Version : 1.0
Date:
Description : 1 st Version
Author:
Approved:

1.5.5.4 Approval, Retirement & Records

As noted previously, the process for approval depends on who is responsible for the OP. However, the retirement forms and the record keeping are at the Quality Coordinator level for all of the OPs, including historical records. The following form shall be used: *COO-F-002 Form Approval*.

1.5.6 Distribution

Personnel are notified about each new or revised operating procedure, as it is approved. If training is required, the Quality Coordinator shall be informed in order to address the training needs. Staff members responsible for each operating procedure receive any new or revised version of the OP from the Quality Coordinator. Controlled copies are provided to all responsible staff members, as requested. Responsible staff members update their OP and forward any out of date OP to the Quality Coordinator for destruction. A controlled copy of the OP is also placed in the appropriate Quality Management folder on RDIMS.

1.5.7 Training and Records

COO staff shall be provided access to a copy of the COO QMS Manual. Or, staff shall be given a copy of any OP that is required for their day to day work.

COO staff must be familiar with those OPs that affect their work. The training records shall reflect that the COO staff have received a copy, have read the copy and fully understand the OP. Staff shall only receive those OPs for which they have need (see procedure *COO-QMS -001-Quality Management System Familiarization*)

1.5.8 Data Management

This section describes the policies for handling the documents and records related to the COO activities and outline the procedures used for control of documents to ensure that they remain readily identifiable with current version status, distributed as appropriate and that obsolete versions are removed from circulation.

All information may be recorded or written in either official language. Any handwriting must be in blue ink.

1.5.9 Data Traceability and Security

Since more than one person can be involved in a single project, it is crucial that the Program generate a proper recording and referencing system.

All data or information must be well recorded so that its origin can be easily identified. All personnel participating in any step of the process must be recorded

1.5.10 Data Acquisition and Recording

Data on file must identify all personnel who produced the document and handled it. There must be sufficient detail to trace all corresponding information and/or data and to permit traceability and protocol duplication if required.

1.5.11 Record Archiving

Any files are stored by the Quality Coordinator. Records are kept in the building for two years and then are filed and archived according to the Central Filing System Index.

1.5.12 Proprietary Rights and Confidentiality

Access to COO files by others is established according to guidelines documented in the Federal Government's Access to Information Policy. In some circumstances supporting documentation are provided to the Agency but with the provision that the information is to be considered proprietary. Use or release of this information must be approved by the client.

1.6 COO QMS Review and Assessment

This section outlines the policy and procedures for monitoring COO QMS to ensure: continued compliance with requirements; management's awareness of the QMS' status; and the system's continual improvement.

1.6.1 Internal Audit

The purpose of the internal audit is to evaluate the performance of the Program and verify adherence to QMS. Quality Coordinator is responsible for internal audits. The internal audit must be performed once every fiscal year and can be done all at once or it can be conducted throughout the year. In either case, the Quality Management System must be fully audited every fiscal year. In certain circumstances, the Manager can request a full or partial audit.

Compliance with established policies and procedures is assessed through discussion with employees, and by an on-site review of any or all activities, documents and records of the QMS. Findings are compared to Quality Management Objectives and requirements as outlined in the QMS Manual, OPs and as designated in ISO 9001:2000, "Quality Management Systems – Requirements."

The findings of the internal audits and proposed corrective actions are included in form *COO-F- 003 Internal Audit Report Form* and are to be included in a yearly Quality Report.

1.6.2 Quality Management System

The COO team holds a meeting every week. QMS is on the agenda for each meeting. Any changes to the QMS, major or minor, shall be addressed at these meetings (see procedure *COO-QMS -001 Quality Management System Familiarization*).

1.6.2.1 Management Reviews

A review of the COO QMS Manual is required at least once every fiscal year to ensure its continuing suitability and effectiveness.

The Quality Coordinator shall initiate the review by first demonstrating, to the Manager, the need for a review. The review shall encompass all ISO requirements (quality reports, audit findings, corrective actions,) and any changes to ISO requirements. To begin the review, the Manager must appoint

a team leader and team members to conduct it (the Quality Coordinator is included as one of the team members).

The Quality Coordinator provides a written report based on the findings of the review. The report must outline the steps taken to perform the review, the considerations and the findings. The report also includes recommendations to the Manager for any changes. The recommendations shall outline a proposal for changes, expected outputs, concerns and time frames.

The Manager shall accept or reject the recommendations. A team leader shall be assigned to implement those recommendations that are accepted. The team leader prepares a plan and identifies resources required to complete the implementation, for approval from the Manager. Any changes to the QMS shall follow the requirements of the QMS Manual. Any recommendations that are rejected by the Manager must be documented to ensure traceability.

The review includes the following elements:

- Audits findings (1st, 2nd or 3rd party);
- Client feedback (survey relating to service provided from internal and external client);
- Process performance and service conformity;
- Corrective and preventive actions status;
- Follow-up actions from previous management reviews;
- Change in the volume and type of the work that could affect the Quality Management System;
- Complaints;
- Recommendations for improvement;
- Improvement of the effectiveness of the QMS and its processes. Improvement of service related to customer requirements; and
- Resource needs.

Findings from quality management reviews and resulting actions are recorded. The Quality Coordinator ensures that all such actions are discharged within appropriate time-lines established in consultation with the Manager and Quality Coordinator and that the requirements of the QMS are met.

1.6.2.2 Quality Report

The Quality Coordinator prepares quality report for the review of the QMS along with appropriate comments.

The report is to include items such as:

- Complaints, non-conformance, corrective action summaries
- Quality training (course, other activities)
- Summary of Quality documents reviewed/revised
- Internal/External Audit

In addition, the Quality Coordinator highlights any nonconformities and requests corrective action plans. Late or missing reports are included in the Quality Coordinator's report to the Manager.

1.6.3 Management Assessment and Review Records

All data generated by the audit procedure, QMS review as well as all Quality report and correspondence are maintained on file by the Quality Coordinator in a secured location, chronologically by record type.

1.6.4 Complaints, Deficiencies, Discrepancies, Non-Conformities, Corrective Actions and Preventive Actions (COO –QMS -004 Deviation Observation)

This procedure outlines the management of complaints regarding the COO and its operations.

1.6.4.1 Complaints

Complaints are defined as any concerns with COO and service provided expressed by clients. Clients are defined as industry, AAB, CB, consumers, program staff, Other Government Departments (OGDs), and CFIA staff.

The complainant is referred to the responsible person or to the Manager. A detailed record of the complaint is made. The Manager assigns an investigator to compile records and to collect data to be used to assess if the complaint is valid or not (see Section 4.4.2 of OP COO –QMS- 004 Deviation Observation). The Quality Coordinator is responsible for verifying the work of the investigator (see Section 4.4.3 of the OP COO-QMS-004 Deviation Observation).

Once the investigator's assessment is complete, the Manager and Quality Coordinator must decide whether the complaint warrants further follow-up. If a deficiency, discrepancy or nonconformity was identified, the Manager must follow those

procedures outlined in Section 1.6.4.2. If corrective action is proposed, the procedures set out in Section 1.6.4.3 must be followed.

The Quality Coordinator and COO Manager are kept informed through the record tracking process and through quality reports.

After consulting with the person involved and reviewing the documents, the Quality Coordinator discusses the appropriate action with the complainant or responsible person.

Detailed procedures relating to documentation, records, investigation, etc. are available in the OP *COO-QMS-004 Deviation Observation*, and the form *COO-F-004 Deviation Observation* provides the tracking process.

1.6.4.2 Detection of Deficiencies, Discrepancies and Conformities

The Quality Management audit, Quality Management review, verification practices, complaints, out of control situations, etc., may uncover deficiencies, discrepancies, nonconformance to or unauthorized deviations from policies or procedures. The term nonconformance or nonconformity is used to identify all of these conditions.

A nonconformance may be reported to the Manager by any COO team member. When the Manager receives a non-conformity report, they must appoint a person to lead an investigation. Form *COO-F -004 Deviation Observation* is used to track the process. The following information must be documented throughout the investigation:

- an outline of the problem;
- persons responsible for investigation and resolution;
- the process of investigation and the cause(s) for the complaint;
- a proposed corrective action plan; and
- an incident closing statement (actions complete, situation resolved).

Should the investigation lead to corrective actions, a corrective action plan must be prepared. A corrective action plan shall prevent a reoccurrence of the nonconformity.

Audits, reviews, and complaints are covered in other sections of this manual. Further details about the investigations, their documentation and records can be found in the OP COO-QMS - 004 *Deviation Observation*.

1.6.4.3 Corrective Action Plan

The process of correction, verification of the correction, and documentation of these actions, is defined as corrective action. Corrective actions usually can be designated as either short term or long term, and in many cases both designations may apply. It is the responsibility of the appropriate staff member and the Manager to address both the immediate solution and the long-term action to eliminate the causes of nonconformity.

For each nonconformity and/or valid complaint, a corrective action plan is developed, that includes:

- a person assigned to manage and complete the action plan;
- a definition of the nonconformity, proposal to correct, expected outputs (measurable or tangible, e.g., revised OP);
- concerns that need to be considered or addressed;
- steps required to implement the corrective action;
- persons assigned to complete the various steps;
- target dates for completion; and
- verification that corrective action eliminates the nonconformity.

The specific nonconformity and corrective actions must be closely examined in subsequent audits.

Each corrective action plan must be documented and filed by the Quality Coordinator. Form *COO -F-004 Deviation Observation* is used to track the process.

1.6.4.4 Preventive Action

The Program is committed to identifying and implementing changes in the QMS when it is determined that these changes shall improve our performance or prevent nonconformities from occurring. These preventive actions may be suggested by employees or clients; or they may be identified through the audit or management review process. Changes suggested as preventive actions should be evaluated thoroughly to determine if the suggestion shall improve performance or eliminate or reduce the potential for nonconformity. The extent of the

evaluation process shall be determined by the scope of the proposed change and the impact that it shall have. When a proposed change is determined to offer a net benefit to the Program, an action plan shall be developed and implemented. The preventive action process is found in OP COO -F 005 *Preventive Action*.

1.6.4.5 Records

Records pertaining to complaints and their investigations, nonconformities and their investigations and corrective action plans and their implementation are maintained as follows:

COO-F- 005 Preventive Action
Quality Coordinator + a copy on a file in the appropriate filing cabinet

COO-F-005 Preventive Action
indicates on which file the historical information can be found.

All records pertaining to Preventive Actions are filed under Quality Management Requirements - Preventive Action, according to the established filing system.

1.6.5 Outside Support Services

The COO must ensure that satisfactory quality is provided by outside support services. If no independent assessment of the outside support service is available, then the COO must ensure that services comply with specified requirements.

Where feasible, contracts must be arranged in such a manner that they detail the service to be provided. Contracts are reviewed and approved by the Manager. The Manager recommends that a contract be adopted or rejected. Poor performance by the servicing agent is recorded in the log books and reported to the Manager for corrective action with the contractor.

Concerns about the quality of support services are treated as problems and corrective actions. Any documentation related to outside support services must be documented in the corresponding log book or kept on file.

1.7 QMS Forms and Procedures

1.7.1 COO Procedures

- *COO- QMS- 001 Quality Management System Familiarization*
- *COO- QMS-002 Improving the Quality System*
- *COO- QMS- 003 Document and Record Control*
- *COO-QMS-004 Deviation Observation*

1.7.2 COO Forms and Letter Templates

1.7.2.1 COO Forms

- *COO- F -001 Quality Management System Familiarization Record*
- *COO-F -002 Form approval*
- *COO-F-003 Internal Audit Report Form*
- *COO-F-004 Deviation Observation*
- *COO-F-005 Preventive Action*
- *COO-F-006 Receipt of Form*
- *COO-F-007 Missing Information Form Letter*
- *COO-F-008 Complaints register*
- *COO-F-009 Request for information form*
- *COO-F- 010 Application form for use of Canada Organic Logo in Advertising*

1.7.2.2 Forms and Letter Templates for Recognition Process

- *COO- RAB-001 Document Checklist*
- *COO-RAB-002 Document Review report*
- *COO-RAB-003 Notice of audit*
- *COO-RAB-004 Audit Plan*
- *COO-RAB-005 Audit Checklist*
- *COO-RAB-006 Audit Findings*
- *COO-RAB-007 Evaluation report*
- *COO-RAB-008 Recognition decision letter*
- *COO-RAB-009 Surveillance visit notice*
- *COO-RAB-010 Appeal Form*

1.7.2.3 Lists

- *COO- L- 001 Distribution list*
- *COO- L -002 Document register*
- *COO-L -003 Recognized Accreditation Advisory Bodies list*

- *COO-L -004 Accredited Certification Bodies list*
- *COO-L- 005 Certified Operators list*

1.8 COO Public Website (under revision)

The CFIA has an external website that faces the public. It is anticipated that the public facing website shall be linked to a Canada Organic National Informatics System (Database) (currently being designed). The public website is one tool in the COO's communications plan.

1.8.1 Objective

To educate the organic industry sector, consumers, and domestic and foreign governments about the *Organic Products Regulations (OPR)* and of the Canada Organic Regime (COR).

1.8.2 Information to be Included on the COO's Website

The COO maintains a public website. Below is a list of information to be included on the website:

- Up-to-date information on COO, including COO policies and contact information;
- Fact Sheets, Questions and Answers;
- Archive newsletters and bulletins;
- Conditions which must be met (Procedures to follow) for Accreditation Advisory Bodies to be recognized, for Certification Bodies to be accredited and operators to be certified under the COR;
- Recognition, accreditation (including standards accreditation) and certification procedures (steps to follow);
- Foreign Accreditation Advisory and Certification Body recognition procedures;
- Foreign country equivalency evaluations procedures;
- Conditions which must be met for standards accreditation; (What standards accreditation mean)
- Access to downloadable forms;
- Regulations and standards;
- The Canada Organic Quality Management System Manual;
- Canada Organic mark; and
- Related links, including a link to the National Informatics System.

The website shall include lists of:

- Recognized Domestic and International AABs; (The preferred term according to AABs is where the regulator “recognizes” AABs and AABs accredit CBs)
- Accredited Domestic and International CBs;
- Certified producers, processors, distributors and exporters; (the inclusion of lists of certified operators on the public website may be violation of the operators rights under the Privacy Act. It has been experience that many operators do not wish to publicly release their contact information or organic status for variety of reasons, including privacy. The COO could maintain a list of certified operators which could be used to confirm the status of a particular operator upon request for the same;
- Foreign countries having equivalency status.

1.8.3 Link to a Canada Organic National Informatics System

(under revision)

Currently, the COO is designing a National Informatics System for the Canada Organic Regime. One objective for developing this system is to provide a method for the COO to capture data that shall be made public. Specifically, the lists of organic stakeholders described in Section 1.8.1, above. For information regarding the Canada Organic National Informatics System, please see section 1.9.

On an ongoing basis, the COO updates the information on the public website.

Errors on the website are corrected by the Systems Intelligence Officer.(Program administrator)

The public has the possibility to transmit their comments and suggestions regarding the website by contacting the Systems Intelligence Officer. (Program administrator)

Website statistics reports generated by the COO

The Traffic Analysis report could give the following information:

- Total visits;
- Total page views
- Total hits;
- Total megabytes transferred;
- Average visits per day, week and month;
- Average pages viewed per visit;

- Average pages viewed per day;
- Highest volume time of day;
- Highest volume day of the week.

1.9 Canada Organic National Informatics System *(under revision)*

The Canada Organic Office (COO) requires a record keeping system to assist in the implementation and delivery of the Canada Organic Regime (COR). This system shall be an Information Management/Information Technology solution (i.e., a computer application). This system shall be referred to as the Canada Organic National Informatics System.

1.9.1 Functions

The National Informatics System shall have internal and external components. The internal components shall be designed to provide electronic assistance to CFIA's enforcement and monitoring processes in support of the Organic Sector. The internal components shall also assist the COO in automating several of its processes (e.g., manage correspondence, agreements, and complaints).

The National Informatics System shall be a tool for all participants of the regime. Thus, an external component shall be included through the web. Stakeholders such as Accreditation Advisory Bodies, Certification Bodies, and Operators shall have the ability to view lists of all recognised/accredited/certified AABs, CBs, and Operators. Also, these stakeholders shall have the ability to access various forms.

The National Informatics System shall also provide the following functions:

- Facilitate online applications. COR participants shall have the ability to apply online for recognition, accreditation and certification. Information captured by the application shall be forwarded to the relevant AAB or CB. The applicant shall be notified of the receipt of their application and the status of the application. All application forms shall be made available online (downloadable forms), including the export certificate form.
- A list of recognized Domestic and International AABs and CBs.
- A list of countries having equivalency status.
- Information on complaints / appeals relative to recognition, accreditation and certification. This information shall be made available only to the party filing the complaint or appeal.

1.9.2 User Access

The National Informatics System provides information on every participant of the regime and their activities. To maintain the

confidentiality of the participants, the system shall have various user access profiles. Below is a description of each profile:

- CFIA inspectors and COO employees shall have access to the information regarding all participants of the regime.
- AABs shall have access to the information concerning their own accreditation activities. For example, information on the CBs that they recommend for accreditation and information on the operators certified by these CBs.
- CBs shall have access to the information concerning their own Certification Body, e.g. the information on the operators they certify.
- Operators shall have access to the information concerning their own activities.
- User Access shall be controlled on a password basis.

1.9.3 Information to be included on Public Website

Much of the information captured by the National Informatics System shall be made public, on the CFIA's public Website. Below is a list of information that shall be made public, sorted by the stakeholder.

1.9.3.1 Accreditation Advisory Bodies (AABs)

- List of all CFIA recognised Domestic and International AABs.

The following information, for each AAB, shall be made available:

- Contact information (i.e., name, address, phone number, email address);
- Status of their recognition;
- List of Domestic and International CB's accredited by the AAB;
- Link to the AAB's website.

1.9.3.2 Certification Bodies (CBs)

- List of all CFIA accredited Domestic and International CBs.

The following information, for each CB, shall be made available:

- Contact information (i.e., name, address, phone number, email address);

- Status of their accreditation;
- List of Operators certified by the CB; and
- Link to the CB's website.

1.9.3.3 Operators:

- List of all certified Operators.

The following information, for each Operator, shall be made available:

- Contact information (i.e., name, address, phone number, email address);
- Status of their certification;
- Operations data (e.g. type of production, name of their Certification Body);
- Export certificates delivered by CBs.

1.10 Inspection and Enforcement Policy (under revision)

Section to be reviewed/revised in Phase II – after amendment of Organic Products Regulation

1.10.1 Background/Reference

The CFIA has developed a comprehensive enforcement and compliance policy and strategy to support its integrated inspection system. The Enforcement and Compliance Policy establishes uniform policies and procedures for monitoring compliance, carrying out inspections and conducting investigations. Enforcement and Investigation Services (EIS) Division is capable of responding to and supporting responses to non compliance in an effective, consistent and fair manner. In order to ensure consistency in the application of enforcement and compliance measures, linkage between the COO, Programs and Operations and the EIS Division become critical at both the national and regional levels. This linkage shall allow the COO to keep consistency in the application of CFIA's enforcement and compliance activities.

1.10.1.1 Inspection Stage

While conducting inspections, numerous activities relating to the follow up of non-compliance are undertaken. Regions - District Operations, Programs & EIS shall be cooperatively involved in this process.

Once a contravention is suspected, the matter is presented in the Inspectors Non Compliance Report (INCR). The COO Manager is responsible to coordinate the investigation and refer the report to EIS for Issue Analysis.

1.10.1.2 Issue Analysis Stage

Once an INCR is received, EIS follows the established procedures.

Copies of all enforcement action related documentation (warning letters, letters related to revocation or suspension, etc.) are to be sent to EIS for the case file and to the Manager of the COO.

1.10.1.3 Investigation Stage

Investigations shall either be carried out by Inspectors in consultation with Investigation Specialists or by an Investigation Specialist. Inspectors and investigational specialists conducting investigations shall adhere to the Charter of Rights and Freedoms, use proper investigational techniques, provide continuity of evidence, follow the rules for the admissibility of evidence and obtain search warrants, where required.

The role of COO is to coordinate investigations and provide advice, guidance and assistance to persons involved in conducting the investigation.

Upon completion of the investigation, a determination shall be made, through the Issue Analysis team, whether to recommend prosecution action.

1.10.2 Authority

Pursuant to section 11 of the *Canadian Food Inspection Agency Act*, The CFIA is responsible for the administration and enforcement of the *Agriculture and Agri-Food, Agri-Food Administrative Monetary Penalties Act, Canada Agricultural Products Act, Feeds Act, Fertilizers Act, Fish Inspection Act, Health of Animals Act, Meat Inspection Act, Plant Breeders' Rights Act, Plant Protection Act* and *Seeds Act*.

The Agency is also responsible for the enforcement of the *Consumer Packaging and Labelling Act* as it relates to food, as that term is defined in section 2 of the *Food and Drugs Act*.

In addition, the CFIA is responsible for the enforcement of the *Food and Drugs Act* as it relates to food, and the administration of the provisions of the *Food and Drugs Act* as they relate to food, except those provisions that relate to public health, safety or nutrition.

1.10.3 Objective

Ensure enforcement and compliance services consistent with CFIA's enforcement and compliance policy, and assure participant's compliance with the Canada Organic Regime requirements.

1.10.4 Procedures

Inspectors shall conduct regulatory verification activities to assess industry's compliance with the *Organic Products Regulations*, in accordance with established policies and procedures. With respect to organic products, these activities include:

Product Inspections:

- Inspection activities such as sample, pesticide residue testing, detention, report processes done according to the commodities' program Manuals and codes of practice;
- Inspectors verify if the organic product is properly labeled;
- Inspectors verify if the Certification Body is on the COO's list of accredited Certification Bodies under the Canada Organic Regime.
- Inspectors send a report to the operator. Reports regarding the compliance of a certified operator should be copied to the applicable C.B. in addition to the operator.

