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INTERNATIONAL ORGANIC ACCREDITATION SERVICE Inc.

OPERATING MANUAL

for

Accreditation under the Canadian Organic Regime

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Preface

This Operating Manual is provided to give an overview of the IOAS and the service it offers as an approved Accreditation Advisory Body under the Canadian Organic Regime for certification bodies active in organic agriculture and food production in any part of the world.

The manual is divided into four parts:

Section A is an introduction to the IOAS, and the background to the Canadian Organic Regime.

Section B covers the scope, structure, and some fundamental policies of the IOAS programme under the Canadian Organic Regime.

Section C explains the application, evaluation, and accreditation procedures.

Section D provides information on the rights and responsibilities of applicants, accredited bodies, and the IOAS.

The manual should be regarded as a guide to the operation of IOAS accreditation programme under the Canadian Organic Regime. It is provided to all applicants and is available to other interested parties. It is not the official policy manual of the IOAS. Full policies are contained in the IOAS Quality Manual. Individual policies referenced here are available from IOAS offices.

The IOAS Quality Manual describes the measures in place to guarantee a high quality of work and continuous improvement in its implementation of the accreditation under the Canadian Organic Regime. As part of its efforts to continuously improve its performance the IOAS periodically amends its policies and procedures. Resulting differences between the descriptions of policies contained in this manual and the actual policy may occur. In such event the official policy document of the IOAS takes precedence over the description provided herein.

Ken Commins
Executive Director
Jamestown, ND
USA

February, 2008

Definitions

The following definitions apply within the context of this manual:

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 *Definition to be reviewed/revise 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*)

Accreditation certificate: formal document or set of documents stating that accreditation has been granted for the defined scope.

Accreditation Contract: A formal agreement between the IOAS and an accredited body which lays out the rights and responsibilities of an accredited body. The contract permits the body to use its accreditation status subject to the limitations stated in the contract.

Accredited Certification Body: A certification body that has been accredited.

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

Agricultural Primary Products: Means livestock, plants or unprocessed single-ingredient livestock or plant products.

Annual Update Report: A report submitted annually to the IOAS by accredited certification bodies as part of the Annual Surveillance procedure.

Appeal: Request by a CAB for reconsideration of any adverse decision made by the accreditation body related to its desired accreditation status.

Applicant Body: A certification body that has applied for accreditation.

Audit: *Definition to be reviewed/revise 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.

Category of Certification: A field of certification activity such as crop production, input manufacturing, or aquaculture.

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

Certificate of Accreditation: Document issued by an accreditation body, declaring that a certification body meets the requirements of a specified accreditation programme.

Certification Programme: System operated by a certification body with its own rules and procedures and management for carrying out certification of conformity.

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

Compliance: *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)

Complaint: An objection to the policies, procedures or performance of the IOAS. A complaint may also be an objection to the performance or activities of an accredited body lodged with the IOAS by a third party.

Deficiency: A failing on the part of the certification body to comply with reference standards and criteria but of a lesser grade than a non-conformity. Generally, this will mean that while the procedure or policy is in place, the details of the criteria or standards have not been fulfilled.

Evaluation: The systematic process of examining the extent to which the performance of a certification body fulfills specific requirements.

Evaluation Report: The written findings of the evaluator, following the evaluation visit.

Evaluation Visit: The visit to the premises of the certification body and subcontracted parties and to the premises of the operators certified under the relevant certification programme as part of the evaluation.

Evaluator: Person appointed by the IOAS to carry out the evaluation visit.

Input Manufacturing: Manufacturing of production or processing inputs.

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)

Inspector: Person appointed by a certification body or by an inspection body to undertake the inspection of an operator.

Interested parties: Parties with a direct or indirect interest in accreditation.

Internal Review: An assessment of the objectives and performance of a body that is undertaken by the body itself.

Investigation: 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: 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”: 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: 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.

Non-compliance: A failing on the part of the certification body to comply with reference to standards and criteria. A non-compliance may be either a non-conformity or a deficiency.

Non-conformity: The absence of, or the failure to implement and maintain, a required system element of the reference standards and criteria, or a situation which would raise significant doubt as to the credibility of the certification.

Operator: 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: 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: 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: 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: 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 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*)

Programme Manager: The person appointed by the IOAS to administer the accreditation programme.

Review Audit: A review operator inspection conducted by the IOAS evaluator during the evaluation visit in which the accuracy of a previously conducted inspection is assessed. (see also witness audit)

Review Evaluation: The process of re-evaluating an accredited certification body to ascertain whether it continues to be in compliance with the accreditation programme's requirements.

Sanction: An action taken by the IOAS in response to a failure by the certification body to meet the requirements of accreditation.

Scope of accreditation: Specific conformity assessment services for which accreditation is sought or has been granted.

Screening: An initial process whereby the IOAS, as part of the evaluation, assesses the conformity of an applicant body based on its documentation.

Standards: The standards for agricultural production or processing used by a certification body, to which certified operators must adhere

Suspending accreditation: Process of temporarily making accreditation invalid.

Surveillance: Procedure involving submission of an annual update report and on-site visits to a specified schedule, whereby the IOAS monitor ongoing compliance of accredited certification bodies.

Trade-mark: 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: 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.

Withdrawing accreditation: Process of cancelling accreditation in full.

Witness Audit: An operator inspection performed under normal certification body procedures in the presence of the IOAS evaluator.

Abbreviations

The following abbreviations occur in the text:

ED:	Executive Director, IOAS
PM:	Programme Manager, IOAS
AC:	Accreditation Committee of the IOAS
AMC:	Accreditation Management Committee
CB:	Certification Body
CFIA:	Canadian Food Inspection Agency
COO:	Canadian Organic Office
COR:	Canadian Organic Regime
IAF:	International Accreditation Forum
IOAS:	International Organic Accreditation Service Inc.
IFOAM:	International Federation of Organic Agriculture Movements
ISO:	International Organisation for Standardisation
OPR:	Organic Products Regulations - Canada
WBOD:	The World Board of Directors of IFOAM.

Section A: Introduction

A1 IOAS Accreditation Programme under the Canadian Organic Regime

A1.1 Following the audit of the IOAS by the Canadian Organic Office in March on April 10th, the IOAS received a [letter](#) from the Canadian Food Inspection Agency confirming compliance with the Canadian Organic Regime. This means that the IOAS is now able to accept applications from certification bodies anywhere in the world for accreditation under the Canadian Organic Regime. The IOAS Accreditation Programme under the COR is open to all certification bodies active in the field of organic agriculture. This means the IOAS may provide this additional service to the organic certification community who, either operate inside Canada or who are involved in the conformity assessment of products destined to enter Canada.

A1.2 The IOAS Accreditation Programme under the COR complements the main business of the IOAS, that of IFOAM Accreditation, which is performed under license to the International Federation of Organic Agricultural Movements (IFOAM) and that of ISO/IEC Guide 65 accreditation. All accreditations stand alone but where required, a certification body may apply for any or all simultaneously, benefiting from savings on combining the evaluation and surveillance process.

A1.3 For background, the remainder of this section describes the origins of IOAS and the COR.

A2 International Organic Accreditation Service Inc.

A2.1 The IOAS was established in 1997 by the International Federation of Organic Agriculture Movements to operate the IFOAM Accreditation System, a private organic guarantee which had been operating within IFOAM since 1992. International Organic Accreditation Service Inc. is registered as a non-profit company in the United States. The IOAS continues to operate the IFOAM Accreditation Programme under a licensing agreement with IFOAM.

A2.2 In 2003, the IOAS launched an accreditation programme against ISO/IEC