1.10.5 Frequency

Sampling plans, inspection work plans, when and how often are the inspections carried out are defined in the CFIA's commodity programs. For details, please consult the CFIA website (<http://www.inspection.gc.ca/english/toce.shtml>).

1.10.6 Person Responsible

Enforcement officials are individual designated as inspectors, veterinary inspectors, graders, analysts and officers. It also includes investigation specialists, other government employees such as Canadian Border Services Agency (CBSA) officials and the Royal Canadian Mounted Police (RCMP) who are assigned responsibility to ensure that the CFIA's legislation is enforced.

1.10.7 Corrective Actions

Product Inspection:

- The COO informs AAB and Certification Bodies, which certified the product, to proceed with the necessary verification with the operator,

- According to the product and the inspection program applied to it, the product can be seized, detained, re-labelled, destroyed, etc. in accordance with the CFIA multi-commodity inspection procedures,
- Corrective actions are taken in accordance with the Enforcement and Compliance Policy guidelines of the CFIA

1.10.8 Records

In case of investigation, COO will keep the following information:

- Inspection report including the name of the Certification Body
- Name of the Operator
- Identification of the commodity
- Explanation of the deviation from the requirement, if any
- Country of origin, if applicable

1.10.09 Training

CFIA's inspector training plan

1.10.10 Performance Indicators

- number of non-compliances
- number of notices/warnings sent
- number of non-compliance resolved
- number of investigations
- number of prosecutions
- number of de-certifications
- number of inspections performed
- corrective actions/follow-up

1.10.11 Statistics Reports

- The Multi-Commodity Activities Program (MCAP) shall record the results of inspections, audits and verifications by field inspectors and the responses to non compliance. SPRINT and PMC can also be used to obtain the indicators.
- The National Enforcement Tracking System (NETS) shall record enforcement measures taken against contraventions of the law and responses to non-compliance.

2.0 PRESCRIBED PROCEDURES FOR DELIVERY CANADA ORGANIC REGIME (COR)

2.1 Definitions

Accreditation (Accreditation)

is the procedure by which a government agency having jurisdiction formally recognizes the competence of an inspection and/or Certification Body to provide inspection and certification services. For organic production, the competent authority may delegate the accreditation function to a private body.

Accreditation Advisory Body (Organisme Consultatif d'Accréditation) *Definition to be reviewed/ revised in Phase II – after amendment of Organic Products Regulation*

Means a body that has entered into an agreement with the Agency under subsection 14(1) of the *Canadian Food Inspection Agency Act* to administer certain tasks, including assessing, recommending and monitoring the accreditation of Certification Bodies. (Source: *Organic Products Regulations*)

Advertise (Publicité ou annonce)

Means make any representation to the public by any means whatever, other than a label, for the purpose of promoting directly or indirectly the sale of a product. (Source: *Consumer Packaging and Labelling Act*)

Agency (Agence)

Means the Canadian Food inspection Agency established by section 3 of the *Canadian Food Inspection Agency Act*. (Source: *Organic Products Regulations*)

Agricultural Primary Products (Produits agricoles primaires)

Means livestock, plants or unprocessed single-ingredient livestock or plant products.

Audit (Audit)

Definition to be reviewed/ revised in Phase II – after amendment of Organic Products Regulation A systemic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

CB Inspector (Agent de vérification)

Person assigned by the Certification Body to conduct inspections.

Certification – (Certification)

The procedure whereby a (officially accredited) certification body provides written assurance that products or production systems conform to specified requirements. Certification of products may be based on a range of inspection activities including verification of management practices, auditing of quality assurance systems, and in/out production balances. (Source : CAN/ CGSB – 32.310 2006)

Certification Body (Organisme de certification)

Means a body that is accredited as a Certification Body in accordance with section 5 of the *Organic Products Regulations*. (Source: *Organic Products Regulations*)

Certified Product (Produit certifié)

Any product subjected to certification by an accredited certifying body, be it a tangible product intended for consumption (finished) or processing (primary) in the form of an ingredient, and distributed by the enterprise responsible for ensuring that products meet and, if applicable, continue to meet requirements upon which the certification is based.

Claim (Allégation)

Means any statement in labelling, advertising or commercial documents about an agricultural primary product or food or food ingredient that is intended to highlight the presence or absence of a specific characteristic of an agricultural primary product or food or an ingredient or the food or ingredient itself. (Source: adapted from the national standard for Voluntary Labelling and Advertising of Foods)

Competent Authority (Autorité compétente)

Means the official government agency having jurisdiction. (Sources: Canada organic standard and Codex)

Compliance (Conformité)

Definition to be reviewed/revised in Phase II – after amendment of Organic Products Regulation

Means the state of conformity with the law. The CFIA secures compliance with its acts and regulations through inspections and the use of statutory powers and authorities bestowed on agency officials. Inspection authorities may also use education, publication, of information and consultation with affected parties, when responding to non compliance, inspection, monitoring and auditing to verify compliance, responding to complaints of non compliance. (Source: CFIA enforcement policy)

Equivalency (Équivalence)

Is a mechanism to recognize and accept another system by acknowledging that variations between the systems uphold the respective system's (WTO, 1994). With respect to conformity assessment, ISO defines equivalence as the sufficiency of different conformity assessment results to provide the same level of assurance (ISO/IEC). It, therefore, refers to achieving the same outcome even though either technical regulations and/or the conformity assessment mechanism is/are not the same.

Inspection (Inspection)

Examination of foods or systems for control of food, raw materials, processing and distribution including in-process and finished product testing. In order to verify that they conform to requirements. (Source: adapted from ISO / IEC 17000)

Investigation (Enquête)

Involves the gathering of evidence and information, from a variety of sources, relevant to a suspected violation or offence and is intended to refute the defence of due diligence and/or establish intent (Source: CFIA enforcement policy)

Labelling (Étiquetage)

Means any written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near the food, including that for the purpose of promoting its sale or disposal.

“Manufacturer” or “distributor” (Fabricant ou distributeur)

means a person, including an association or partnership, who under their own name, or under a trade-, design or word mark, trade name or other name, word or mark controlled by them, sells a food; (*fabricant*) or (*distributeur*) (Source: adapted from *Food and Drugs Regulations*)

Mark of Certification (Marque de certification)

Mark vouching for the certification control of a product and obligatorily including the name of the certifying body and optionally the logo of the certification program.

Operator (Exploitant)

Means any person, firm, company or organization that produces, prepares, distributes, exports or imports, with a view to the subsequent marketing of products referred to as organic. (Source: adapted from the Canada organic standard)

Organic Product (Produit biologique)

Means an agricultural product that has been certified as organic in accordance with these Regulations or in respect of which an attestation

referred to in section 10 has been obtained. (Source: *Organic Products Regulations*)

Organic Production (Production biologique)

Means the use of organic production methods on the farm holding, as well as activities involved in the further processing, packaging and labelling of a product, in compliance with the objectives, principles and rules established in the *Organic Products Regulations*.

Permitted Substances Lists (Listes des substances permises)

Means lists of substances maintained by the competent authority meeting the criteria described in the accredited standards for permitted use under this Regulation. (Source: adapted from the Canada Organic standard)

Preparation (Préparation)

Includes, in respect of an agricultural product, processing, slaughtering, packing, assembling, pricing, marking and labelling. (Source: adapted from *Canada Agricultural Products Act* and the Canada organic standard)

Processed (Transformé)

means in respect of a food product, canned, cooked, frozen, concentrated, pickled or otherwise prepared to assure preservation of the food product in transport, distribution and storage, but does not include the final cooking or preparation of a food product for use as a meal or part of a meal such as may be done by restaurants, hospitals, food centres, catering establishments, central kitchens or similar establishments where food products are prepared for consumption rather than for extended preservation. (Source: *Processed Products Regulations*)

Trade-mark (Marque de fabrique)

A word, symbol or design (or combination of these), used to distinguish the wares or services of one person or organization from those of others in the marketplace. (CIPO definition)

Verification (Vérification)

Application of methods, procedures, tests and other checks, in addition to monitoring to determine compliance with COO approved plans, programmes, and systems and to confirm the ongoing applicability of those.

2.2 Prescribed procedures for Accreditation Advisory Body Applying for Recognition under Canada Organic Regime

THE REQUIREMENTS ARE ONLY APPLICABLE TO THE ACCREDITATION SERVICES PROVIDED TO THE COO. MOST AAB'S SHALL OFFER ACCREDITATION SERVICES WHICH ARE OUTSIDE THE PURVIEW OF CFIA AND THE COO.

FURTHER, CONSIDERATION MUST BE GIVEN TO ADDRESSING COO REQUIREMENTS OR REQUESTS FOR CORRECTIVE ACTIONS THAT MAY BE AT ODDS WITH THE IAF REQUIRMENTS FOR ISO/IEC 17011:2004.

2.2.1 Background Documentation/Reference

Annex 1 contains the Requirements and Procedures for the recognition of Accreditation Advisory Bodies.

2.2.2 Authority

Section 1 of the *Organic Products Regulations*.

2.2.3 Objective

This section outlines the procedures to be used by domestic and international Accreditation Advisory Bodies when applying for recognition under the Canada Organic Regime (COR). Applicants may be either private or government entities.

2.2.4 Procedures

- Applicant applies for recognition within the COR National informatics system
- Applicant must submit to the COO all documents listed in Appendix A of Annex 1,
- Applicant must pay the application fee (when applicable)
- The application and accompanying documents shall be reviewed to determine if the Accreditation Advisory Body complies with the procedures and standards established under COR,
- Applicant's conformance with ISO/IEC 17011:2004 shall be assessed by COO's Lead Auditor,
- The on-site evaluation shall occur after the document review is completed and satisfactory.
- Following the evaluation report prepared by COO Lead auditor, National Manager makes recommendation to the Director of Agrifood Division of CFIA

- Final recognition decision by the Director of the Agrifood division of CFIA shall be rendered between 9-12 months following the application date,
- When recognized, the Accreditation Advisory Body shall sign an agreement with the CFIA which details the obligations and responsibilities of each signatory party,
- The agreement between the CFIA and the Accreditation Advisory Body shall be renewed every five years following the recognition.

2.2.5 Frequency

On-site evaluation for recognition:

- Performed at the time of the application

Surveillance visit:

- Surveillance visit must take place within twelve months following the accreditation date; and then shall take place every 24 months.
- Otherwise, at any time and upon its own discretion, the COO may carry out additional visits for any major non-conformities with CFIA recognition requirements
- The COO may conduct unscheduled assessments or visits as a result of valid complaints or changes to the regulations.

2.2.6 Person Responsible

Lead auditor:

- In charge of Accreditation Advisory Body application, documents review, on-site evaluations, surveillance visits and any other unscheduled assessments.

National Manager:

- Following the Lead auditor evaluations and assessments, the National Manager makes recommendations to the Agrifood Division Director on any issues related to the recognition status of the Accreditation Advisory Bodies

Director of the Agrifood Division of CFIA:

- Recognizes Accreditation Advisory Bodies based on the COO's recommendations.

2.2.7 Deficiencies and Corrective Actions

Inadequate application information from applicant:

- Communicate to applicant list of deviations in application within one month from the document screening.

Conditional requirements resulting from document review or visit not met (See Annex 1):

- Communicate to applicant list of deviations;
- Extension of the period of time (to be determined) for applicant to meet requirements;
- Refusal or revocation of recognition status.

Non respect of agreement:

Suspension of recognition status:

- The Manager of the COO shall communicate with the applicant and provide assistance, guidance to bring the Accreditation Advisory Body into compliance,
- Files for Certification Bodies shall be managed by CFIA.

Revocation of recognition status:

- The Manager of the COO shall communicate with the applicant and provide assistance, guidance to bring the Accreditation Advisory Body into compliance,
- Files for Certification Bodies that have not already transferred their accreditation to another Accreditation Advisory Body shall be managed by CFIA,
- Within the three months following the revocation of the recognition status of the Accreditation Advisory Body, the COO shall assist the Certification Bodies affected by this situation to find a new Accreditation Advisory Body.

2.2.8 Records

COO needs to maintain records on Accreditation Advisory Bodies listed in section 11.1 of the Annex 1 to demonstrate that requirements for recognition, including competence, have been effectively fulfilled:

Relevant correspondence between COO and Accreditation Advisory Body,

- Assessment records and reports,
- Records specific to organic activities of committee deliberations, if applicable, and accreditation decisions,
- Copy of the most recent IAF evaluation or other third party assessment against ISO/IEC 17011:2004 standard,
- An update of documents required to obtain recognition (Appendix A)
- All major changes that took place during the previous year and that have affected corporate structure and directors, the administrative structure, the main managers of the organization and members of the committees,
- All modifications made to policies, internal procedures and regulations governing the organization and its accreditation system,
- The number of organic accreditations newly issued, renewed, suspended and withdrawn, listed by certifier
- List of all appeals filed pertaining to accreditation decisions handed down by the organization and from accredited certifiers,
- Copy of the file containing complaints against the organization and complaints about certifiers accredited to operate in the COR,
- Audited Annual Financial accounts
- All records pertaining to Accreditation Advisory Bodies are filed under Quality Management Requirements – Accreditation Advisory Bodies according to the established filing system.

2.2.9 Training

Ensure that the expertise of the CFIA assessment team and/or lead auditor is appropriate (See Annex 1). In particular knowledge of:

- standards development processes
- international organic standards, including Codex requirements
- bilateral and multilateral agreements (e.g. WTO, NAFTA)
- auditing

The COO Lead Auditor shall have:

- appropriate knowledge of the ISO/IEC 17011:2004 standard and ISO/ IEC 65 Guidelines,
- understanding sufficient to make a reliable assessment of the competence of the Accreditation Advisory Body to operate within Canada Organic Regime.
- CFIA auditor training or equivalent.

2.2.10 Performance Indicators

COO shall use performance indicators to define and measure progress toward organizational goals. The following indicators reflect the critical success factors of COO:

- Number of applications,
- Number of planned audits,
- Number of audits completed,
- Number of recognized applicants,
- Number of complaints/appeals on the evaluation process,

2.2.11 Audit and Surveillance

There are two type of audits related to Accreditation Advisory Bodies:

2.2.11.1 External:

- Conduced by COO :

Initial recognition

- COO shall conduct paper audit which includes a review of all relevant documents and records.
- COO shall conduct an on-site evaluation after the document review is completed and satisfactory.
- COO shall observe the performance of an auditor performing on-site evaluation to assess the competence of the Accreditation Advisory Body across the scope of recognition.

Reassessment and Surveillance

- The Accreditation Advisory Body shall be subject to surveillance on-site assessments. Surveillance on-site assessments are lees comprehensive then reassessment and shall target verification of specific program elements.

- Surveillance visit must take place within twelve months following the accreditation date; and then shall take place every 24 months.
 - The reassessment and re-evaluation visit shall take place once every five years.
- Conducted by AABs when evaluating Certification Bodies

Initial Accreditation

As part of ISO/IEC 65 Guidelines Compliant Accreditation Program the Accreditation Advisory Body shall conduct on-site evaluation of the conformity assessment services of Certification Body at the premises of the Certification Body.

In addition, the Accreditation Advisory Body shall review the performance of a representative number of staff at minimum one per office staff visit and inspection. A witness audit of a CB inspector shall be conducted to provide assurance of the competence of the Certification Body across the scope of accreditation.

Reassessment and Surveillance

- Refer to ISO/ IEC 17011
- The frequency and scheduling of surveillance visits are at the discretion of the Accreditation Advisory Body.
- The reassessment visit shall take place every five years.

2.2.11.2 Internal: Conducted by the Accreditation Advisory Bodies

The Accreditation Advisory Body shall establish procedures for internal audits to verify that they conform to the requirements of ISO/IEC 17011 and the management system is implemented and maintained. Internal audits shall be performed at least once a year.

2.2.12 Statistics reports

Organic application and National Informatics System -

- List of recognized AB's.
- List of complaints/appeals
- Complaints/appeals' results
- Decisions on recognition.

2.3 Prescribed procedures for accreditation of Certification Bodies operating under Canada Organic Regime

2.3.1 Background documents / Reference

Criteria are set out in the *Organic Products Regulations* and Annex 2 of this manual (Accreditation Procedures for Certification Bodies), and ISO/IEC Guide 65.

2.3.2 Authority

Sections 4, 5, 6, and 7 of the Organic Products Regulations.

2.3.3 Objective

This section outlines the procedures to be followed by Domestic and International Certification Bodies when applying for accreditation under the Canada Organic Regime (COR).

2.3.4 Procedures

- Applicant must apply for accreditation within the COR by sending an application to a recognized Accreditation Advisory Body..
- Applicant must provide its Quality Management System Manual, and any additional documents deemed essential to the assessment to the Accreditation Advisory Body. See Appendix B of Annex 2 for a complete list of documents to submit along with application,
- The Accreditation Advisory Body sends acknowledgement of receipt within five working days after reception of the application and proceeds with the assessment,
- Applicant must pay the application fees.
- AAB recommends accreditation of the CB to the CFIA and the CFIA grants accreditation to the CB.

2.3.5 Frequency

On-site evaluation:

- Evaluation for accreditation shall be carried out a least every five (5) years..

Surveillance visit:

- AAB shall establish procedures and plans for carrying out periodic surveillance on-site assessments, other surveillance activities and reassessments at significantly close intervals to monitor the accredited CBs continued fulfilment of requirements for accreditation.
- At any time, and upon its own initiative, the AAB may carry out a supervision visit for any major non-conformance with Canada Organic Regime.
- The AAB may conduct unscheduled assessments as a result of valid complaints or changes that have affected corporate structure and directors, the administrative structure, etc. (See Annex 2 for further details).
- The COO may conduct unscheduled assessments as a result of valid complaints or changes that have affected the CBs.

2.3.6 Person Responsible for accreditation of CBs

- The AAB shall formally appoint an Assessment Team consisting of a Lead assessor and where required a suitable number of assessors.
- COO Lead Auditor may accompany the assessment team to observe the accreditation process for CBs.

2.3.7 Deviations and Corrective Actions

The AAB shall establish procedures for identification and management of nonconformities.

- Accreditation Advisory Body shall communicate with the Certification Body to correct deviations, when:
 - The applicant provided inadequate and/or incomplete application information,
 - The applicant sends incomplete or no application fees. The Certification Body must proceed with the payment in order for the Accreditation Advisory Body to begin the analysis of the application.
- Accreditation requirements of Annex 2 not met:
 - The AAB shall communicate to the applicant the list of deviations,

- The AAB shall give an extension of the period of time for the applicant to meet the requirements,
- If the Certification Body does not meet the accreditation requirements, the COO may refuse to either give or renew the accreditation status based on AAB recommendations.

- Breach of accreditation agreement:
 - The COO may suspend or cancel the accreditation status and accreditation number based on AAB recommendations.

- Suspension or cancellation of accreditation:
 - The AAB shall communicate with the Certification Body and ensure the CB understands the requirements to come back into compliance.
 - Within the six months following the revocation of the accreditation of the Certification Body, COO shall assist the operators affected by this situation to find a new Certification Body.

2.3.8 Records

- Records maintained by Accreditation Advisory Body:

The Accreditation Advisory Body must maintain records on the Certification Bodies accredited by them to demonstrate that the requirements for recognition of accreditation, including competence, have been effectively fulfilled. The records to be maintained are listed in section 1 of Annex 2 and include:

- general features of the Certification Body, including corporate entity, name, addresses, legal status and human and technical resources;
- general information concerning the certification body such as its activities, its relationship in a larger corporate entity if any, and addresses of all its physical location(s) to be covered by the scope of accreditation;
- clearly defined, requested, scope of accreditation;
- an agreement to fulfil the requirements for accreditation and the other obligations of the Certification Body, including submitting all necessary documentation requested in Appendix B (Documents to submit along with application)
- a description of the conformity assessment services that the Certification Body undertakes, and a list of standards, methods, or procedures for which the Certification Body seeks accreditation, including limits of capability where applicable;
- a copy (on paper or in electronic form) of the quality manual of the Certification Body, and relevant associated documents and

records (see Appendix B; Documents to submit along with application).

- Records maintained by COO:
 - general features of the Certification Body, including corporate entity, name, addresses;
 - a description of the conformity assessment services that the Certification Body undertakes;
 - accreditation status of CB.

2.3.9 Training

- The Accreditation Advisory Body must ensure that the expertise of the assessment team and/or lead auditor is appropriate (See section 3.2 of Annex 2). In particular:
 - shall have appropriate knowledge of the specific scope for which accreditation is sought, and;
 - shall have understanding sufficient to make a reliable assessment of the competence of the Certification Body to operate within its scope of accreditation.

2.3.10 Performance Indicators

Following performance indicators shall be used to measure progress toward COO goals and objectives. The AAB should maintain and provide to COO upon request the following:

- Number of applications,
- Number of acknowledgement of receipt sent within five (5) working days;
- Number of planned audits,
- Number of audits completed,
- Number of accredited applicants,
- Number of nonconformities
- Number of complaints/appeals on the evaluation process.

2.3.11 Audit

Audits Conducted by Certification Body:

2.3.11.1 Internal Audits:

The internal audit shall be conducted according guidelines outlined in ISO19011.

In accordance with Annex 3 of the Organic Policies and Procedures Manual, the Certification Body must conduct periodic internal audits covering all procedures in a planned

and systematic manner, to verify that the quality system is implemented and is effective. It must ensure that:

- Personnel responsible for the area audited are informed of the outcome of the audit,
- Corrective action is taken in a timely and appropriate manner,
- The results of the audit are documented.

In accordance with Annex 3 of the Organic Policies and Procedures Manual, the Certification Body must review its quality system at defined intervals which are sufficiently clear to ensure its continuing suitability and effectiveness in satisfying the requirements of the accreditation criteria of the Canada Organic Regime.

- *Evaluation of products against a standard:*

In accordance with Annex 3 of the Organic Policies and Procedures Manual, the Certification Body must conduct an evaluation of all production and processing operations, including packaging and labelling pertaining to the product. Regular visits must include, among other things, a visit to all premises and locations preparation operations take place (See Annex 3 for details). Evaluations must be conducted for each certification application, including its renewal. Certification renewal applications must be done at least every five years.

In addition to the annual regular visits, the Certification Body may carry out surveillance activities, including unannounced on-site visits, in accordance with Annex 3 of the Organic Policies and Procedures Manual.

Evaluation of products against Canada Organic Production System Standards:

In accordance with Annex 3 of the Organic Policies and Procedures Manual:

- A regular site visit must be made to each location where each supplier is operating, at least once per calendar year, and with the intention of determining whether the certification shall be maintained,
- If a regular visit must occur on a date beyond a period of twelve months following the inspection from the previous year, this postponement must not exceed three months and must be justifiable by reasons,
- When the interval between two regular visits has

exceeded twelve months, the certifier must make sure that subsequent inspections restore the parity between the number of calendar years and the number of regular inspections over a given period.

2.3.11.2 External- Conducted by AAB when evaluating Certification Body.

- *Initial Accreditation*

As part COR Compliance, the Accreditation Advisory Body shall conduct on-site evaluation of the conformity assessment services of Certification Body at the premises of the Certification Body. In addition, the Accreditation Advisory Body shall review the performance of a representative number of staff at minimum one per office staff visit and inspection. A witness audit of a CB inspector shall be conducted to provide assurance of the competence of the Certification Body across the scope of accreditation.

- *Reassessment and Surveillance*

- The Certification Body shall be subjected to periodic surveillance on-site assessments, other surveillance activities and reassessments in accordance with the provisions of ISO 17011. (Surveillance on-site assessments are less comprehensive than reassessment)
- The frequency and scheduling of surveillance visits are at the discretion of the Accreditation Advisory Body.
- The reassessment visit shall take place at least every five years.

2.3.12 Statistics Reports

- *List of accredited CBs,*
- *List of complaints/appeals to accreditation process,*
- *Complaints/appeals' results,*
- *Decisions on accreditation.*

2.4 Prescribed procedures for Certification of Operators

2.4.1 Background/Reference

Criteria are set out in the *Organic Products Regulations*.

CGSB Standards

Annex 2 – Accreditation procedures for Certification Bodies

Appendix C- Required data for each operator

Annex 3 – General Requirements for Certification Bodies

2.4.2 Authority

Organic Products Regulations, sections 8, 11, 13.

2.4.3 Objective

These guidelines describe procedures to be followed by Operators and Certification Bodies during an application for certification under the Canada Organic Regime (COR).

2.4.4 Procedures

- Applicant can apply for certification within the COR sending application to an accredited Certification Body
- Applicant must provide all the relevant documents and information deemed essential to the assessment to the Certification Body as described in Annex 3 and Appendix C of Annex 2 of the Organic Policies and Procedures Manual. CB may require additional documents, if considered necessary,
- The Certification Body sends acknowledgement of receipt within ten working days after reception of the application and proceeds with the assessment,
- The applicant must pay the fees for certification according to the CB's contract for services and in accordance in the CB's fee schedule."

2.4.5 Frequency

- CBs conduct scheduled inspections at least once per calendar year, and in accordance with CB and QMS.
- In addition to scheduled ones, unannounced inspection visits shall be done by CB every year on 3% for primary producers and 5% for others of the Certification Body's clients (certified operators).

- CB may decide (Ref. to Annex 2) to add additional requirements to these already stated.

2.4.6 Person Responsible

- Assessment team or assessor identified by the Certification Body.
- COO Lead Auditor may accompany CB to observe the certification process.

2.4.7 Deviations and Corrective Actions

- Certification Body Corrective Actions:
 - The applicant provided inadequate and/or incomplete application.
- Requirements of CGSB Standard not met:
 - The Certification Body shall communicate to the applicant the list of deviations,
 - The Certification Body shall give an extension of the period of time by which the applicant must demonstrate the non-compliance no longer exists.
 - If the applicant does not meet the certification requirements, the Certification Body shall refuse to give or can cancel the certification. Certification Body shall communicate with the operator to correct deviations, when: The applicant provided inadequate and/or incomplete application information.
- The applicant sends incomplete or no application fees. The applicant must proceed with the payment in order for the Certification Body to begin the analysis of the application.
- Certification requirements of Annex 3 are not met:
 - The Certification Body shall communicate to the applicant the list of deviations,
 - The Certification Body shall give an extension of the period of time by which the applicant must demonstrate that non-compliance no longer exists,
 - If the applicant does not meet the certification requirements, the Certification Body shall refuse to give or can cancel the certification.
- Breach of certification contract:
 - The Certification Body may suspend or cancel the certification.

2.4.8 Records

- Certification Body Records:
The Certification Body must:
 - Maintain records on required data from operators listed in Appendix C of Annex 2 to demonstrate that requirements for certification have been effectively fulfilled,
 - Keep evaluation report and notification of non-compliance,
 - Keep the request for remedial action for each non-compliance and the date by which the applicant must demonstrate that the non-compliance no longer exists or that remedial actions were taken,
 - Keep the decision on certification.
- Operators Records:
 - According to CGSB Standard

2.4.9 Training

Certification Body

- The Certification Body must ensure that it employs a sufficient number of personnel having the necessary education, training, technical knowledge and experience for performing certification functions relating to the type, range and volume of work performed, under a responsible senior executive (See Annex 3).

2.4.10 Statistics Reports

- List of certified operators
- List of complaints/appeals to certification process
- Complaints/appeals' results
- Decisions on certification
- Data on operators.

2.5 Requirements for Numbering Domestic Certification Bodies

2.5.1 Background/Reference

A Certification Body operating in Canada is given an accreditation number allowing it to provide certification services in the country, and would be entitled to keep its accreditation number until the establishment demonstrates that it is not in compliance with the organic program.

Domestic and International Certification Bodies shall be numbered by the COO. Only numbered Certification Bodies would be allowed to certify to the standards of the Canada Organic Regime. Only the COO can revoke the accreditation number.

2.5.2 Authority

Section 5 of the Organic Products Regulations.

2.5.3 Objective

To describe procedures to be followed when numbering Certification Bodies.

2.5.4 Procedures

In order to receive an accreditation number:

2.5.4.1 *Certification Bodies must:*

- Be assessed by a recognized Accreditation Advisory Body,
- Meet the provisions of the *Organic Products Regulations* and the criteria listed in Annex 3 of the Organic Policies and Procedures Manual,
- Be recommended for accreditation by the recognized Accreditation Advisory Body,
- Pay the accreditation fees.

2.5.4.2 *Canada Organic Office:*

- The Manager of the COO shall assign the accreditation number no later than 14 days after receiving the Accreditation Advisory Body's recommendation for accreditation.

2.5.5 Frequency

Accreditation is renewed at least every five (5) years, when Certification Bodies reapply for accreditation and after a reassessment (see Annex 2: Accreditation procedure for Certification Bodies). The Certification Body shall keep the same accreditation number that they have received originally. Certification Bodies follow the procedures of section 5 above for reapplication.

2.5.6 Person Responsible

The Manager of the COO assigns the accreditation numbers.

2.5.7 Corrective Actions

- The COO may suspend the accreditation of a Certification Body based on AAB recommendations, when:
 - the Certification Body does not meet the provisions of the Organic Products Regulations, and the criteria of Annex 3 in the Organic Policies and Procedures Manual,
 - the Certification Body has failed or is unable to take immediate corrective measures.

- The COO may revoke the accreditation number of a Certification Body based on AAB recommendation when:
 - the Certification Body does not submit a corrective action plan that is acceptable to the Manager of the COO within the 30-day period following the day on which the accreditation number was suspended or within any longer period of time allowed under section III;
 - when there has been a change in ownership that involves a change of management of the establishment ownership by the Certification Body, or;
 - when the application for accreditation contains false or misleading information.

- No accreditation number shall be cancelled under section II unless:
 - the Certification Body was advised by letter of an opportunity to be heard in respect of the cancellation and was given that opportunity; and
 - a written notice by registered mail of cancellation of accreditation number was delivered to the Certification Body.

- If a Certification Body's accreditation number is suspended or cancelled, the Certification Body shall surrender the accreditation number attestation to the Manager of the COO.

2.5.8 Records

Historical records of numbering that certifiers keep.

2.5.9 Statistics Reports

The Canada Organic Office (COO) records all corrective measures taken against contraventions of the law and responses to non-compliance through the Organic Application and National Informatics System.

2.6 Guidelines for Complaints / Appeals

2.6.1 Complaints / Appeals: Certification Body

2.6.1.1 Background/Reference

The appeal process is based on ISO Guide 65:1996.
An operator or any other party wishing to contest a certification decision must attempt to resolve the matter with Certification Body. If this is not possible then the next step is the Certification Body's Accreditation Advisory Body. If the dispute cannot be resolved at the Certification Body and Accreditation Advisory Body levels then the Manager of the COO is the final step to hear the issue.

2.6.1.2 Authority

Canadian Food Inspection Agency Act

2.6.1.3 Objective

To provide operators and/or other parties with a process to contest any certification decisions made by a Certification Body, or to provide a complaint process for COR operators.

2.6.1.4 Procedures

Appeals, complaints and disputes brought before the Certification Body by operators or other parties shall be subject to the procedures established in the COR in Annex 3 of the Organic Policies and Procedures Manual.

These procedures must allow, among others, the implementation of an impartial appeal authority to deal with appeals from COR operators against decisions made by the Certification Body.

2.6.1.5 Frequency

As required.

2.6.1.6 Person Responsible

Director of the Certification Body, Accreditation Advisory Body and Canada Organic Office

2.6.1.7 Corrective Actions

To be done by CB and verified by the Accreditation Advisory Body during AABs audit.

2.6.1.8 Records

Each Certification Body must:

- keep a record of all appeals, complaints and disputes and remedial actions relative to certification;
 - appeals related to certification decisions;
 - complaints or objections from operators regarding the Certification Body's program application;
 - complaints or objections from outside persons or organizations about the Certification Body's operations.
- document the action taken and its effectiveness.

2.6.1.9 Performance Indicators

- Number of appeals lodged,
- Number of successful/ unsuccessful appeals
- Number of appeals decisions made by the CB
- Number of complaints or objections submitted
- Number of complaints and objections resolved

2.6.1.10 Audit

Recognized Accreditation Advisory Bodies shall audit Certification Bodies on a regular basis to make sure that Certification Bodies follow the guidelines of Annex 3 of the Organic Policies and Procedures Manual.

2.6.1.11 Statistics Reports

Keep records on:

- all appeals, complaints, disputes and remedial actions relative to certification,
- complaints or objections from operators regarding the CB's program application,
- complaints or objections from outside persons or organizations about the Certification Body's operations,
- number of appeals resolved,
- number of unresolved appeals.

2.6.2 Complaints / Appeals: Accreditation Advisory Body

2.6.2.1 Background/ Reference

The appeal process is based on the ISO 17011:2004 standard.

A Certification Body wishing to contest an accreditation decision must first try to resolve the issue with the concerned Accreditation Advisory Body who made the assessment for the COO. If this does not produce results the CB may bring the issue to the next higher level of authority, the COO. Only when the problem could not have been resolved, at the level of the Accreditation Advisory Body, shall the Manager of the COO examine the possibility of setting a hearing to resolve the issue.

2.6.2.2 Authority

Canadian Food Inspection Agency Act

2.6.2.3 Objective

To provide Certification Bodies with a process to contest any accreditation decisions made by an Accreditation Advisory Body, or to complain about or object to an Accreditation Advisory Body's program application or Accreditation Advisory Body's operations.

2.6.2.4 Procedures

Appeals, complaints and disputes brought before the Accreditation Advisory Body by Certification Bodies shall be subject to the procedures established in the ISO 17011:2004 standard.

- Appeals:
The Accreditation Advisory Body shall:
 - appoint a person, or group of persons, who are competent and independent of the subject of the appeal, to investigate the appeal;
 - decide on the validity of the appeal;
 - advise the Certification Body (and/or other parties) of the final decision(s) of the Accreditation Advisory Body within reasonable timeframe; and

- take follow-up action where required.
- Complaints:
The Accreditation Advisory Body:
 - shall establish procedures to address complaints by Certification Bodies;
 - shall respond to the Certification Body within 15 days following the date of receiving the complaint;
 - May also accept complaints or even verification requests relative to the performance of an accredited program;
 - Upon reception of such a complaint, it should determine its validity;
 - If it seems appropriate, the Accreditation Advisory Body shall both inform the Certification Body and invite it to comment; and
 - The case should be heard by the concerned assessment team as soon as enough evidence has been gathered.

2.6.2.5 Frequency

As required.

2.6.2.6 Person Responsible

Director of the Accreditation Advisory Body.

2.6.2.7 Corrective Actions

To be done by AAB and verified by the Canada Organic Office Lead auditor during AABs audit.

2.6.2.8 Records

- Each Accreditation Advisory Body must:
 - keep a record of all appeals, complaints and disputes and remedial actions relative to accreditation, that is;
 - appeals related to accreditation decisions;
 - complaints from Certification Bodies regarding violation of rights; and
 - complaints regarding the performance of an accredited program.
- Document the action taken and its effectiveness.

2.6.2.9 Performance Indicators

- Number of appeals
- Number of successful/ unsuccessful appeals

2.6.2.10 Audit

Canada Organic Office Lead auditor shall audit recognized Accreditation Advisory Bodies on a regular basis to make sure that Accreditation Advisory Bodies follow the guidelines of Annex 1 of the Organic Policies and Procedures Manual

2.6.2.11 Statistics Reports

Accreditation Advisory Bodies must keep records on:

- all appeals, complaints, disputes and remedial actions relative to accreditation,
- complaints from CBs on violation of rights,
- complaints on the performance of a CB's accredited program,
- follow-up actions,
- Final decisions must be sent to the Manager of the COO.

2.6.3 Complaints / Appeals: Canada Organic Office

2.6.3.1 Background/Reference

The appeal process is based on ISO guide 65:1996 and 17011:2004 standards. An Accreditation Advisory Body or any other party wishing to contest a "recognition status" granted or not to the AAB must address the issue with the Manager of the COO. Appeal from CB against accreditation decision that has not been resolved at the AAB level must be addressed with the Manager of COO.

Contest or complaint of a CB that has not been resolved at the AAB level must be addressed with the Manager of COO. Contest or complaint of an operator that has neither been resolved at the CB level, nor at the AAB level must be addressed with the Manager of COO.

The Manager of the COO may establish a hearing related to a contest or complaint on certification or accreditation decisions, only if the case is eligible and has not been resolved at the certification or accreditation appeal process levels.

2.6.3.2 Authority

Canadian Food Inspection Agency Act

2.6.3.3. Objective

To provide Accreditation Advisory Bodies, Certification Bodies, producers, processors, handlers and/or other parties with a process to request hearings on decisions impacting their operations.

2.6.3.4 Procedures

2.6.3.4.1 General Appeal

To be eligible, an appeal must follow the procedures below.

- Appeals against recognition decisions shall be addressed to COO.
- Appeals must be written down and sent to the Manager of the COO within 30 days of the original decision.
- An appealed decision must not have been the result of a previous hearing by the Manager of the COO.
- The Manager of the COO shall respond to the complainant within 15 days following the date of receiving the appeal.
- When the hearing is rejected, the Manager of the COO shall inform the applicant by a letter of decision.
- The Manager of the COO is in charge of the hearing, shall convene the hearing, may call witnesses and may consult with whoever he or she wishes to seek advice or expertise prior to rendering a decision.
- The decision of the Manager shall be sent in writing to the complainant within 10 working days after the end of the hearing.
- The decision of the Manager of the COO is final in all hearings.

2.6.3.4.2 General Complaint

To be eligible, a complaint must follow the procedures below.

- Complaints regarding the conduct of the COO personnel excluding COO National Manager shall be directed to COO National Manager
- All complaints must be submitted in writing.
- On receipt of a complaint the COO shall appoint a person to investigate the complaint.
- The receipt of the complaint shall be acknowledged within 15 working days
- The validity of the complaint shall be determined.
- Where a complaint is considered valid an investigation shall be carried out.
- The investigator shall review all information obtained and formulated a recommendation.
- The recommendation and necessary supporting documentation shall be submitted by the investigator to COO at the conclusion of the investigation.

2.6.3.5 Person Responsible

National Manager of the Canada Organic Office.

2.6.3.6 Records

The COO must:

- Keep full records of all appeals, of final decisions and follow-up actions (if any)
- Keep complete files containing all information related to the investigation of complaints.

2.6.3.7 Performance Indicators

- Number of requests for hearings,
- Number of hearings rejected,
- Number of hearing accepted,
- Number of hearing heard annually,
- Number of response letters sent within the 15 day window,
- Number of final decision letters sent within the 5 day window.

2.6.3.8 Statistics Reports

Keep records on:

- all hearings, appeals, complaints, disputes and remedial actions,

- Final decisions made by the Manager of the COO.

2.6.4 Complaints/ Appeals: Illegal Labelling (*under revision for further consultation*)

2.6.4.1 Background/Reference

The CFIA multi-commodity and labelling programs

2.6.4.2 Authority

Organic Products Regulations, sections 14 and 15

2.6.4.3 Objective

To protect consumers against the fraudulent and unauthorized use of the “Canada Organic” or “Biologique Canada” designations and/or the logos as specified in the *Organic Products Regulations*, through controlling their use and suppressing any illicit use”.

2.6.4.4 Procedures

2.6.4.4.1 Detection of non-compliant products:

2.6.4.4.2 Receiving a complaint or denunciation:

Organic products, like conventional food products, must meet the requirements of the *Consumer Packaging and Labelling Act*. In addition, organic products must meet the requirements of the labelling section of the *Organic Products Regulations*. A person may lodge a complaint regarding an organic product whose advertising, labelling, presentation, as well as related commercial document, appear to be non-compliant with the *Consumer Packaging and Labelling Act* and/or the *Organic Products Regulations*.

2.6.4.4.3 *Filling the complaint:*

- A complaint regarding organic labelling must be filled using the same procedures as a complaint on conventional food. The complainant may call the CFIA 1-800 line for general concerns including labelling. The number to call is 1-800-442-2342.

2.6.4.4.4 *Treatment of the Complaint:*

- The CFIA shall address the complaint pursuant to the Labelling program Manual and codes of practice.
- CFIA inspectors shall notify the Manager of the COO of a complaint on organic labelling.
- If the product is certified by an accredited Certification Body recognized by the COO, the COO contacts the Certification Body which certified the product to follow-up with the operator on corrective actions.
- The corrective actions must be taken in accordance with the enforcement guidelines of the CFIA.

2.6.4.4.5 *CFIA Inspection*

To ensure that the organic designation of products meets the requirements of the *Organic Products Regulations*, the CFIA incorporates labelling inspections within its regular inspection activities. For domestic organic products: See CFIA inspection activities and procedures in the section 11.0 on CFIA Inspection in the Organic Policies and Procedures Manual.

- For foreign organic products: See CFIA inspection activities and procedures in the section "Import Control Program: Product Inspection Program (PIP)".
- In the case of fraudulent labels, CFIA designated inspectors shall contact the responsible party listed on the label.

2.6.4.4.6 *Search for the Responsible Part:*

In order to determine who was responsible for marketing these products in Canada, the investigation's focus shall be tracing backwards along the distribution chain:

- In cases involving a Canadian product, this

refers to any company producing or manufacturing the product in order to sell it, or any company breaking it up or assembling the content of certified products in order to resell them under its own brand name.

- In cases involving products originating from outside Canada, this refers to any company operating in Canada (broker, distributor, retailer, etc.) that has acquired the above-mentioned products from a supplier based outside Canada, in order to sell them in Canada.

2.6.4.5 Frequency

Examination of a complaint is done upon reception of a complaint.

2.6.4.6 Person Responsible

National Manager, CFIA designated inspectors and managers of recognized Certification Bodies.

2.6.4.7 Corrective Actions

See sections:

- CFIA Inspection;
- Import Control Program: Product Inspection Program; and
- Enforcement.

2.6.4.8 Records

- Complaints received from CFIA regional offices
- Inspection reports

2.6.4.9 Training

CFIA's inspectors training plan within CFIA's commodity programs.

2.6.4.10 Performance Indicators

- Access MCAP: number of organic inspections performed, number of inspections classified as non-compliant.
- Number of complaints received.

- Number of complaints resolved.

2.6.4.11 Audit

Audit shall be performed in accordance with the CFIA multi-commodity inspection program in each of the program areas.

2.4.6.12 Statistics Reports

Through MCAP, SPRINT, PMC, the following Statistics Reports shall be gathered:

- Number of inspections;
- Compliance level (number of non-compliant inspections);
- Number of complaints; and
- Corrective actions/follow-up.

2.7 Guidelines for Labelling *(under revision for further consultation)*

2.7.1 Background/ Reference

The labelling and advertising of organic foods must be truthful and not misleading, as required by subsection 5(1) of the *Food and Drugs Act* and section 7 of the *Consumer Packaging and Labelling Act*, and in compliance with all other regulatory requirements as set out in the *Food and Drug Regulations*, the *Consumer Packaging and Labelling Regulations*, the *Competition Act*, the *Canada Agricultural Products Act* and any other relevant legislation, as well as the *Guide to Food Labelling and Advertising*.

In addition, organic foods must comply with the labelling requirements of the *Organic Products Regulations*.

2.7.2 Authority

Organic Products Regulations, sections 14 and 15, *Food and Drugs Act*, subsection 5(1), *Consumer Packaging and Labelling Regulations*, section 7, *Canada Agricultural Products Act*.

2.7.3 Objective

The objective of this section and Annex 4 are to:

- Describe labelling requirements for organic products pursuant to the *Organic Products Regulations*;
- Describe requirements for the control of references to the certification system or misleading uses of a Certification Body's certificates or marks; and
- Describe procedures for the calculation of the percentage of organic ingredients in a product.

2.7.4 Procedures

2.7.4.1 Certified Operators must:

- determine if the organic term (or synonyms allowed under the *Organic Products Regulations*) can be used on the label;
- choose the organic term to be used on the label;
- in the case of products containing multiple organic ingredients, calculate the percentage of organic ingredients used to determine the classes of labelling (see Annex 4, or contact your CB for verification);

- assure that all the mandatory labelling requirements are respected (see Annex 4 for details); and
- obtain label registration (if required), by contacting the Label Registration Unit of CFIA.

2.7.4.2 Certification Bodies must:

- For production of multi-ingredient products, verify the operators' calculations of the percentage of ingredients (see Annex 4);
- assure that their trademark/logo is properly applied, where applicable; and
- document non-compliance issues.

2.7.5 Frequency

Label verifications by CFIA shall be integrated with existing commodity inspection programs. The frequency of organic label inspections shall be determined annually, based on existing criteria. Periodic blitzes shall be held, and identified problem areas shall be monitored.

Operators must verify labels on an on-going basis.

Certification Bodies must verify label procedures during each calendar year and as needed.

2.7.6 Person Responsible

Operators are responsible for labels applied to their products, and Certification Bodies must exercise proper control over ownership, use and display of certificates, marks of conformity, or logos (when applicable), and shall verify the operator's calculation of percentage of all organically produced ingredients in a multi-ingredient product.

The person who prepares the product and affixes the label on a consumer package and whose work has been verified by a Certification Body, is responsible for ensuring its compliance with any federal and provincial labelling requirements.

The lead auditor in the Canada Organic Office of the Canadian Food Inspection Agency is responsible for implementing an organic label inspection program and for taking appropriate actions to rectify non-compliances.

CFIA inspectors are responsible for the enforcement of the labelling requirements and for the label registration.

2.7.7 Corrective Actions

Corrective actions shall be consistent with the procedures described in the CFIA Inspection and Enforcement section, and the procedures described in the Complaints/ Appeals section.

2.7.8 Records

Registered labels maintained by CFIA Label Registration Unit

- Non-compliance reports and actions taken and received from certifiers and CFIA inspectors maintained by the COO.

2.7.9 Training

N/a

2.7.10 Appraisal

- compliance levels
- adherence to inspection plan
- seriousness of non-compliance
- number of complaints
- number of resolved issues

2.7.11 Audit

- As part of the Product Inspection Program (see Section 11. CFIA Inspection and Enforcement Policy)
- CBs evaluations

2.7.12 Statistics Reports

- Annual internal report on verification activity, number of non-compliances, actions taken and outstanding issues.
- Multi-Commodity Activities Program (MCAP) / CFIA's non-compliance reports.
- National Informatics System Program (list of CBs, list of operators, etc...).

2.8 Import Control Program

The Canada Agricultural Products Act has been amended, SOR/2006-338, on December 14, 2006, to incorporate the Organic Products Regulations (Regulations), P.C. 2006-1535, come into force two years after the day on which they are registered. The Regulations regulate the processing, handling, labelling of all raw and processed agricultural products to be sold, labelled, imported or represented as organic in Canada. Section 10 of the Regulations provides that “a person who wishes to market an organic product in import trade shall apply in writing to the competent authority of the country of origin for an attestation conforming that the product meets the requirements of these Regulations.”

2.8.1 Procedures for Equivalency Determination

2.8.1.1 Background/Reference

An equivalency determination allows two differing standards, regulations or procedures to remain as is but treats them as if they are the same as long as they achieve the same results and policy objectives even if through different means.

2.8.1.2 Authority

The authority for the determination of a foreign country's equivalency status is provided by:

- the *Canada Agricultural Products Act*
- Sections 10 the *Organic Products Regulations*

2.8.1.3 Objective

This section outlines procedures to be followed by the competent authority having jurisdiction in Foreign Country in order to obtain an equivalency agreement with Canada.

The applicant country seeking equivalency should apply to Canada Organic Office (COO). Equivalency means that the Canada has determined that the exporting country's regulatory and technical measures and conformity assessment system achieve the level of compliance and meet the same objectives desired by Canada concerning the agricultural organic product. These measures may be

acceptable even if they are not identical to those used by the importing country.

The terms “regulatory and technical measures” refer to a system of relevant laws, regulations, practices, and procedures related to the production, handling, and processing and certification of organic agricultural products. The term “conformity assessment” includes all activities undertaken by a government to ensure that the technical measures are fully and consistently applied.

To determine equivalency with Canadian standards and inspection measures, the COO will require a side-by-side comparison of the Canadian and foreign country’s regulatory and technical measures and conformity assessment in order to assess the similarities and differences that may exist between the two organic regime. Obligations, as a result of equivalency negotiation, may vary in some respects depending on the circumstances of the particular determination.

Each party will notify the other of any planned legislative changes or revised equivalency determination including changes in policies, procedures, standards or documents (certificates) which are relevant to this agreement.

2.8.1.4 Procedures

2.8.1.4.1 Foreign Country will have to submit, in writing to the following address, an application for Equivalency Determination to the COO. The official letter should include the following requested information. All documents must be submitted in one of the official languages of Canada, English or French.

COO address: Canada Organic Office
 Canadian Food Inspection Agency
 159 Cleopatra Drive
 Ottawa, Ontario , K1A 0Y9

Requested information:

- The competent authority’s contact person(s) and contact information;

- The legal basis for the foreign government technical measures and assessment system;
- The scope of the requested determination
- A detailed side-by-side comparison of the technical measures and conformity assessment with a detailed documentation explaining the foreign government's position on the difference;
- Supporting documentation describing all part of the conformity assessment procedure used in the foreign country. This documentation should include legal, specification and procedures, compliance and enforcement process. The information should be sufficient to demonstrate the ability of foreign country to address non-compliance, corrective actions and enforcement.

2.8.1.4.2 Acknowledge receipt of submission by official letter

2.8.1.4.3 COO will review equivalency submission.

1.8.1.4.4 In formal negotiations, COO will work with International Trade Canada and Agriculture and Agri-Food Canada to determine equivalency status.

2.8.1.4.5 COO will coordinate communication with foreign country regarding equivalency determination.

2.8.1.4.6 COO may request on-site audit (see section E).

2.8.1.4.7 COO to deliver to foreign country results of equivalency status by official document,

2.8.1.4.8 COO will maintain list of foreign countries, including component of their Regime (Accreditation & Certification bodies)

2.8.1.5 Frequency

On-site evaluation for equivalency determination:

- Performed at the time of the application

- CFIA-COO may carry out further on-site verification for the purpose of audit.
- The re-evaluation visit shall take place once every five years.

Surveillance visit:

- Otherwise, at any time and upon its own discretion following an agreement with the competent authority, the COO may carry out additional visits in case of any major non-conformity.

Modification of foreign country's Organic Regime:

- Each party will notify the other of any planned legislative changes or revised equivalency determination including changes in policies, procedures, standards or documents (certificates) and component or their Regime which are relevant to this agreement
- COO evaluates modification and impact to equivalency status.

The equivalency agreement between the Canada and the exporting country will become effective upon signatures by both parties and will continue indefinitely, may be amended at any time by mutual understanding of the parties, or terminated by either party upon ninety days written notice to the other party.

2.8.1.6 Person Responsible

International Equivalency and Analysis Officer:

- In charge of coordination of the evaluation and assessment of the applications from foreign Competent Authorities.
- Responsible for the International issues of the COR.

National Manager:

- Following the Lead auditor evaluations and assessments, the National Manager makes recommendations to the Agrifood Division Director on any issues related to the equivalency status of the Foreign country.

Director of the Agrifood Division of CFIA:

- Determination of the Equivalency Agreement based on the COO's recommendations.

2.8.1.7 Deficiencies and Corrective Actions

Non-compliance product:

- Each party will notify the other of any product which is found to be in non-compliance, for example, as a result of unsatisfactory findings during monitoring, or as a result of consumer or trade complaint.
- Upon receipt of such a notification, the exporting country should undertake the necessary investigation to determine the cause of any problem that has led to the rejection of the consignment.
- Enforcement of adequate activities.
- Bilateral discussions should take place as necessary.

Non respect of equivalency status (agreement):

- The COO will communicate with the competent authority in respect of the deficiency
- The obligation to provide CFIA with information regarding corrective or enforcement actions imposed by the competent authority.
- Revocation of the agreement by Government of Canada

2.8.1.8 Records:

COO will maintain records on country equivalency list

Relevant correspondence,

- Assessment records and reports,
- An update of documents required to obtain equivalency status
- All major changes affected corporate structure
- All modifications made to policies, internal procedures and regulations governing the organization and its accreditation system,
- Accreditation and Certification Bodies newly issued, renewed, suspended and withdrawn, listed by certifier
- File of complaints.

2.8.1.9 Training

Ensure that the expertise of the CFIA assessment team is appropriate. In particular knowledge of:

- standards development processes
- international organic standards, including Codex requirements
- bilateral and multilateral agreements
- auditing

2.8.1.10 Performance Indicators

COO will use performance indicators to define and measure progress toward organizational goals. The following indicators reflect the critical success factors of COO:

- Number of applications,
- Number of planned audits,
- Number of audits completed,
- Number of recognized Foreign competent authority with the component of their Regime,
- Number of complaints/appeals on the evaluation process.

2.8.1.11 Audit

Initial equivalency determination

- COO will conduct paper audit which includes a review of all relevant documents and records.
- In formal negotiations to determine equivalency status
- COO will conduct an on-site evaluation after the document review is completed and satisfactory.
- COO shall coordinate on-site verifications.

Reassessment and Surveillance

- The Foreign competent authority will be subject to periodic audit.
- The re-evaluation visit shall take place once every five years.

2.8.1.12 Statistics reports

Organic application and National Informatics System

- List of countries that have equivalency status,
- List of countries that have applied for equivalency status,
- Updates of status of foreign countries equivalency evaluation status, procedural progress, update on evaluation.
- List of recognized accreditation and certification bodies under their regime
- List of complaints/appeals recognition process involving the import/export activities with the final decisions on recognition.

2.8.2 Procedures for recognition of Foreign Accreditation Advisory Bodies

2.8.2.1 Background/ Reference

Section 10 of the Regulations provides that “a person who wishes to market an organic product in import trade shall apply in writing to the competent authority of the country of origin for an attestation conforming that the product meets the requirements of these Regulations.”

2.8.2.2 Authority

The authority for the determination of a foreign country’s equivalency status is provided by:

- the *Canada Agricultural Products Act*
- Sections 10 the *Organic Products Regulations*

2.8.2.3 Objective

This section outlines procedures to be followed by a foreign accreditation advisory body requesting recognition under the COR. Applicants may be either private or government entities.

Foreign accreditation advisory body is eligible for recognition under COR only if there is no equivalency agreement between Canada and this country.

In addition to the requirements outline in **Chapter 2.2. Prescribed procedures for Accreditation Advisory Body recommending CBs operating under Canada Organic Regime**, that should be followed by the Foreign Accreditation Advisory Body, the applicant has the obligation to notify COO, of any certification body, located in another country, prior to proceeding with its accreditation under COR.

2.8.3 Procedures for accreditation of Foreign Certification Bodies

2.8.3.1 Background/ Reference

Section 10 of the Regulations provides that “a person who wishes to market an organic product in import trade shall apply in writing to the competent authority of the country of origin for an attestation conforming that the product meets the requirements of these Regulations.”

2.8.3.2 Authority

The authority for the determination of a foreign country’s equivalency status is provided by:

- the *Canada Agricultural Products Act*
- Sections 10 the *Organic Products Regulations*

2.8.3.3 Objective

This section outlines the procedures to be followed by foreign certification bodies when applying for accreditation under the Canada Organic Regime (COR).

Foreign Certification Body is eligible for certification under COR by a recognized Accreditation Advisory Body only if there is no equivalency agreement between Canada and this country.

Refer to the requirements outline in **Chapter 2.3. Prescribed procedures for accreditation of Certification Bodies operating under Canada Organic Regime.**

**2.8.4 Prescribed procedures for Importers/Distributor
(awaiting policy decision and further consultation)**

**2.8.5 Prescribed procedures for Import Product Inspection Program
(PIP)**

2.8.5.1 Background/Reference

Based on the above legal requirements, the CFIA has integrated the inspection activities, related to organic products, to the existing Product Inspection Programs (PIP). Each following CFIA-program will incorporate the organic label verification, according to the requirements outline in the Section **2.7 Guidelines for Labelling**, within policies, inspection procedures, training and verifications:

- 1) Dairy
- 2) Honey
- 3) Eggs and Eggs products
- 4) Consumer Protection - labelling
- 5) Feed
- 6) Fertilizer
- 7) Food Safety Investigation - products covered solely under F&D
- 8) Fresh Fruits and Vegetables
- 9) Meat Hygiene
- 10) Fish
- 11) Processed Products - processed fruits and vegetables
- 12) Plant Health
- 13) Animal Health
- 14) Seeds

These CFIA-programs will amend its existing Product Inspection Manual and Product Establishment Inspection Manual. These manuals describe the PIP and provide inspectors the procedures to follow in their inspection activities. All programs are designed to monitor domestic, imported and exported products ensuring that they comply with the all relevant Acts and Regulations.

2.8.5.2 Authority

- The *Canada Agricultural Products Act*;

- Sections 14 & 15 of the Regulations.

In discharging its responsibility, the COO also takes into consideration the requirements of other Canadian Acts and Regulations applicable to the inspection of food.

2.8.5.3 Objective

These guidelines outline procedures and program elements that must be followed by CFIA inspectors when evaluating compliance on imported organic product in their respective activities. These guidelines will help ensure that imported organic products comply with the Canada Organic Regime's requirements.

2.8.5.4 Procedures

2.8.5.4.1 CFIA inspectors will follow the normal inspection activities including the organic requirements.

2.8.5.4.2 When product is identified as Organic, CFIA inspectors are to verify the veracity of the certification & logo:

- *For domestic product (Canada Organic Logo):*
 - Verification on the list of Certification Bodies (CB) if the CB is accredited to operate under COR
- *For imported product (Foreign or Canada organic Logo):*
 - Verification on the list if the foreign CB is accredited to operate under his country Regime, or under COR if there is no equivalency with the country
 - Verification on the list of Foreign Country if the exporting country has an equivalency with Canada

2.8.5.4.3 CFIA inspectors will deliver inspection report as indicated in their PIP.

2.8.5.4.4 CFIA inspectors will report to COO results of organic inspection activities

2.8.5.4.5 COO to establish a system where organic inspection results are compiled then relayed to CBs or Foreign Countries for follow up at origin

2.8.5.5 Frequency

As the organic requirements are integrated to the existing inspection programs, the frequency of the inspection is indicated in the relevant manuals to CFIA-program.

As a rule there are 3 frequency levels of product inspection:

1. Monitoring
 - normal inspection level
 - this is different for each program - 5% -25%
2. Surveillance
 - consistency level
 - 100% for an established number of shipments/lots to determine consistency of infraction.
3. Compliance
 - 100% - until problem is eliminated
 - Import Lookout

When non-compliance is identified:

Surveillance of imported Organic products

- 100% for next 5 shipments of same commodity from same country.

When problem is consistent under Surveillance (i.e. 2/5 are non compliant):

- Compliance of imported Organic products - 100% (**For six months, or until problem is corrected**)

2.8.5.6 Persons Responsible

CFIA-programs inspectors

- monitoring the inspection

CFIA Enforcement Officer:

- maintenance of inspection procedures
- investigation of complaints
- enforcement activities

Certification Bodies operating under COR:

- follow up at importers/operators;
- evaluation of compliance level;
- enforcement activities; and
- investigations.

Foreign Countries:

- follow up at country of origin;
- evaluation of compliance level;
- development of a corrective action plan;
- enforcement activities;
- investigations.

2.8.5.7 Deficiencies and Corrective actions

The deficiencies and corrective actions process is described in section **2.6.4 Complaints/ Appeals: Illegal Labelling**

Organic Products not complying with Regulations:

- In the case of fraudulent labels, designated CFIA-inspectors shall contact the responsible party listed on the label.
- CFIA inspectors will notify the Manager of the COO of a complaint on organic labelling.
- Take necessary enforcement action on shipment;
- Initiate Target Program, on non-compliant issue;
- COO to communicate with the Certification Body for the evaluation of compliance level, enforcement activities and investigations, if applicable.
- COO to contact importer to notify on non-compliance issue, and obtain corrective action plan, if applicable.
- COO to communicate foreign competent authority, if applicable, the deviation

2.8.5.8 Records

- Inspection reports (CFIA staff monitoring reports);
- Complaints received from CFIA regional offices

2.8.5.9 Training

CFIA's inspectors training plan within CFIA's commodity programs.

2.8.5.10 Performance Indicators

- Access MCAP: number of organic inspections performed, number of inspections classified as non-compliant.
- Number of complaints received.
- Number of complaints resolved.

2.8.5.11 Audit

Audit will be performed in accordance with the CFIA multi-commodity inspection program in each of the program areas.

2.8.5.12 Intelligence Reports

Through MCAP, SPRINT, PMC, the following intelligence reports will be gathered:

- Number of inspections;
- Compliance level (number of non-compliant inspections);
- Number of complaints; and
- Corrective actions/follow-up.

2.9 Prescribed procedures for Export Certificate Delivery

2.9.1 Background/Reference

Agricultural product exported to a foreign country using the Canada Organic Logo or Designations shall comply with the requirements set out in *Organic Products Regulations*. A person who wishes to market an organic product in export trade shall apply in writing to a Certification Body for a certificate confirming that the product is an organic product.

Foreign countries of destination sometimes require mandatory Export Certification to accompany shipments of products. This type of Certification is required from a governmental authority.

2.9.1.2 Authority

Section 9 of the Organic Products Regulations.

2.9.1.3 Objective

The main objective is to provide Canada traders of organic agricultural products an easy access to export markets.

The guidelines below describe the management system for the delivery of Export Certification.

2.9.1.4 Procedures

- Applicant applies for Export Certification to their Certification Body (CB)
- CB shall review the Export Certification application.
- CB shall perform verification to support Export Certification.
- CB should inform the COO within the COR National Informatics System (NIS).
- CB shall deliver Export Certification to the applicant for the specific product.
- COO shall maintain Export Certification information on the NIS, for administration use

2.9.1.5 Frequency

Submission of application for Export Certification - submitted once per product, when required, by applicant.

Delivery of Export Certification - when required, by CB.

Verification (documentation) of Export certification delivery - once a year per CB, by the AAB.

2.9.1.6 Person Responsible

CBs will deliver Export Certification activities.

COO to maintain operational procedures for the delivery of Export Certification and to evaluate export certification delivery.

Accreditation Advisory Body will verify Export Certification at CB level.

2.9.1.7 Deviations and Corrective Actions

Inadequate application information from applicant:

- Communicate to applicant; and
- list of deviations in application.

Inadequate delivery of Export Certification program:

- Advise CB of deviations;
- Initiate Training Program;
- Initiate enhanced (surveillance) verification level; and
- Prohibit CB from delivering Export Certificates.

Complaints from Foreign Countries (of destination):

- COO to coordinate communication with foreign country;
- COO coordinates complaint review with AABs; and
- AABs to coordinate review with CB.

Unacceptable Corrective Action Plan or Correction action from CB:

- COO to Initiate procedures to revoke/modify accreditation of CB; and
- Modify CB status in National Informatics System.

2.9.1.8 Records

- Checklist of information that is to be included in the application for Export Certification; and
- Export Certificate.

2.9.1.9 Training

Export Certificate delivery procedures:

- Training delivered by AABs and/or COO.

2.9.1.10 Performance Indicators

Review of Export Certificates:

- To determine compliance levels of delivery procedures for the Export Certification Program (AABs and COO).

On-site verification:

- To determine compliance level of Export Certification Program delivery by CBs (AABs and COO).

2.9.1.11 Audit

Review of Export Certificates (COO) - Paper audit.

On-site verification.

2.9.1.12 Statistics Reports

Organic application and National Informatics System:

- list of CBs,
- Export Certificates delivered.

Website:

- list of CBs.

2.10 Prescribed Procedures for Maintaining Canada Organic Standards

2.10.1 Background/Reference

The Organic General Principles and Management Standard (CAN/CGSB-32.310) was developed within the National Standards System (NSS) by industry, under the auspices of the Canadian General Standards Board (CGSB), an accredited standards development organization (SDO). The Standards Council of Canada (SCC), which is responsible for overseeing the NSS, has accredited CAN/CGSB-32.310 as a “National Standard of Canada (NSC)”.

The CGSB has the copyrights to CAN/CGSB-32.310 and amendments can only be accepted if they have undergone CGSB procedures for determining consensus (unless through regulation). The central feature of the standards development and maintenance process is the reliance by CGSB on a volunteer technical committee (Organic Agriculture Committee 32/20 (OAC)), comprised of industry and other stakeholders.

Section 11 of the *Organic Principles and Management Standard* (CAN/CGSB 32.310) contains the conditions which must be met for substances to be added to the Permitted Substances Lists (PSL). The PSL are maintained as a separate standard (CAN/CGSB 32.311) by the Canadian General Standards Board (CGSB). The CGSB Organic Agriculture Committee 32/20 (OAC 32/20) must approve by consensus any amendments (i.e. additions, deletions or use restrictions) to CAN/CGSB 32.311

2.10.2 Authority

Organic Products Regulations pursuant to the *Canada Agricultural Products Act*.

2.10.3 Objective

To elaborate on procedures for review, revision and maintenance of CAN/CGSB-32.310. and for managing the Permitted Substances Lists (CAN/CGSB 32.311).

2.10.4 Procedures

2.10.4.1 Procedure for CAN/CGSB-32.310

CAN/CGSB-32.310 is maintained by CGSB using an

ongoing amendment process with periodic publication of revised editions.

- Proposals for amendments are submitted by individuals or organizations to the CGSB who incorporate the proposal into the Future Work List (FWL).
- The CGSB presents outstanding FWL items to the OAC which meets annually, or as needed, to prioritize, review and discuss proposed amendments.
- Proposals for amendments shall be offered for public review.
- Proposals which have received the approval of the OAC to proceed are balloted by the CGSB between meetings.
- Proposals which do not receive the approval of the OAC to proceed to ballot are either dropped or placed back on the FWL for further review, usually by a Working Group.
- Proposals which are balloted and do not achieve consensus may not be brought forward again for three years, unless new information becomes available.

2.10.4.2 Procedures for PSL Maintenance

The PSL Maintenance Sub-Committee is appointed by the OAC 32/20. The OAC 32/20 reviews nominations at large and appoints suitably qualified persons.

The PSL Maintenance Sub-committee consists of technical experts in the disciplines of:

Crop Production: pest and disease control; Soil Chemistry and Fertility; Animal Nutrition and Health; and Food Processing and Handling.

In addition, a person classified as a "Practical User" e.g. from a Certification Body, and the Regulations and Standards Officer from the Canada Organic Office are included as full members.

The Sub-committee recruits others with expertise relevant to specific production or processing issues as necessary.

Recommendations to include new substances are determined by unanimous agreement of the Sub-committee. Recommendations are reviewed and approved by the OAC 32/20 through the normal standards maintenance procedures of the CGSB.

2.10.5 Frequency

Proposals for amendments may be submitted to CGSB at any time. The OAC reviews proposals at least annually.

According to CGSB and NSS requirements, standards shall be reviewed every five years, or at shorter intervals as may be justified.

2.10.6 Person Responsible

The Canadian General Standards Board is responsible for maintenance of CAN/CGSB-32.310.

2.10.7 Corrective Actions

- To the extent possible, corrective actions are taken while proposed amendments are being developed and discussed by the OAC.
- Individuals may appeal to the CGSB under CGSB operating procedures.

2.10.8 Records

- The CGSB maintains records regarding all aspects of a proposal for an amendment, including the original proposal, minutes of OAC meetings where the proposal was discussed, Working Group documents (if applicable), decisions taken by the OAC, ballot results (if applicable), and final published amendments.
- The CFIA maintains records of CAN/CGSB-32.310, as amended by the CGSB and by the organic regulation.

2.11 Guideline for Logo Use During Transition Period, and in Advertising

(Waiting for policy decision and consultation process)

2.12 Use of Logo in Advertising (not on product labels)

2.12.1 Background/Reference

Section 16 (1) of the Organic Products regulations comes into force two years (Transition Period) after the day on which these regulations are registered. That date shall be December 14th, 2008. However, Section 3 (use of the Canada Organic Logo), comes into force on the day the regulations were registered (December 14th, 2006).

Stakeholders may request to use the Canada Organic Logo, which is defined as an 'agricultural product legend' on their advertising materials – brochures, posters, hand-outs, in newspapers and other publications, on television, etc. CFIA policy is to grant the use of the Logo, provided that certain conditions are met.

2.12.2 Authority

Sections 2 and 3 of the *Organic Products Regulations*, the CFIA Act and Legislation related to Trademarks and Copyright.

2.12.3 Objective

To ensure that use of the logo is well controlled and administered.

To set up application procedures for the use of the Logo in advertising.

2.12.4 Procedures

- Upon receipt of an inquiry, an application form shall be emailed, faxed, or mailed to the applicant. The application form shall include the name, address, contact details, intended use, duration of use, and other relevant details. The CFIA's **Terms and Conditions for Use of the Logo in Advertising** shall be included on the application along with a Statement that, by signing, the applicant agrees to these terms and conditions. The application must be completed and signed and returned to the CFIA.

- The application shall be reviewed by the COO and either approved or rejected. The COO shall notify the applicant of the decision.
- The COO shall maintain a list of Stakeholders that have received permission for use of the Logo in advertising.
- The COO shall require a copy of any brochures, posters, hand-outs, newspapers and other publications documents where the logo is advertised.

2.12.5 Frequency

Application for use of the Logo - submitted once.

2.12.6 Person Responsible

COO Program Administrator

2.12.7 Corrective Actions

Improper use of Logo
- COO to communicate with CFIA

Enforcement and Investigations for enforcement actions.

2.12.8 Records

- All application forms shall be retained in COO records.
- Lists of all Stakeholders granted permission to use the logo shall be maintained.
- Copies of advertising documents using the logo shall be maintained in a file system.
- Lists of attempted fraudulent users shall be maintained.

2.12.9 Performance Indicators

On-site verification to determine that the terms and conditions are being complied with.

2.12.10 Statistics Reports

Organic application and tracking system
- List of stakeholders approved to use the logo in advertising.

3.0 Annexes

ANNEX 1: REQUIREMENTS AND PROCEDURES FOR THE RECOGNITION OF DOMESTIC AND INTERNATIONAL ACCREDITATION ADVISORY BODIES

Introduction

The Canada Organic Regime (COR) criteria used by the COO for the selection of Domestic and International Accreditation Advisory Bodies are those of ISO/IEC 17011:2004 criteria (Conformity assessment – General requirements for Accreditation Advisory Bodies accrediting conformity of assessment bodies). The Canada Organic Regime references Sections 1 to 7 of the ISO/ IEC17011 with additions as noted below. In Canada, Accreditation Advisory Bodies shall operate in agreement with CFIA.

1.0 Scope

Refer to ISO/IEC 17011:2004, Section 1.

2.0 Normative References

Refer to ISO/IEC 17011:2004, Section 2

3.0 General Requirements for the Recognition of Domestic and International Accreditation Advisory Bodies by the COO

- a) A person, organization or government department that wishes to assess, recommend and monitor the accreditation of organic products Certification Bodies shall apply in writing to the CFIA;
- b) The applicant shall provide the name, complete address and telephone number of the Accreditation Advisory Body, sign and date the application;
- c) The Accreditation Advisory Body shall be a registered legal entity¹.
- d) The applicant Accreditation Advisory Body shall submit with its application, all documents listed in Appendix A;

¹ Governmental Accreditation Advisory Bodies are deemed to be legal entities on the basis of their governmental status. Where the governmental Accreditation Advisory Body is part of a larger governmental entity, the government is responsible for identifying the Accreditation Advisory Body in a way that no conflict of interest with governmental CBs occur. This Accreditation Advisory Body is deemed to be the "registered legal entity" in the context of the *Organic Agricultural Products Regulations*.

- e) The Accreditation Advisory Body shall demonstrate compliance with the ISO/IEC 17011:2004 standard;
- f) When applicable, the Accreditation Advisory Body shall provide a copy of its assessment through the peer evaluation process of the International Accreditation Forum (IAF) or other third party assessment.
- g) All accreditation recommendations must be made by a recognized Accreditation Advisory Body.

4.0 Terms and Definitions

For the purposes of this annex, the terms and definitions given in section of the Organic Policies and Procedures Manual apply. Where the terms and definitions are not included in the Organic Policies and Procedures Manual, the terms and definitions of ISO 9000, ISO/IEC 17000 or the International vocabulary of basic and general terms in metrology (VIM) apply.

5.0 Evaluation Criteria

The COO uses ISO/IEC 17011:2004 requirements to recognize and to enter into agreement with the Accreditation Advisory Bodies that shall have an active role within the COR. Refer to sections 4.0 to 6.0 of ISO/IEC 17011:2004 for a complete list of requirements related to Accreditation Advisory Bodies, management and human resources.

6.0 Application for recognition of Domestic and International Accreditation Advisory Body Operating within the COR

6.1 Any Accreditation Advisory Body seeking information from the Canadian Food Inspection Agency (CFIA) regarding the conditions under which it recognizes Accreditation Advisory Bodies may consult the CFIA Web site and access information from COR QMS Manual

6.2 Any Accreditation Advisory Body may submit an application to the COO. To do so, it must submit a properly completed and signed application form including payment of registration fees, if required. A copy of the application form can be acquired by contacting the lead auditor of the COO or by printing a copy of the form available on the CFIA Web site.

The COO shall require a duly authorized representative of the applicant Accreditation Advisory Body to make a formal application that includes the following:

- a) general features of the Accreditation Advisory Body, including corporate entity, name, addresses, legal status and human and technical resources;
- b) general information concerning the Accreditation Advisory Body such as its activities, its relationship in a larger corporate entity if any, and addresses of all its physical location(s);
- c) an agreement to fulfil CFIA's requirements and the other obligations of the Accreditation Advisory Body, including submitting all necessary documentation requested in Appendix A.

6.3 The COO shall require the applicant Accreditation Advisory Body to provide at least the following information relevant to the selection of the Accreditation Advisory Bodies:

- a) When applicable, a copy of a peer evaluation against ISO/IEC 17011:2004 standard or other third party assessment;
- b) a copy (on paper or in electronic form) of the Quality Management System Manual of the Accreditation Advisory Body, and relevant associated documents and records (See Appendix A);
- c) payment of the application fee, if applicable. At this point of time it is 0.

6.4 The COO shall review for adequacy the information supplied by the Accreditation Advisory Body.

7.0 Resource Review

7.1 The COO shall review its ability to carry out the assessment of the applicant Accreditation Advisory Body, in terms of its own policy, its competence and the availability of suitable assessors and experts.

7.2 The review shall also include the ability of the COO to carry out the initial assessment in a timely manner.

8.0 Preparation for Assessment

8.1 The COO shall formally appoint an assessment team consisting of a lead assessor and, where required, a suitable number of assessors and/or experts for the scope. When selecting the assessment team, the COO shall ensure that the expertise brought to each assignment is appropriate. In particular, the team as a whole:

- a) shall have appropriate knowledge of the ISO/IEC 17011:2004 standard, and;
- b) shall have understanding sufficient to make a reliable assessment of the competence of the Accreditation Advisory Body to operate within Canada Organic Regime.
- c) shall have CFIA auditor training or equivalent.
- d) shall communicate in the two official languages.

8.2 The COO shall ensure that team members act in an impartial and non-discriminatory manner. In particular,

- a) assessment team members shall not have provided consultancy to the Accreditation Advisory Body which might compromise the recognition process and decision, and;
- b) the assessment team members shall inform the Manager of the COO, prior to the assessment, about any existing, former or envisaged link or competitive position between themselves and the Accreditation Advisory Body to be assessed.

8.3 The COO shall clearly define the assignment given to the assessment team. The task of the assessment team is to review the documents collected from the Accreditation Advisory Body.

8.4 The COO shall ensure that the assessment team is provided with the appropriate criteria documents, previous assessment records, and the relevant documents and records of the Accreditation Advisory Body.

9.0 Document and Record Review

9.1 The assessment team shall review all relevant documents and records supplied by the Accreditation Advisory Body (as described in 5.2 and 5.3) to evaluate its system, as documented, for

conformity with the relevant standard(s) and other requirements for the selection of Accreditation Advisory Bodies.

9.2 The COO may decide not to complete an assessment based on the nonconformities found during document and record review. In such cases, the nonconformities shall be reported in writing to the Accreditation Advisory Body. The COO may also communicate with the Accreditation Advisory Body or an independent source, in order to obtain any other information needed to examine the application, with costs being paid by the Accreditation Advisory Body.

9.3 Upon completion of the steps of the provisions 8.1 and 8.2 above, the lead auditor shall inform the Manager of the COO of its intention to proceed with the assessment.

10.0 On- Site Visit

10.1 As a part of the assessment COO Lead auditor shall conduct on-site audit to the Accreditation Advisory Body's offices from where all the activities take place.

10.2 Upon completing the audit, COO Lead auditor shall prepare evaluation report.

11.0 Decision-making and recognition of a Domestic and International Accreditation Advisory Body

11.1 The CFIA will base its decision upon the results of the Evaluation Report. The decision will be made by the Director of the Agrifood Division.

11.2 Once the decision is made, the COO shall establish the status of the applicant body as:

- a) recognition granted or renewed, or
- b) recognition pending program amendment requirements,
or
recognition refused.

The applicant Accreditation Advisory Body shall be advised in writing of any decision made by the CFIA.

11.3 In the case of a refusal, the COO shall inform any Accreditation Advisory Body not meeting minimum requirements of the corrective measures that are necessary before submitting a new application.

11.4 In the case of recognition pending conditional requirements (corrective action requirements), the COO may submit to the Accreditation Advisory Body one or more conditional requirements to which it must comply, along with a realistic implementation schedule (TBD) needed to meet these requirements. The COO may require that certain conditions be met before letting the public know of its status and the recognition decision.

11.5 Should the Accreditation Advisory Body be unable to meet the requirements as presented, it may request that the COO reconsider one or more of them, or even their timeframe, in light of supplementary information provided. The COO should thus reassess this information regarding whether they maintain the initial requirements, establish new requirements, or drop specific requirements.

11.6 The COO shall send the Accreditation Advisory Body a recognition agreement binding the latter to comply with the requirements submitted.

11.7 Any recognition granted by the COO to an Accreditation Advisory Body is valid for a period of five (5) years, beginning on the date the recognition agreement is signed. An agreement defining the roles and responsibilities of each party shall be signed. Surveillance and maintenance of the agreement shall be done annually.

11.8 Any recognized Accreditation Advisory Body whose program was subject to corrective action must submit a report within the required deadline describing what measures they shall be putting into place to meet these requirements.

11.9 Should a recognized Accreditation Advisory Body fail to respect the terms of their recognition agreement, the COO shall suspend or even withdraw its recognition status from the accreditation program.

11.10 In order to have its recognition renewed, a recognized AAB shall be subjected to re-evaluation on its 5th anniversary after the initial recognition date.

11.11 The accreditation program shall only be recognized for the scope covered by the Canada Organic Regime.

11.12 The recognized Accreditation Advisory Bodies must automatically and unconditionally accept the accreditation decisions under the COR made by any other recognized Accreditation Advisory Body. (for further discussion)

11.13 The COO shall grant a recognition status to the recognized Accreditation Advisory Body.

12.0 Records on Accreditation Advisory Bodies

12.1 The COO shall maintain records on Accreditation Advisory Bodies to demonstrate that requirements for recognition, including competence, have been effectively fulfilled. The records must be kept secure to ensure confidentiality. After each calendar year, all recognized Accreditation Advisory Bodies must submit to the COO an annual report containing the following:

- a) Assessment records and reports,
- b) Records of committee deliberations, if applicable, and recommendation decisions,
- c) Copy of the most recent IAF evaluation or other third party assessment against ISO 17011:2004 standard, if applicable.
- d) An update of documents required to obtain recognition (see Appendix A),
- e) All major changes that took place during the previous year and that have affected corporate structure and directors, the administrative structure, the main managers of the organization and members of the committees,
- f) All major and significant modifications made to policies, internal procedures and regulations governing the organization and its accreditation system,
- g) The number of recommendations for accreditation made, listed by certifier,
- h) Audited Annual Financial Accounts

12.2 The Accreditation Advisory Body's annual report must be signed by authorized personnel.

12.3 The annual report must be submitted to the COO during the first quarter following the end of the accreditation program's fiscal year. The COO can demand any relevant document to maintain the recognition status.

13.0 Surveillance

13.1 In addition to the initial evaluation, the Accreditation Advisory Body shall be subjected to scheduled on-site surveillance assessments.

13.2 The surveillance visits include the verification of specific program elements.

13.3 At any time, and upon its own initiative, the COO may carry out a supervision visit for any major non-conformities with CFIA recognition requirements.

13.4 When, during surveillance, nonconformities are identified, the COO shall define strict time limits for corrective actions to be implemented.

13.5 The COO shall confirm the continuation of the recognition based on the results from surveillance described above.

13.6 The COO may conduct unscheduled assessments as a result of valid complaints or changes. The COO shall advise the Accreditation Advisory Bodies of this possibility.

14.0 Renewal, Suspending, Withdrawing Recognition Status

14.1 The COO shall establish procedures for the renewal, suspension, withdrawal of recognition status.

14.2 The COO shall make decisions to suspend and/or withdraw recognition when an Accreditation Advisory Body does not to meet the requirements of recognition or to abide by the rules of the agreement.

NOTE: The Accreditation Advisory Body may ask for suspension or withdrawal of recognition status.

15.0 Responsibilities of the COO and the Accreditation Advisory Body

15.1 Obligations of the Accreditation Advisory Body

15.1.1 Accreditation Advisory Body shall comply with the following :

- a) The Accreditation Advisory Body shall commit to fulfil continually the requirements for recognition set by the COO. This includes agreement to adapt to changes in the requirements for accreditation, as set out in 14.2.4.
- b) When requested, the Accreditation Advisory Body shall afford such accommodation and cooperation as is necessary to enable the COO to verify fulfilment of requirements for recognition. This applies to all premises where the conformity assessment services take place.
- c) The Accreditation Advisory Body shall provide access to information, documents and records as necessary for the assessment and maintenance of the recognition status.
- d) The Accreditation Advisory Body shall provide access to those documents that demonstrate the level of independence and impartiality of the Accreditation Advisory Body from its related bodies, where applicable.
- e) The Accreditation Advisory Body shall arrange the witnessing of Accreditation Advisory Body's services when requested by the COO.
- f) The Accreditation Advisory Body shall claim recognition by CFIA only with respect to the scope for which the organic program is developed.
- g) The Accreditation Advisory Body shall not use its recognition status in such a manner as to bring the COO into disrepute.
- h) The Accreditation Advisory Body shall pay fees, if required by the COO.

15.1.2 The AABs shall inform the COO without delay, of significant changes relevant to its recognition status, in any aspect of its status or operation relating to;

- a) its legal, commercial, ownership or organizational status,
- b) the organization, top management and key personnel,
- c) main policies,
- d) resources and premises, and
- e) other such matters that may affect the ability of the Accreditation Advisory Body to fulfil requirements for recognition.

15.2 Obligations of the COO

15.2.1 The COO shall make publicly available information about the current status of the recognitions that it has granted to Accreditation Advisory Bodies. This information shall be updated regularly. The information shall include the following:

a) name and address of each recognized Accreditation Advisory Body;

b) dates of granting recognition status and expiry dates, as applicable.

15.2.2 The COO shall provide the Accreditation Advisory Body with information about suitable ways to track the results in relation to the scope for which accreditation is provided.

15.2.3 The COO shall, where applicable, inform the organic sector and federal/provincial/territorial governments about international arrangements in which it is involved.

15.2.4 The COO shall give due notice of any changes to its requirements for the recognition of Accreditation Advisory Bodies. It shall take account of views expressed by interested parties before deciding on the precise form and effective date of the changes. COO shall allow appropriate time for AABs to implement the changes. Following a decision on, and publication of, the changed requirements, it shall verify that each Accreditation Advisory Body and each Certification Body carry out any necessary adjustments.

15.3 Reference to Recognition Status and Use of Symbols

15.3.1 A recognized Accreditation Advisory Body must obtain permission from the CFIA to use the “biologique Canada organic” agricultural product designation and logo on its reports or certificates issued, within the scope of the *Organic Products Regulations*.

15.3.2 The COO shall take effective measures to ensure that the recognized Accreditation Advisory Body;

a) fully conforms with the requirements of the COO for claiming recognition status, when making reference to its recognition in communication media such as the Internet, documents, brochures, or advertising,

- b) only uses the “biologique Canada organic” agricultural product legends for premises of the Accreditation Advisory Body that are specifically included in the recognition,
- c) does not make any statement regarding its recognition that the COO may consider misleading or unauthorized,
- d) takes due care that no report or accreditation nor any part thereof is used in a misleading manner,
- e) upon suspension or withdrawal of its recognition status (however determined), discontinues its use of all advertising matter that contains any reference to a recognition status, and
- f) does not allow the fact of its recognition to be used to imply that a service, process, system or person is certified by the COO.

15.3.3 The COO shall take suitable action to deal with incorrect references to recognition status, or misleading use of the “biologique Canada organic” agricultural product legends found in advertisements, catalogues, etc.

NOTE: Suitable actions include request for corrective action, withdrawal of recognition status, publication of the transgression and, if necessary, other legal action.

16.0 Appeals

- 16.1** COO shall establish procedure to address appeals against recognition decisions made by COO.
- 16.2** COO National Manager shall:
- a) appoint a person or group of persons to investigate the appeal who are competent and independent of the subject of appeal ;
 - b) decide on validity of the appeal
 - c) advise the AAB of the final decision(s) of the COO
 - d) take follow-up action where required;
 - e) keep records of all appeals, of final decisions and of follow-up actions taken.

17.0 Complaints by Accreditation Advisory Body

17.1 The COO shall establish procedures to address complaints by Accreditation Advisory Bodies.

17.2 Should an Accreditation Advisory Body believe that its rights have been violated, it may file a complaint directly to the Manager of the COO.

17.3 Upon receipt of any complaint from an Accreditation Advisory Body, the Manager of the COO shall respond to the Accreditation Advisory Body within 15 days following the date of receiving the complaint.

18.0 Complaints against Recognized Accreditation Advisory Body

18.1 The COO may also accept complaints or even verification requests relative to the performance of a recognized Accreditation Advisory Body.

18.2 Every complaint concerning an Accreditation Advisory Body must be submitted in writing and accompanied by justifying evidence or documents. Upon receipt of a complaint the COO should determine its validity.

18.3 If it seems appropriate, the COO shall both inform the Accreditation Advisory Body concerned by the denunciation and invite it to comment. The COO could initiate a confidential investigation in order to provide elements of proof.

18.4 The case should be heard by the COO assessment team as soon as enough evidence has been gathered.

18.5 Should it be justified by the results of the investigation, the COO might impose disciplinary measures.

18.6 Complaints must be acted by the COO upon 30 days.

ANNEX 2: ACCREDITATION PROCEDURES FOR DOMESTIC AND INTERNATIONAL CERTIFICATION BODIES

Introduction

This annex describes the accreditation procedures for Certification Bodies that certify agricultural and food products as organic in accordance with the *Organic Products Regulations*, allowing the products to bear the organic legends or the designation “Canada Organic” or “Biologique Canada” as specified in the Regulations.

The general requirements of the Canada Organic Regime used to evaluate Certification Bodies that submit applications to obtain an accreditation, are those of ISO/IEC Guide 65. In addition, the Canadian Food Inspection Agency (CFIA) is also imposing its own requirements which are described in this annex.

Accreditation is obtained as a result of a rigorous process. Respect of the different control stages: analysis of preliminary request, examination of documentation, formation of audit team, on-site evaluation, drafting of audit report, analysis and evaluation of report, accreditation decision and delivery, described in this annex shall assure that Accreditation Advisory Bodies recognized by the Canada Organic Office shall manage the accreditation process in a consistent and reliable way.

The accreditation number granted by the CFIA to a Certification Body means the latter, being a responsible and qualified third party, has the financial and organizational capacity to manage a certification program that shall result in consistent and credible decisions. An accreditation is valid for one year, and in order to have its accreditation renewed once this period has ended, the body must be re-evaluated and again be granted accreditation by one of the Accreditation Advisory Bodies under contract with the CFIA.

Participation in the Canada Organic Regime accreditation program is not intended to prevent Certification Bodies from carrying out other business activities, especially those involving the certification of agricultural foods and products not covered by the *Organic Products Regulations*. Operations resulting from these other activities however should neither constitute an infringement nor result in conflicts of interest with the certification program accredited by the CFIA.

GENERAL REQUIREMENTS – ACCREDITATION PROCESS

1.0 Application for accreditation

Any Certification Body seeking information from the Canadian Food Inspection Agency (CFIA) regarding the conditions under which recognized Accreditation Advisory Bodies evaluate accreditation requests from Certification Bodies may

consult the CFIA Web site and access the following information in the Organic Policies and Procedures Manual.

Any Certification Body may submit an application to one of the recognized Accreditation Advisory Body. To do so, it must submit a properly completed and signed application form including payment of application fees to a recognized Accreditation Advisory Body.

1.0.1 In addition to ISO/IEC 11011 criteria, the CFIA added the following requirements:

Certification Body must submit all necessary documentation requested in Appendix B.

1.2 Resource review

Refer to ISO/IEC 11011:2004.

1.3 Subcontracting the assessment

1.4 Please refer to ISO/IEC 11011:2004.

1.5.2 Refer to ISO/IEC 11011:2004. In addition, the CFIA brings the following clarification:

In order to complete its evaluation, the accrediting organization may obtain a copy of the evaluation report drafted for another Accreditation Advisory Body but pertaining to the certification program being subjected to an evaluation by the accrediting organization under the condition that this report is about an on-site evaluation visit that took place within last 12 months.

1.6 Refer to ISO/IEC 11011:2004.

1.7 Preparation for assessment

Refer to ISO/IEC 11011:2004.

1.8 Document and record review

1.8.1 Refer to ISO/IEC 11011:2004.

1.8.2 Refer to ISO/IEC 11011:2004.

1.8.3 The Accreditation Advisory Body may also communicate with the certification applicant or an independent source, in order to obtain any other information needed to examine the application, with costs being paid by the certifier.

1.8.4 Upon completion of the steps of the provisions 1.6.1 and 1.6.2 above, the Accreditation Advisory Body shall record in the COR's informatics' system of its intention to proceed with the analysis and the assessment. The COO shall publish the applicant's name on its Web site (CFIA Web site).

1.9 On-site assessment

1.9.1 Refer to ISO/IEC 11011:2004. The CFIA is adding the following requirements:

a) The Accreditation Advisory Body shall mandate an assessment team that shall proceed with an on-site evaluation covering the Certification Body's monitoring procedures. In order to carry out this evaluation, the Accreditation Advisory Body may assign one or more members of its personnel and may also retain the services of external evaluators, recognized for their professional expertise.

b) The one or more evaluators appointed should not have been employed by a Certification Body in a position or within a period of time that might reduce their impartiality.

c) The criteria relative to an evaluator's expertise may include, among others:

1) Knowledge and understanding of the COR's accreditation program (accreditation criteria and procedures);

2) Knowledge of Canada's national organic standard and generally accepted experience (practical experience in production, processing, inspection or certification management would be a major asset) relative to conformity assessments;

3) Knowledge of evaluation methods including, among others, interviewing techniques and an ability to draft reports;

4) No current involvement in certification management or certification inspection activities.

1.9.2 Refer to ISO/IEC 11011:2004. In addition, the CFIA adds the following requirement:

In circumstances where the Certification Body has more than three offices, including its main office, the Accreditation Advisory Body shall use a sampling process in order to determine which offices shall be visited, based on the following criteria:

a) An obligatory visit to the main office, then

b) The two offices handling most of the Certification Body's clients, or

- c) The two offices carrying out the most important tasks concerning the certification process.

1.9.3 Refer to ISO/IEC 11011:2004.

1.9.4 The Accreditation Advisory Body shall send to the Certification Body the information, documentation and instructions needed to conduct witness audit visits, as well as an estimate of expenses pertaining to this visit. The names of the assigned evaluators shall also be communicated to the Certification Body, who may, when based on serious motives, object to the assignment of any evaluator mentioned. In light of the reasons stated by the Certification Body, the Accreditation Advisory Body shall appoint another evaluator or shall retain the one initially selected.

1.10 Analysis of findings and assessment report

Visits to Certification Bodies' offices

1.10.1 Please refer to ISO/IEC 11011:2004.

1.10.2 Where the assessment team cannot reach a conclusion about a finding, the team should refer back to the Accreditation Advisory Body for clarification.

1.10.3 The Accreditation Advisory Body's reporting procedures shall ensure that the following requirements are fulfilled.

- a) Every visit begins with an opening meeting with the Certification Body's administrative officers, in order to explain the audit's objectives relative to accreditation criteria and to announce the work schedule, and at the same time confirming the extent of evaluation to be conducted.
- b) Following an introductory meeting with those responsible for the certification program, the evaluator shall meet managers and employees so as to conduct the necessary interviews.
- c) The evaluator shall carry out rigorous examination of a sample of the certifying body's certification files. The examination of all files ensures that:
 - The documentation found in a case file (i.e. signed contracts, updated production/preparation plans, inspection reports, decision sheets and other correspondence, copies of certificates, etc.) are complete and up to date,
 - The inspection reports include a sufficient quantity of information elements needed to make a certification decision,

- The decision made by the certifying body is congruous with the evaluation of the production/preparation plan as submitted by the applicant and the report resulting from inspection visits to operation sites,
- The certifying body has monitored the implementation of all necessary corrective measures that it requested from each operator having products certified.

d) The evaluator shall base the quantity and choice of files examined on the following sampling rules:

- In the event of an initial accreditation application, the evaluator shall carry out an in-depth verification of 10% of all certification files (no fewer than 10 files and up to a maximum of 50 files) selected at random, according to the category of operations being carried out by the enterprises that joined the body's certification program, or a number corresponding to all operators registered with the certifier, whichever of the two numbers is smaller, (to be removed)
- In the event of an application for accreditation renewal, the evaluator shall examine a smaller number of files, proportional to the number of operators registered with the certifying body concerned, and based on the formula shown below:

Number of Canadian Operators Registered with the Body	Minimum Required on Pro Rata Basis	Total Result
240 or less	5% of files or minimum of 10	Between 10 and 12 files, according to actual number of files
400 or less	5% of first 240 files, 2.5% of additional files	Between 12 and 16 files, depending on the actual number of files
1000 or less	4% of the first 400 files, 2% of additional files	Between 16 and 28 files according to actual number of files
More than 1000	2.8% of first 1000 files, 1% of additional files	At least 28 files, with one (1) more file for each additional 100 firms.

Note: Decimal numbers are to be rounded to the nearest whole number.

- At least two thirds of the files included in the sample must be randomly selected, with consideration given to the various categories of operations being carried out by the enterprises registered with the certifying body. The remaining third may include files targeted in advance, at the discretion of the evaluator. The batch of files targeted in advance may include files for companies based outside of Canada, when the company's products are being sold on Canadian territory. If the number of files targeted exceeds one third of the sample targeted, the total number of files examined by the evaluator may then exceed the number of files required, based on the above-mentioned sampling rules.

e) The evaluator shall verify the competence of significant number of personnel involved in the certification activities of the Certification Bodies, within the framework of the positions they occupy. To do so and in compliance with Privacy law, the evaluator shall scan these employees' competence, training and education and shall conduct interviews with some of them.

f) An exit meeting shall take place between the assessment team and the Certification Body prior to leaving the site. At this meeting, the assessment team shall provide a written and/or oral report on its findings obtained from the analysis (see 7.8.1). An opportunity shall be provided for the Certification Body to ask questions about the findings, including nonconformities, if any, and their basis.

g) The assessment team must submit a draft evaluation report to the Certification Body that has applied for accreditation. This assessment report shall contain comments on competence and conformity, and shall identify nonconformities, if any, to be resolved in order to conform with all of the requirements for accreditation. The certifier is thus invited to comment on the report's content and verify its accuracy. Comments and requests of modifications sent by the certifier must be included in the report. If there are any divergences in opinion with the certifier relative to comments and requests made, explanations shall be provided in the report.

h) The final report shall be transmitted to the Certification Body by the Accreditation Advisory Body.

1.10.4 Refer to ISO/IEC 17011:2004.

1.10.5 Refer to ISO/IEC 17011:2004.

1.10.6 Refer to ISO/IEC 17011. In addition, the CFIA imposes the following requirements:

i) the assessment report on the evaluation visit, shall include the people met, the enterprises visited and the observations noted;

j) any further information mention in 7.8.6 i) shall include a brief history of the certification program, an evaluation of the certification program's independence from other activities conducted by the applicant body and, an evaluation of the compliance with the certification program's standards relative to universal reference standards;

Visits to Operators registered by Certification Bodies

1.10.7 The assessment team shall select a certain number of the Certification Body's certification files in order to make a visit of the enterprises involved, relative to their compliance. The number of visits shall be determined on the basis of the numbers provided in the table below. The choice of sampling method shall be left up to the Accreditation Advisory Body.

Number of Canadian Operators Certified per Certification Body	Minimum Required on Pro Rata Basis	Total Visits per Certifier
240 or less	1% of files	Minimum of 2 visits
400 or less	0,1% of first 240 files and 0.05% of additional files	2 to 3 visits (according to the size of the CB)
1000 or less	0.075 % of the first 400 files 0.033% of additional files	Between 3 and 5 visits according to the actual number of files
More than 1000	0,005% of the first 1000 files and 0,0025% of additional files	Minimum 5 visits

1.10.8 Following an in-depth review of the selected files (the assessment team might request to see records from previous years), the team shall visit the premises of the selected enterprises and conduct a post-audit inspection to verify the information appearing in the file. The purpose of this visit is not to "re-inspect the enterprise" for the purposes of a certification decision, but rather to make sure that the certification process and also the application of control measures relative to this specific case are carried out in compliance with requirements.

1.10.9 The assessment team shall verify, among other matters, that:

a) The operator has on hand a copy of the Certification Body's requirements, including the specific standards to be respected, as well as any requests for corrective measures submitted to the operator by the Certification Body;

- b) The production specifications are covered in the scope of the organic regulation;
- c) The inspection report adequately describes the production system;
- d) The inspection process was able to adequately reveal points of non-compliance with standards specifications.

1.10.10 The assessment team shall witness an inspection of an operations site in at least one registered enterprise per certifier.

1.11 Decision-making and granting accreditation

1.11.1 Refer to ISO/IEC 17011:2004.

1.11.2 Refer to ISO/IEC 17011:2004. In addition;

The Accreditation Advisory Body shall send the recommendation report to the COO:

- a) accreditation granted or renewed,
- b) accreditation along program amendment requirements,
- c) accreditation refused.

The applicant Certification Body shall be advised in writing of any decision made by the COO regarding the delivery of its accreditation number.

- In the case of a refusal, the Accreditation Advisory Body shall inform any Certification Body not meeting minimum requirements of the corrective measures that are necessary before submitting a new application, pursuant to the terms of accreditation program.
- In the case of accreditation with conditional requirements (corrective action requirements), the Accreditation Advisory Body may submit to the Certification Body one or more conditional requirements to which it must comply, along with a realistic implementation schedule needed to meet these requirements. The COO may require that certain conditions be met before letting the public know of its status.
- The Accreditation Advisory Body shall send the Certification Body an accreditation contract binding the latter to comply with the requirements submitted. Any accreditation granted by the Accreditation Advisory Body is valid

for a period of one year, beginning on the date the accreditation agreement is signed.

- Any accredited certifier whose program was subject to requirements (corrective action requirements) must submit a report within the required deadline describing what measures they shall be putting into place to meet these requirements.
- Should the accredited certifier fail to respect the terms of their accreditation contract, the Accreditation Advisory Body may suspend or even withdraw its accreditation certificate from the certification program.
- In the transition period of the COR implementation, the Certification Body shall be subjected to a complete re-evaluation against the COR requirements an year after the initial accreditation date.
- The certification program shall only be accredited for product classes covered by the *Organic Products Regulations*.
- The accredited Certification Bodies must automatically and unconditionally accept the certification decisions made by any other accredited certifier under the COR.

1.11.3 Refer to ISO/IEC 17011:2004.

1.11.4 Refer to ISO/IEC 17011:2004.

1.11.5 Refer to ISO/IEC 17011:2004. Section a)

1.11.6 Information on Operators

a) Any Certification Body accredited under the COR must regularly record information relative to each operator who is under its supervision in the informatics system of the COR.

b) The Certification Body must record and throughout the year, all information updated annually on December 31st. Exceptions being withdrawals.

c) Information required by the COO is listed in Appendix C of this annex and applies to any company falling under or the other of the following categories:

- A company holding a compliance certificate for the certified products they sell;
- A company having subcontractor status with another operator whose products are certified;

- A company holding recognition of services certificate. In this category of operators, only truckers shall not need to be certified.

1.12 Appeals

1.12.1 Refer to ISO/IEC 17011:2004.

1.12.2 Refer to ISO/IEC 17011:2004.

1.12.3 The Canada Organic Office;

Accreditation Advisory Bodies, Certification Bodies and operators may request a hearing on decisions made by COO, Accreditation Advisory Bodies or Certification Bodies impacting their operations. The appeal flow from operator to CB to AB. COO is the final level of appeal. Requests must follow the conditions outlined below:

- a) any request must be submitted, in writing, to the manager of the COO within 30 days of the original accreditation/certification (or revocation of accreditation/certification) recommendation/decision;
- b) the original accreditation/certification (or revocation of accreditation/certification) recommendation/decision must not have been the subject of a previous hearing.

Organic products in violation of organic and any safety regulations cannot be subject to a hearing.

- c) The manager of the COO shall respond to the appellant within 15 days following the date of receiving the appeal, whether the hearing is rejected or not.
- d) If the COO rejects a hearing, it shall inform the applicant of its decision.
- e) The manager of the COO shall be in charge of the hearing, shall set up the hearing, may call witnesses and may consult with whomever he or she wishes to seek advice or expertise prior to rendering a decision.
- f) The decision of the manager shall be sent in writing to the appellant within 5 working days after the end of the hearing.
- g) The decision of the national Manager of the COO is final in all hearings.

1.13 Reassessment and surveillance

1.13.1 Refer to ISO/IEC 17011:2004. In addition, the CFIA brings the following requirements to AAB:

- Additional to the initial evaluation visit, the Certification Body shall be subjected to annual surveillance assessments.
- The surveillance visits target the verification of specific program elements

1.13.2 Refer to ISO/IEC 17011:2004.

1.13.3 Refer to ISO/IEC 17011:2004. In addition the CFIA provides the following optional recommendations:

a) On - site surveillance for evaluation must take place within twelve months of the initial accreditation date. Thereafter, an on- site surveillance visit must take place in each subsequent calendar year. The Accreditation Advisory Body, however, cancel the surveillance visit planned for the coming year, when the certifying body demonstrates that its certification program and activities continue to meet CFIA accreditation requirements and that all incidences of non- compliances identified in the course of previous surveillance activities of the accrediting organization have been corrected. In such case, the Accreditation Advisory Body shall insure that the subsequent surveillance visit takes place no later than two years following the date of the most recent on-site evaluation.

b) At any time during the accreditation period, and upon its own initiative, the Accreditation Advisory Body may carry out a supervision visit for any serious reason, at the expense of the certifying body when non-conformities are found.

c) A reassessment visit is to be conducted at least every five years.

1.13.4 to 1.13.7 Refer to ISO/IEC 17011:2004.

1.14 Extending accreditation

Refer to ISO/IEC 17011:2004.

- In addition, the Certification Body must state the objectives and the reasons associated with this request.
- When applying for an extension of its scope of accreditation, the Certification Body must also supply documents relative to the monitoring measures intended to be implemented as to support this extension.

1.15 Suspending, withdrawing or reducing accreditation

Refer to ISO/IEC 17011:2004.

1.16 Records on Certification Bodies

1.16.1 Refer to ISO/IEC 17011:2004.

1.16.2 Refer to ISO/IEC 17011:2004.

1.16.3 Refer to ISO/IEC 17011:2004. Additional CFIA requirements are:

- e) An update of documents required to obtain accreditation and included on the list the Accreditation Advisory Body transmits to Certification Bodies each year,
- f) All major changes that took place during the previous year and that have affected corporate structure and directors, the administrative structure, the main managers of the organization and members of the committees,
- g) All modifications made to policies, internal procedures and regulations governing the organization and its certification system,
- h) For Canadian products, the number of certificates newly issued, renewed, suspended and withdrawn, listed by operator category and under the program concerned (COR program, USDA, EU, etc),
- i) List of all appeals filed pertaining to certification decisions handed down by the organization and regarding products that originated from Canadian operators,
- j) Copy of the files containing complaints against the organization and complaints about operators certified to do interprovincial or international trade,
- k) A short financial statement showing the organizations income and expenses related to its overall certification activities during the period covered, along with details on income obtained from its certification activities within Canada.
- l) In the event the agreement between the Accreditation Advisory Body and the CFIA terminates or ceases, the Accreditation Advisory Body shall send to the CFIA all the records on the Certification Bodies that it had accredited under the COR.

1.16.4 The Certification Body's annual audit report must be signed by authorized personnel.

1.16.5 The Certification Body's annual audit report must be submitted to the Accreditation Advisory Body during the first quarter following the end of the certification program's fiscal year. The COO can demand any relevant document to maintain the accreditation status.

2.0 Responsibilities of the Accreditation Advisory Body and the Certification Body

2.1 Obligations of the Certification Body

2.1.1 Refer to ISO/IEC 17011:2004.

2.1.2 Refer to ISO/IEC 17011:2004.

2.2 Obligations of the Accreditation Advisory Body

Refer to ISO/IEC 17011:2004.

2.3 Reference to Accreditation and use of Symbols

Refer to ISO/IEC 17011:2004.

ANNEX 3: GENERAL REQUIREMENTS FOR CERTIFICATION BODIES

Introduction

The COR requirements for Certification Bodies are those of ISO/IEC Guide 65:1996 (General Requirements for Bodies Operating Product Certification Systems).

Organic certification is a certification of a process, and the ISO 65:1996 criteria have required some addition. This Annex provides the COO's requirements that were added to those of the ISO/IEC Guide 65:1996.

1. Scope

Refer to section 1.1 and 1.2 of the ISO/IEC Guide 65:1996.

1.3 Certification Scope and the Chain of Custody

1.3.1 The Certification Body must ensure that all previously certified products or ingredients have been certified under the COR. The Certification Body shall not allow the use of its certification mark or issue certificate for any product unless it is assured of the chain of custody of the product. Where steps in the production chain have been certified by other Certification Bodies, the criteria in sections 7, 2 and 9 shall be applied.

1.3.2 Any entity in the chain of custody that has produced, processed, or packaged an organic product shall have been certified. Contracted production shall have been inspected.

1.3.3 The Certification Body shall require that the party owning the product at the point of transport shall be responsible for maintaining the organic integrity in the transport process, unless transport operations are certified in their own capacity.

2.0 References

In addition to the list of references of section 2.0 of the ISO/IEC Guide 65:1996, the two following documents were consulted:

The *IFOAM NORMS for Organic Production and Processing* – Version 2005

Quebec Accreditation Criteria

3.0 Definitions

CFIA's additional criteria to paragraph 3.1 of ISO/IEC Guide 65:1996.

- 3.1.1** Every supplier claiming that the products it markets meet the requirements covering designation “Canada Organic” and “Biologique Canada” within the scope of the Organic Regulation, must submit an application to certify those products. In the Organic Policies and Procedures Manual, the terms “supplier” or “operator” are used in an indistinctly manner and generally refer to a company.
- 3.1.2** Every supplier must possess a distinct legal identity.
- 3.1.3** Every firm operating site(s) including land or premises, where operations taking place result in the production of certified products is regarded as a supplier.

Suppliers of certified products (operators) and approved service providers can be distinguished as follows: certified product suppliers have full control over and are responsible for the production or manufacturing process, the raw materials supplying and the sale of certified products. Service providers only carry out a particular activity (packaging, transportation, slaughtering, etc.) within the production or manufacturing chain, according to specifications provided by the supplier (operator), who maintains legal ownership over the product throughout the entire process.

4.0 Certification Body

4.1 General Provisions

- 4.1.1 In addition to section 4.1.3 of the ISO/IEC Guide 65:1996, the documents pertaining to product conformity requirements shall be understandable by the supplier, the Certification Body, and all interested parties.

When a subjective judgment is required to determine compliance, the Certification Body shall document explanatory information, assuring consistent and uniform application of the requirements and certification decisions.

4.2 Structure (Organization)

The CFIA brings additional criteria or clarification points to section 4.2 of ISO/IEC Guide 65:1996:

- a) When the Certification Body identifies and assigns responsibilities and tasks to members of its staff, it must ensure that impartiality is not in jeopardy;
- b) The Certification Body shall take full responsibility for all activities operated or subcontracted out. The Certification Body shall not delegate

authority for granting, maintaining, extending, suspending or withdrawing certification to a separate legal entity;

- c) Identify the management (committee, group or person) which shall have overall responsibility for undertaking monitoring, inspection and certification activities as defined within the accreditation criteria, including execution of inspection, controls, evaluation and certification as defined in these Criteria;
- d) The Certification Body shall demonstrate its legal right to use the commercial name(s) under which it does business;
- e) Certification Bodies rights and responsibilities relevant to its certification activities shall be specified or referred to within an agreement that binds the suppliers and the certifier;
- f) Certification Bodies' financial stability shall include provisions to cover liabilities in situations where there is a significant risk of being sued.

The Accreditation Advisory Body may require from any Certification Body on which it has reservations regarding viability, a business plan showing the objectives and the methods it shall implement to comply to the above-mentioned criteria.

- g) Personnel, including contracted CB inspectors, shall be assigned to inspection and certification work that is appropriate to their skills;

The Certification Body shall require all persons involved in the certification process to sign a contract or other document by which they commit themselves to the rules and procedures of the Certification Body;

Personnel shall have job descriptions describing their duties and responsibilities;

- h) Specific advice given to the applicant should be limited to explanations of the standards or certification requirements. This information shall not be offered for additional fees and shall not prescribe solutions.
- i) These procedures must allow, among others, the implementation of an impartial appeal authority to deal with appeals from suppliers against decisions made by the body. This authority shall not be the

same as the one that made the decision for which an appeal is being filed.

4.3 Operations

Refer to section 4.3 of the ISO/IEC Guide 65:1996.

4.4 Subcontracting

In addition to ISO/IEC Guide 65:1996 criteria;

- a) The Certification Body which subcontract to individual CB inspectors shall ensure:
 - 1) The minimal qualifications required for CB inspectors must be described – they must ensure relevant professional training or experience in compliance with the Quality Management System requirements.
 - 2) The CB Inspector must have signed a formal agreement to refuse any work that would create a conflict-of-interest situation with the enterprise that is applying for certification, either because of a family link, or because of a business relationship with the applicant during the twelve months preceding its application to the Certification Body.
 - 3) The subcontracting CB Inspector shall not undertake any contractual relation or resume employment with a certification applicant that has received sub-contracted operations for a minimum period of twelve months following the certification decision.

Quality System

Please refer to section 4.5 of the ISO/IEC Guide 65:1996. In addition, the CFIA specifies that the procedures referred to in this section 4.5.3 I) of ISO/IEC Guide 65:1996 shall include rules to be applied for inspection, and in particular:

- i) CB inspectors' selection;
- ii) grounds on which an applicant might refuse this choice;
- iii) terms defining the verification mandate;

- iv) minimal requirements for the verification procedure;
- v) frequency and estimated duration of verification, taking into account the intensity of the production system, the production type, the company's size, the results of the previous verification, complaints received, parallel production;
- vi) minimum requirements for any audit trail, in relation to traceability;
- vii) sampling requirements (when applicable);
- viii) deadlines for representation of verification report.

4.6 Conditions and Procedures for Granting, Maintaining, Extending, Suspending and Withdrawing Certification

4.6.2 The Certification Body shall establish procedures for granting, extending, suspending and withdrawing certification:

The CFIA adds the following clarification to ISO/IEC Guide 65:1996:

- a) In case of suspension, the Certification Body shall require, at the date of notification of the suspension, and during all the following period, that the supplier makes no misleading claims as to the status of certification, and ceases to use certification mark on the products concerned by the suspension. If relevant, the Certification Body may require in addition that no certified product is put up for sale (embargo) and that potentially non conformed existing product be subject to a corrective action, including product recall and label correction.

4.7 Internal Audits and Management Reviews

Refer to ISO/IEC Guide 65:1996 criteria.

4.8 Documentation

Refer to ISO/IEC Guide 65:1996 criteria.

4.9 Records

Refer to section 4.9 of ISO/IEC Guide 65:1996. The CFIA is adding the following clarification to 4.9.1:

- a) The records shall be kept for a period of five years so that continued confidence may be demonstrated. The records created by the certifying body within the framework of initial or renewal certification demand processing shall be kept for ten (10) years.

4.10 Confidentiality

Refer to ISO/IEC Guide 65:1996 criteria.

5.0 Certification Body Personnel

5.1 General

Refer to ISO/IEC Guide 65:1996 criteria.

5.2 Qualification Criteria

Refer to ISO/IEC Guide 65:1996 criteria.

6.0 Changes in Certification Requirements

In addition to the ISO/IEC Guide 65:1996 criteria, the CFIA brings the following clarification:

Requirements pertaining to the granting of certification shall include:

- a) standards to which the product must be compliant;
- b) control plan;
- c) procedures related to certification granting.

7.0 Appeals, Complaints and Disputes

7.1 Refer to ISO/IEC Guide 65:1996.

7.2 Each Certification Body shall:

- a) The CFIA makes the following clarification to section 7.2.a) of the ISO/IEC Guide 65:1996 criteria;

- 1. appeals related to certification decisions;

2. complaints or objections from operators regarding the Certification Body's program application;

3. complaints or objections from outside persons or organizations about the Certification Body's operations.

8.0 Application for Certification

8.1 Information on the Procedure

8.1.1 In addition to ISO/IEC Guide 65:1996 criteria of section 2.1.1, the Certification Body shall, provide to applicants a current version of the Canada National organic standards to which the applicant wishes to be certified for.

8.1.2 The Certification Body shall require that the applicant:

In addition to ISO/IEC Guide 65:1996 criteria under this section, the CFIA add the following requirements:

- a) does not put up for sale any product for which it has requested certification; and bearing the word organic or its derivatives and the Certification Body's mark, for as long as it has not been informed of the decision made by the Certification Body stating that the products are certified;
- b) reveals beforehand to the Certification Body the identity of any other company for which it intends to manufacture products under license, and thus as a result can use the certifier's mark (name and logo) on the label of the products that it intends to market under its own brand name even though it does not hold a compliance certificate for those products;
- c) allows representatives from the Accreditation Advisory Bodies to access during normal working hours, documentation and sites used to produce certified products, for the purposes of examination and copying within as part of accredited certifier assessment;
- d) pays the corresponding fees requested by the certification organization.
- e) makes all necessary arrangements for the processing of any complaints directed towards them;

8.1.3 Refer to ISO/IEC Guide 65: 1996.

8.1.4 Refer to ISO/IEC Guide 65:1996.

8.2.2 The Certification Application

Refer to ISO/IEC Guide 65:1996.

8.2.1 Refer to ISO/IEC Guide 65:1996. The CFIA is adding the following criteria:

a) a definition of the products upon which the application is based, and indicating their nature as selected from one of the following:

1) tangible products to be certified relative to the certification system and also the standards against which each product must be certified, to the best of the applicant's knowledge;

2) services (intangible products) to be approved, consisting of operations to be carried out by a supplier at the request of a client, within the framework of an activity applied to a tangible product, in order to ensure or to maintain its conformity to prescribed standards;

3) inputs to be approved, consisting of non-edible substances used in the organic production process that shall not remain within the processed product;

4) in the case of an agricultural product containing more than one agricultural product, a statement setting out the percentage by weight of each of those products and the percentage by weight of each of them that are organic products;

5) pre-certification period to be attested.

b) production and/or preparation specifications for products to which the application applies;

c) evidence that the site(s) where operations take place and from where products mentioned in the application are produced are indeed operated by the applicant, and if not, the names of the other companies involved in the production of the products, along with a description of the business connections linking them and the applicant, and transaction flows between them;

d) names of Certification Bodies to which prior applications for certification, recognition, or evaluation were submitted by the applicant

within the previous years, including all details pertaining to processing the application, and the resulting decision by one or more of the targeted certifiers.

In light of the presented documents, the certifier shall determine whether or not the certification applicant is truly a product supplier, or if other suppliers must in addition to, or instead of, apply for certification of the products they are marketing and that are included in the application concerned.

9.0 Preparation for Evaluation

9.1 Refer to ISO/IEC Guide 65:1996.

9.2 In addition to ISO/IEC Guide 65:1996, the CFIA adds the following requirements. Evaluation activities include:

- a) an evaluation of the applicant regarding its admissibility to the certification program as a supplier;
- b) an evaluation of the documentation accompanying the application, including specifications for the production or preparation that the supplier submitted to the certifier, followed by a transmission of relevant remarks to the applicant, within a reasonable deadline;
- c) once an examination of the attached documentation confirms that operations carried out by the supplier seem to comply with the certifier's specifications, an inspection of the production site(s) and the supplier's premises.

9.2.1 For pre-certification, certification or any service for which certification is requested, the Certification Body must conduct an initial inspection of each production unit, building, or site (including vehicles) where production or preparation of agricultural and food products carried out.

9.2.2 The timing of the site inspection must be determined according to the following parameters:

- a) In cases of agricultural operations, it must take place during the production season. This period begins as soon as all operations subject to inspection (seeding, tapping, etc.) begin and ends with the packaging or placing in containers for storage of products to be certified;
- b) The inspection, including document review, shall include non-organic units where there is reason to suspect undeclared split

production of similar products, and in any situation revealing high risk of cross-contamination;

Where agricultural producers carry out split production, inspections must allow visual determination of what is being planted in all cultivated fields within the production unit;

c) In cases involving processing operations, inspections may be carried out any time during the year.

On the other hand, for separated production (i.e., when both certifiable and non-certifiable products are manufactured at the same facility), the inspection must be carried out at time when the products that are targeted for certification are being processed.

9.2.3 Applicants whose production system is not yet in operation may be exempted from inspection for as long as their system is not in operation.

9.2.4 The certifying body and its designated CB inspectors must have access to the premises, documents or person in charge for whatever is referenced in the certification application.

9.3 In addition to ISO/IEC Guide 65:1996, the CFIA adds the following criteria:

Operators shall have neither the right to choose nor to recommend CB Inspectors. Except for cases of unannounced visits, operators shall have the right to be informed about the identity of the CB Inspector before the inspection visit. Operators shall in any case have the right to raise objections based on conflict of interest or other reasons. The Certification Body shall rule whether the reasons are accepted.

9.4 In addition to ISO/IEC Guide 65:1996, the CFIA adds the following criteria: The documents must include, among others:

- a) production description;
- b) maps and plans;
- c) list of inputs (ingredients and agricultural substances);
- d) a copy of organic production and/or preparation plans;
- e) remedial actions required by the certifying body during the previous certification cycle, as well as any corrective measures implemented by the operator concerning these requests.

10.0 Evaluation

In addition to ISO/IEC Guide 65:1996, the CFIA adds the following criteria:

10.1 All applications for pre-certification, initial product certification or pertaining to its renewal, approval of services or even inputs must be the subject of evaluation. Regardless of the case, the evaluation must concern a production system that is currently operational (being actively managed).

10.2 The evaluation of a product must cover all production and processing operations, including packaging and labelling pertaining to the product. For an application for pre-certification and also certification (including its renewal), systems and facilities upon which a company relies to produce and/or prepare each product included within its application must be visited by the CB officer from the organization responsible for ensuring that the standards are fully applied, corresponding to the submitted production or preparation specifications. The complete application of standards implies an active management of the production system, and not only the non-use of prohibited substances or the summarily use of record of operations by the operator. To this end the CB inspector must witness the way the operator proceeds at a given point within the production cycle, thus implying that the inspection shall be carried out when grounds, premises, and activities subjected to compliance requirements may be observed.

10.3 Regular inspection must include, among other things:

- a) a visit to premises, storage units and fields where production operations take place, thus ensuring that they properly correspond to the specifications submitted by the applicant;
- b) a visit to all locations where preparation operations, including those where processing, packaging and labelling take place, thus allowing CB inspectors to ensure that they properly correspond to the specifications submitted by the applicant;
- c) identification and investigation of areas of risk;
- d) an examination of records related to production (ex: inventory, sales, purchases) and to management (e.g., accounting, complaints, etc.);
- e) for producers, an estimate of the potential yield for the coming year, as well as an audit of the balance in the quantities produced and sold over the previous period, and including amounts still in inventory during this same period (trial balance);
- f) For applicants performing operations related to food preparation (processing and/or packaging), an audit of the balance-statement for acquired commodities,

and for the corresponding commodities included in the products sold and on inventory;

g) traceback audits applying to certain products taken from the supplier's inventory or from a commercial outlet where its products have been placed for sale;

h) verification that changes that have been place in the standards and requirements of the Certification Body have been effectively implemented by the operator;

i) verification that previously imposed conditions have been fulfilled.

j) sampling, if necessary;

k) interviews with supervisory personnel;

l) a closing meeting at the end of the visit, intended to inform the firm's management of observations made concerning the compliance with certification requirements, without any corrective action request from the CB Inspector.

10.4 The inspection must cover the entire agricultural production system being managed by the firm, even if only part of the firm's operations were targeted by the certification application. The land, premises and equipment not included in the certification application must be identified and inspected, and must at a minimum include the following: crop areas or harvesting zones; harvest storage locations; preparation, processing and packaging sites; application dates for phytosanitary products; and administrative follow-up.

10.5 In the event that samples are taken by the CB Inspector, the CB Inspector shall provide the operator with a receipt for each sample.

11.0 Evaluation Report and Notification of Non-compliance

a) In addition to ISO/IEC Guide 65:1996, the CFIA adds the following criteria: The report shall include the following;

1) date, time and duration of inspection;

2) names of interviewees;

3) identification of land and premises visited on the production/handling site;

4) types of documentation audits performed (in/out balance sheet, yields/sales, audit trails by batches, etc).

b) When the certifying body has reason to believe, based on a review of the information, that an applicant for certification is not in compliance with the certification requirements, a full report on the outcome of the evaluation shall be issued to the applicant by the Certification Body, within a reasonable length of time, indicating all non-compliances that must be eliminated in order to comply with all of the certification requirements, and the extent of further required evaluation or testing. This report, serving as a written notification of non-compliance addressed to the applicant, shall provide among other things:

- 1) the description of each non-compliance;
- 2) the facts upon which the notification of non-compliance is based;
- 3) the request for remedial actions for each non-compliance;
- 4) the date by which the applicant must demonstrate that the non-compliance no longer exists or that remedial actions were taken.

c) If the applicant can show that remedial action has been taken to meet all the requirements within a specified time limit, the Certification Body shall repeat only the necessary parts of the initial procedure, meaning that it must ensure, based on submitted documentation and if necessary, an on-site inspection, whether or not non-conformities were corrected.

11.2 At any point within the certification cycle preceding the certifier's decision, the applicant may request that the processing of its application be stopped. The applicant shall, however, be liable for the costs of services provided up to the time of withdrawal of its application. In such case, the certifying body shall not issue a decision regarding the products that were the subject of the certification request.

12.0 Decision on Certification

12.1 In addition to ISO/IEC Guide 65:1996, the CFIA adds the following criteria:

12.1.1 Approval of Certification

The decision to certify a product shall be taken if the Certification Body determines that all procedures and activities contained in the production or preparation plan are in compliance with requirements and that the applicant is able to conduct operations in accordance with this plan or after the corrections of minor non-compliances. This acceptance is valid until the results of the next annual evaluation are known and that a new decision is made.

The certifying body must issue a written notice of approval of certification to any applicant for whom it accepts to certify the products, specifically with the intention of issuing a license authorizing the operator to use the certifier's certification mark (name/logo) under the conditions as specified in the contract or any other special documents. It must specify in this notice or in any other appropriate document the limits of the use of its mark according to the status of the company.

Status of a company:

1) Company producing and marketing a certified product:

When the company has obtained a compliance certificate for its products, it may then obtain authorization to make use of the certifier's mark within all methods it uses to market its products.

2) Company producing a product exclusively for a company that holds the certificate in order to market it:

When the company does not hold a certificate but has an exclusive affiliation with the operator it supplies, and the operator holds the compliance certificate for the products being supplied, then the compliance mark must only be used on labels of those products it packages, in an exclusive manner for the supplier and on a site falling under its responsibility.

3) Company producing and marketing a certified product in addition to supplying another company that holds a certificate in order to market it as well:

When in a nonexclusive manner a company supplies a client that has obtained a certificate from a certifier for products being marketed under a private brand, and this company already holds for its products a certificate granted by another certifying body, the certifier's mark must only be used on labels placed on products prepared and packaged for this client, on a site falling under the company's responsibility, and as a result of an extension to the license granted to this client by the certifier.

In order to have this license extension granted, the certifier granting it must guarantee its own certification, meaning that the other Certification Body was accredited by recognized Accreditation Advisory Body, that its evaluation and certification procedures include the products concerned, and following what these two certifiers have agreed, the body may have access either to the evaluation report produced by the other Certification

Body or to the supplier's operations site, thus allowing it to proceed with an inspection.

4) Company temporarily not producing any certified product:

When an operator does not hold a certificate because its production system is currently inactive and no certified products are available for sale, even though the system that was set up is compliant with standards, the certifier's mark may only be used on an official letter from the certifying body attesting the compliance of its production system and can be presented to any prospective client for its products.

5) Company not holding certificate but marketing under its own brand a certified product:

When under its own brand the company distributes products provided by a supplier to whom certification was granted by a Certification Body, this means that the company uses the body's certification mark to market these products. Thus even though the company itself possesses no certificate for its private brand products, the certifier must require that the company:

- a) inscribe on the packaging of products being resold under a private brand, a reference to the certified product supplier, indicated such that the supplier may be identified by both the competent authority and the certifier concerned;
- b) maintain a registry of all certified products received from the supplier, distributed, and eventually sold under either one or more previously approved labels;
- c) accept that the certifying body whose name is indicated on product labels be allowed to inspect these records when required and that records kept allow product movement to be traced, from the entry point (reports concerning products obtained from suppliers) up until a product leaves the premises (product sales reports and inventory reports).

The Certification Body must notify the recognized Accreditation Advisory Body of any certification it delivers and provide a copy of the evaluation report.
(for further discussion)

12.1.2 Denial of Certification

The Certification Body must issue a written notice of denial of certification to any applicant to whom it refuses certification, either because operations

resulting in the products included in the application are still noncompliant with requirements or simply because the applicant did not respond to the notification of non-compliance. This notice must state the reason(s) for denial and the applicant's right to:

- (a) file an appeal of the denial;
- (b) reapply for certification to any accredited Certification Body, including the one who refuses certification.

If a Certification Body has reason to believe that an applicant for certification has wilfully made a false statement regarding its production system and operations related to the products included in the application, the Certification Body may deny certification, without issuing a notification of non-compliance.

12.2 Please refer to ISO/IEC Guide 65:1996.

12.3 In addition to ISO/IEC Guide 65:1996, the CFIA adds the following criteria:

- a) the scope of the certification granted, including, as appropriate:
 - 1) the products certified, which must be identified by type or range of products including their specific name and if applicable, the one or more trademarks under which they are being marketed;
 - 2) the product standards or other normative documents concerning, if applicable, state programs under which each product or product type is certified;
 - 3) the applicable certification system with the type(s) of operations and subject of the evaluation by the Certification Body, among the following:
 - crop production;
 - livestock production;
 - grain production;
 - maple syrup production;
 - specialized production (aquaculture, bee-keeping, etc);
 - food processing;

- subsequent packaging (labelling modification following an operation of breaking down or regrouping on products already certified);
- brokerage.

b) the effective date of certification (initial date of certification for a given standard);

c) the date of the most recent certification maintaining decision and an indication of its duration;

d) the location of each operations site (town, province/state, country).

12.4 Refer to ISO/IEC Guide 65:1996.

12.5 In addition to the compliance certificate, the certifier may issue, upon request, other documents proving the certification of products and insuring better traceability, e.g. transaction certificates.

12.6 No certificate shall be issued to a company when it has no products for sale that are compliant with the prescribed standards, either because its production system is not yet operational, or because the operator is currently inactive. In these cases, the certificate shall only be issued following an inspection of the system once the firm begins its operations, thus validating the certification decision. On the other hand, the certifier may grant a license to these companies while they are waiting to obtain their certificate, thus allowing them to prove to any party concerned that they have the capacity to produce products meeting these standards.

13.0 Surveillance

13.1 In addition to ISO/IEC Guide 65:1996, the CFIA adds the following criteria:

a) Among these, there shall be a procedure covering the use and frequency of unannounced on-site inspections, according to which the certification program must plan, at the beginning of the year, some additional unannounced visits, representing 3% of primary producers and 5% of other clients to which it grants certificates for products made in Canada.

13.2 Refer to ISO/IEC Guide 65:1996.

13.3 In addition to ISO/IEC Guide 65:1996, the CFIA adds the following criteria:

a) the controls of requirements stipulated by the Certification Body following the evaluation;

b) all inspection visits made to suppliers;

- c) investigations made to find evidence pertaining to a complaint regarding a supplier.

13.4 In addition to ISO/IEC Guide 65:1996, the CFIA adds the following criteria:

To allow the Certification Body to re-evaluate the product concerned, the operator in charge of the product's conformity must submit within the periods stipulated by the Certification Body a certification renewal application, pay annual certification fees, and submit all information requested by the Certification Body including a mandatory updated production or preparation system plan. The request shall be the subject of a new certification cycle from the Certification Body which, at the end of the re-evaluation of operations from which the products to certify originate, shall make a decision either to maintain or to deny certification. The Certification Body re-evaluations must respect, at a minimum, the following rules:

- a) A regular site inspection must be made to each location where each supplier is operating, at least once per calendar year, and with the intention of determining whether the certification shall be maintained.
- b) If a regular inspection visit must occur on a date beyond a period of twelve months following the inspection from the previous year, this postponement must not exceed six months and must be justifiable by reasons.
- c) When the interval between two regular inspections has exceeded twelve months, the certifier must make sure that subsequent inspections restore the parity between the number of calendar years and the number of regular inspections over a given period.

13.5 The Canada Organic Office can request that additional inspections be conducted by the Certification Body with the intention of verifying the compliance of the operations of an operator or of a type of operators with regard to certification requirements.

14.0 Use of Licenses, Certificates and Marks of Conformity

14.1 In addition to ISO/IEC Guide 65:1996, the CFIA adds the following criteria:

14.1.1 Every company using the certification mark of the Certification Body for products it has ownership of, shall first get authorization from the Certification Body through a license.

14.1.2 The license must be withdrawn if the company:

- a) ceases doing business with the certifier;

b) ceases to supply, as affiliated operator, a customer whose products are certified by the certifier;

c) ceases, if it sells private label products without itself owning a certificate, to purchase from suppliers whose products are certified by the certifier;

d) cannot demonstrate that it is able to comply with the prescribed standards for operations included in its certification application .

14.1.3 The company affected by the attribution, modification (reduction, expansion, extension) or by the pure and simple withdrawal of a license must be informed officially by the certifier.

14.1.4 The certifier must possess procedures to monitor products using its certification mark and being sold on the market, to detect any improper or fraudulent use.

14.2 The Certification Body must possess written rules authorizing the use of its mark (including the recognition of product labels on which it shall be displayed) and is responsible for delivering compliance certificates. The body must have written procedures allowing it to process cases of abusive use, particularly those involving false statements regarding a product's certification or the incorrect use of its certification marks. The certifier must have procedures ensuring that its clients do not allow its certification mark be used in any way likely to lead to confusion among consumers.

14.3 In addition to ISO/IEC Guide 65:1996, the CFIA adds the following criteria:

Provision referred to in section 14.3 of ISO/IEC Guide 65:1996 could include remedial actions, withdrawal of certification, publication of offence, and if necessary, any other legal action.

15.0 Complaints to Suppliers

Please refer to ISO/IEC Guide 65:1996.

ANNEX 4: LABELLING, ADVERTISING, DISPLAY MATERIALS AND COMMERCIAL DOCUMENTS *(for further discussion)*

The following rules must be followed by all enterprises producing and/or preparing regulated organic products for the purpose of selling them on their own behalf and under their own trademark.

1.0 Organic Products Regulations(OPR)

The *Organic Products Regulations* (OPR) apply to:

- a) livestock, plants or livestock or plant products. This includes seed and planting stock and nursery products including sod;
- b) Food or drink products for human consumption, wholly or partly derived from livestock or plants. This includes fresh and processed fruits and vegetables, processed foods (including drinks) which are regulated under the *Food and Drugs Act* (FDA), maple products, dairy products, honey, eggs and eggs products, meat and meat products;
- c) Livestock feed;
- d) Finfish and finfish products and shellfish and shellfish products for human consumption (once an amendment to standard CAN/CGSB-32.310 standard has been made to include aqua cultural products.

Services, such as landscaping, and non-food products containing organic agricultural ingredients such as body care products, cosmetics, pet food, pet treats and nutritional supplements do not fall under the scope of the Organic Products Regulations.

The products listed above must adhere to the labelling requirements of the OPR if they bear indications referring to organic production methods.

2.0 Indications Regarding Organic Production Methods

Regulated products shall be regarded as bearing organic indications where, in the labelling, advertising material or commercial documents, the product, or its ingredients, is described by the term organic, or words of similar intent including diminutives, which suggests to the purchaser the product or its ingredients were obtained according to organic production methods.

Where use of these terms clearly has no connection with the method of production (e.g. ecological house) the term shall not be regarded as bearing organic indications.

3.0 Classes of Organic Products for Foods Containing Ingredients of Organic Origin

Labelling requirements specific to organic products are set out in Section 10 of the Organic General Principles and Management Standard CAN/CGSB-32.310. The Standard establishes three classes of organic products for purposes of labelling and claims in advertising material and commercial documents:

- products with at least 95% organic ingredients: these may freely use the word “organic” in reference to the product;
- products with at least 70% organic ingredients: these may use the term “contains X% organic ingredients”; and
- products with less than 70% organic ingredients: these may not use the term “organic”, except in the list of ingredients to modify those certified organic ingredients which meet the requirements of the Standard.

Products in the first two categories must be certified by an accredited CB

3.1 Regulated Products Containing 95% or more of Organic Agricultural Ingredients

3.1.1 Unprocessed plants and plant products, livestock and livestock products may use the term “organic” only where:

- such indications clearly show that they relate to a method of agricultural production;
- the product was produced in accordance with CAN/CGSB-32.310;
- the product was produced or imported by an operator who is certified in accordance with CAN/CGSB-32.310;
- the labelling refers to the name of the Certification Body that governs the operator of the production or the most recent preparation (processing, packaging and labelling) operation.

3.1.2 Processed agricultural crop and livestock products intended for human consumption may use the term “organic” only where:

- a) such indications clearly show that they relate to a method of agricultural production and are linked with the name of the organic product in question, unless this information is clearly given in the list of ingredients;
- b) all the ingredients of agricultural origin of the product are, or are derived from, products conforming to CAN/CGSB-32.310;

c) at least 95% (by mass or fluid volume, excluding water and salt) of the ingredients are organic and the non-organic ingredients:

- are not commercially available in organic form and the cost of organic ingredients is not to be used as a criterion for commercially available;
- do not include ingredients of non-agricultural origin not listed in the Permitted Substances Lists (CAN/CGSB-32.311);
- have not been produced using genetic engineering techniques;
- have not been produced using ionizing radiation; and
- have not been produced using sewage sludge;

d) the product does not contain both the non-organic and organic form of an ingredient;

e) the final product has not been subjected during preparation to treatments involving the use of ionizing radiation;

f) the product was prepared or imported by a certified operator and all organic ingredients contained in the final composition of a product shall also have been certified;

g) the labelling refers to the name of the Certification Body that certified the operator of the production or most recent preparation (processing, packaging and labelling) operation (see also 4.1.1 below).

3.2 Regulated products containing 70% or more of organic ingredients

Regulated products containing 70% or more of agricultural ingredients (by mass or fluid volume, excluding water and salt) that are organic in accordance with CAN/CGSB-32.310 may use the phrase “Contains X% organic ” only where:

- the actual organic agricultural ingredients are in accordance with CAN/CGSB-32.310 and the product does not contain both the non-organic and organic form of an ingredient;
- the conditions for non-organic ingredients are met;
- the final product has not been subjected during preparation to treatments involving the use of ionizing radiation;
- the product was prepared or imported by a certified operator;
- the labelling refers to the name of the Certification Body that certified the operator of the production or most recent preparation (processing, packaging and labelling) operation (see also 4.1.1 below).

3.3 Regulated products containing less than 70% of organic ingredients

Products containing less than 70% (by mass or fluid volume, excluding water and salt) of ingredients that are organic may have the organic ingredient(s) labelled as organic in the list of ingredients but shall not refer to certification in the labelling, advertising or commercial documents.

Products containing less than 70% of organic ingredients must be subject to audit by a Certification Body. The labels of such products must not make organic claims except in the list of ingredients.

4.0 Calculation of Percentage of all Organically Produced Ingredients in a Multi-Ingredient Product

The percentage of all organically produced ingredients in an organic product that is sold, labelled or represented as organic or that includes organic ingredients, in accordance with the regulations, shall be calculated by the following:

- *Solid Products*: Divide the total net mass (excluding water and salt) of combined organic ingredients in the formulation or finished product, whichever is more relevant, by the total mass (excluding water and salt) of all ingredients;
- *Liquid Products*: Divide the fluid volume of all organic ingredients (excluding water and salt) by the fluid volume of all ingredients (excluding water and salt) if the product and ingredients are liquid. If the liquid product is identified on the principal display panel as being reconstituted from concentrates or by similar phrases, the calculation shall be made using single-strength concentrations of the ingredients or finished product;
- *Solid Products and Liquid Products*: Divide the combined mass of solid organic ingredients and the mass of the liquid organic ingredients (excluding water and salt) by the total mass (excluding water and salt) of all ingredients in the finished product.

The percentage of all organically produced ingredients in an organic product shall be rounded down to the nearest whole number.

The total percentage of organically produced ingredients shall be determined by the person who prepares the product and affixes the label on the consumer package and whose work has been verified by the Certification Body. This person may use, if applicable, information provided by the organic operation that prepared the product previously in determining the percentage.

5.0 Required and Optional Information and Prohibited References on Labels

5.1 Mandatory Labelling Requirements

The following information shall be inscribed on retail packaging in a clear and visible way for every regulated product bearing a label that contains “organic” indications or “Contains X% Organic”:

- 5.1.1** the corporate name or initialism of the Certification Body that certified the operator of the production or the most recent processing, packaging or labelling operation, preceded by the statement “Certified by...” or similar phrase.

Operators that do not take physical possession of the product, including private label owners, brokers and traders, may display the corporate name or initialism of the certification body that certified their label or operation provided that;

- all compliance certificates for products made by suppliers are verified during on-site inspections. The information relating to these certificates is recorded in a register that is kept in the operators file at the Certification Body’s office;
- records on the quantity of products purchased and sold are verified to ensure that more organic product is not sold than was delivered by suppliers;

- 5.1.2** The lot/batch number identifying a meaningful-sized unit of production;

- 5.1.3** Ingredients list requirements:

- a clear distinction in the list of ingredients shall be made between those ingredients that are organic in accordance with CAN/CGSB-32.310 and those that are not;
- all additives and processing aids shall appear on the list of ingredients unless it can be shown by testing that they are not present in the final product;
- water or salt included as ingredients cannot be identified as organic;
- if herbs and spices constitute less than 2% of the total weight of the product, and are not individually listed in the ingredients list, they may be grouped and listed as “herbs” or “spices”, as the case may be.

5.2 Prohibitions in Labelling and Claims

The following are prohibited in labelling and claims:

- 5.2.1** Statements that a food product contains no genetically engineered ingredients, unless:
- this fact is proven by independent tests;
 - the product contains one or more ingredients whose equivalent genetically engineered version is commercially available and included in Health Canada's official list of genetically engineered products;
- 5.2.2** indications on a main display panel that a product is organic if the product contains less than 95% organic ingredients;
- 5.2.3** the indication "Contains X% Organic" on a main display panel if the product contains less than 70% organic ingredients;
- 5.2.4** indications, in other than the list of ingredients, that lead to the belief that the product contains organic ingredients if the product contains less than 70% organic ingredients;
- 5.2.5** the federal organic legend if the product contains less than 95% organic ingredients;
- 5.2.6** the logo or trademark of the Certification Body that certified the product or ingredients if the product contains less than 70% organic ingredients.

5.3 Optional Labelling information

- 5.3.1** The following information may be inscribed on retail packaging, advertising, display materials and commercial documents for products containing at least 95% organic ingredients:
- the federal organic logo and/or word mark;
 - the seal, logo, or other identifying mark of the Certification Body that certified the product, provided that such seals, logos or identifying marks are not displayed more prominently than the federal organic logo;
 - the business address, Internet address, or telephone number of the Certification Body that certified the product;

- provincial or, where Canada recognizes the equivalency of third country programs, foreign country organic legends provided that such seals, logos or identifying marks are not displayed more prominently than the federal organic legend.

5.3.2 Products in **other than packaged form** at the point of retail sale, which contain at least 95% organic ingredients produced in accordance with the Regulation:

- may refer to organic production methods in retail display, labelling and display containers;
- may, if the product is prepared in a certified facility, in the retail display, labelling, and display containers, use:
 - the federal organic logo and wordmark;
 - the seal, logo, or other identifying mark of the Certification Body that certified the operator of the production or the most recent operation, provided that such seals, logos or identifying marks are not displayed more prominently than the federal organic legend;
 - provincial or, where Canada recognizes the equivalency of third country programs, foreign country organic legends provided that such seals, logos or identifying marks are not displayed more prominently than the federal organic legend.

5.3.3 Products in other than packaged form at the point of retail sale which contain at least 70% of ingredients that are organic in accordance with the Regulation:

- may refer to organic production methods in retail display, labelling and display containers as “Contains X % organic”, where the actual organic ingredient is in accordance with CAN/CGSB-32.310;
- may, if the product is prepared in a certified facility, in the retail display, labelling and display containers, use the seal, logo, or other identifying mark of the Certification Body that certified the product;

6.0 Labelling Non-retail Containers

6.1 Non-retail containers used only to ship or to store products with labels containing organic indications may display the following terms or marks:

- the corporate name or acronym and contact information of the Certification Body that certified the product;

- identification of the product as organic;
- special handling instructions needed to maintain the organic integrity of the product;
- the federal organic logo and/or wordmark;
- the seal, logo or other identifying mark of the Certification Body that certified the operator of the most recent handling operation; provincial or, where Canada recognizes the equivalency of third country programs, foreign country organic legends.

6.2 Non-retail containers used only to ship or to store products with labels containing organic indications must display the production lot/batch number of the product if applicable.

6.3 Shipping containers of domestically produced product with organic indications intended for export to international markets may be labelled in accordance with any shipping container labelling requirements of the foreign country of destination or the container labelling specifications of a foreign contract buyer provided that:

- the shipping containers and shipping documents accompanying such products are clearly marked “For Export Only”; and
- proof of such container marking and export must be maintained by the handler in accordance with record-keeping requirements for certification.

7.0 Labelling Livestock Feed Products

7.1 Livestock feed products may display, on any package panel, organic indications provided that the product is in accordance with CAN/CGSB-32.310.

7.2 Products complying with paragraph 6.1., above may display:

- the federal organic logo and/or wordmark;
- the seal, logo, or other identifying mark of the Certification Body that certified the product, provided that such seals, logos or identifying marks are not displayed more prominently than the federal organic logo;
- provincial or, where Canada recognizes the equivalency of third country programs, foreign country organic legends provided that such seals, logos or identifying marks are not displayed more prominently than the federal organic legend.

7.3 Ingredients list requirements for products containing less than 100% organic ingredients:

- a clear distinction in the list of ingredients shall be made between those ingredients that are organic in accordance with the Regulation and those that are not;
- all additives and processing aids that remain in the final product shall appear on the list of ingredients;
- water or salt included as ingredients cannot be identified as organic;

7.4 Livestock feed products must display the corporate name or acronym of the Certification Body that certified the product, preceded by the statement “Certified by...” or similar phrase. The business address, Internet address or telephone number of the Certification Body may be included.

2.0 Advertising, Display Materials and Commercial Documents

Information and claims permitted on labels are also permitted in advertising, display materials and commercial documents for the same product.

9.0 Use of the Federal Organic Legend

9.1 The Federal Organic Legend may be used only for regulated products containing 95% or more of certified organic ingredients.

9.2 The federal organic logo and wordmark must replicate the form and design described in the Regulation.

10.0 Registration of Labels

Certain food labels **must** be registered by the CFIA Formulation and Label Registration Unit. These include:

- labels originating from federally registered Canadian meat, poultry and processed fruit and vegetable establishments;
- labels originating from foreign meat, poultry and processed fruit and vegetable establishments

Label registration requests are to be submitted using form CFIA 1472 accompanied by the appropriate number of labels and recipes. This form is available on the CFIA website: <http://www.inspection.gc.ca/english/for/mpppe.shtml>. Consult the CFIA Fees Notice to determine whether a fee is applicable for your product.

Mail completed registration forms to:
Clerk
Label Registration Unit
Canada Food Inspection Agency
1431 Merivale Road,
Nepean, ON
K1A 0Y9

11.0 CFIA's Food Labelling Information Service

The CFIA Food Labelling Information Service consolidates and coordinates voluntary federal food label reviews. This service is particularly directed to facilitate market entry for new businesses. For more information please refer to the *Guide to Food Labelling and Advertising*.

4.0 Appendices

APPENDIX A: Documents Domestic and International Accreditation Advisory Bodies to Submit Along with Application

#	Required document	Included in submission	YES	NO
1.	Documents to submit along with the application for accreditation.			
1.1	The Corporate Charter			
1.2	Any Government Act, Regulation or Decree that gives the Accreditation Advisory Body the legal authority to accredit.			
1.3	The Corporate structure showing graphically and quantitatively relations of control by shareholders, companies or other groups of the organization.			
1.4	The general bylaws.			
1.5	A list of directors, comprising: a) Members of the board of directors (including specific function, duration of mandate, and affiliation). b) Board members of a sponsoring organization (if applicable).			
1.6	The addresses of all locations where the firm does business and summary of activities from each location.			
1.7	A copy of the compliance mark (body's name such as it appears on accreditation certificates and any property rights related to it).			
1.8	A copy of the liability insurance for directors and employees.			
2.	Description of decision –Making Structures			
2.1	A description of individuals or Internal bodies making decisions covering: a) Assessment of applicants, b) Accreditation of applicants, c) Appeals, d) Complaints.			
2.2	A description of sharing of responsibilities between Head Office and Affiliates (if applicable).			
2.3	An Organization Chart related to the general administration of the program including names of persons occupying managerial positions in both Head Office and Affiliates (when it applies)			

3. Information on Accreditation Advisory Body's Operations				
3.1	Audited Annual Financial Accounts			
3.2	A complete list of all Certification Bodies including the name and address of every one to which the accreditor has granted accreditation for production of organic products.			
3.3	A copy of the board of Director's latest annual report to members or stockholders.			
4. Standards, Policies and Technical Procedures (Quality Manual)				
4.1	The Quality Manual related to the accreditation program.			
4.2	The templates for assessment questionnaires used by inspectors.			
4.3	The templates for accreditation reports.			
4.4	Lists of documents included in the file made up on each certifying body having requested accreditation			
4.5	Copy of IAF evaluation or other third party assessment against ISO/IEC 17011:2004 standard (if available)			
5. Accreditation Advisory Body's Human Resources Management.				
5.1	A complete list of employees including the status and position held by each one.			
5.2	A copy of the standard contract with employees.			
5.3	The selection criteria for persons making accreditation decisions or in charge of overseeing those who make them.			
5.4	The name of person or list of the members of the internal body (Committee, etc.) assigned either to make accreditation decisions or to oversee those who make them (with their experience or specific training).			
5.5	The selection criteria for assessors and experts.			
5.6	A copy of the standard contract with assessors.			
5.7	A complete list of assessors (including their training and years of experience, their commercial or financial affiliation).			
5.8	A copy of the standard contract used with any other type of subcontractors (if applicable).			
6. Information Material and Forms Forwarded to Accreditation Applicants.				
6.1	A detailed fee schedule for the various services offered.			

6.2	Copies of information documents about the accreditation program.			
6.3	A copy of the application forms to be filled out by applicants.			
6.4	A list of documents that must be supplied to the Accreditation Advisory Body by applicants.			
7.	Documents concerning Rights and Obligations of Accredited Certifiers.			
7.1	A copy of the standard contract(s) to be signed by Accreditation applicants, when granted accreditation.			
7.2	An example of an accreditation certificate issued by the Accreditation Advisory Body.			

APPENDIX B: Documents Domestic and International Certification Bodies to Submit Along with Application

#	Required document	Included in submission	YES	NO
1.	Documents Pertaining to Certification Body			
1.1	The Corporate Charter			
1.2	The corporate structure showing graphically and quantitatively relations of control by shareholders, companies or other groups for the organization;			
1.3	The general by laws.			
1.4	A list of directors, comprising: a)Members of the board of directors (including specific function, duration of mandate, and affiliation). b)Board members of a sponsoring organization (if applicable).			
1.5	The addresses of all locations where the firm does business and summary of activities from each location.			
1.6	A copy of the compliance mark (body's name such as it appears on the label or certified product) and any property rights related to it.			
1.7	Copy of the liability insurance for directors and employees			
1.8	In the case of organizations already accredited by an official organization, a copy of their accreditation certificate			
2.	Description of decision –Making Structures			
2.1	A description of individuals or Internal bodies making decisions covering: a) Product certification; b) Appeals; c) Brand name control (certifying body's name and logo); Along with their mandate, their procedures, and the manner in which they are designated			
2.2	A description of sharing of responsibilities between Head Office and Affiliates (if applicable).			
2.3	An Organization Chart related to the general administration of the program including names of persons occupying managerial positions in both Head Office and Affiliates (when it applies)			

3. Information on Certification Body's Operations				
3.1	Copy of the latest annual financial statements, including balance sheet, revenues and expenses			
3.2	List of countries, provinces or states in which the body is carrying out certification activities			
3.3	Complete list of all firms including the name and address of every one to which the body has granted a compliance certificate, in the one or more fields for which it has applied for accreditation: a) A compliance certificate for the certified products with their mention on the list; b) A certificate of recognition for any inputs or services with their mention on the list;			
3.4	Copy of the Board of Director's latest annual report to members or stockholders			
4. Standards, Policies and Technical Procedures (Quality Manual)				
4.1	The Quality Manual related to the certification program.			
4.2	Templates of inspection questionnaires used by CB Inspectors			
4.3	Templates of inspection reports			
4.4	List of documents included in file made up on each operator having requested certification			
5. Certification Advisory Body's Human Resources Management.				
5.1	A complete list of employees including the status and position held by each one.			
5.2	A copy of the standard contract with employees.			
5.3	The selection criteria for persons making certification decisions or in charge of overseeing those who make them.			
5.4	The name of person or list of the members of the internal body (Committee, etc.) assigned either to make accreditation decisions or to oversee those who make them (with their experience or specific training).			
5.5	The selection criteria for CB inspectors			
5.6	Copy of standard I contract between certification program and CB Inspectors			
5.7	Complete list of CB Inspectors (including their training and years of experience, their commercial or financial affiliation)			
5.8	A copy of the standard contract used with any other type of subcontractors (if applicable).			

6. Information Material and Forms Forwarded to Certification Applicants.				
6.1	A detailed fee schedule for the various services offered.			
6.2	Copies of information documents about the certification program			
6.3	Copy of the application forms to fill by applicants			
6.4	Copies of production or preparation compliance plan forms to be filled yearly by applicants			
7. Documents Concerning Rights and Obligations of Certified Operators				
7.1	Contract(s) to be signed by certification applicants, regulating the use of marks of compliance (licenses)			
7.2	Copy of the different types of certificates issued by the Certification Body			
7.3	Example of packaging using the compliance mark (showing name of organization).			

APPENDIX C: Required Data for Each Operator

All data listed below must be recorded by the Certification Body and transmitted to the AAB and COO:

#	Required data	Included in submission	YES	NO
1.	Data Pertaining to Operator			
1.1	Legal (corporate) name of operator			
1.2	Full address of the of company's head office including phone numbers and fax numbers;			
1.3	Type of operation			
1.4	Generic names of the products certified; and			
1.5	Label sample			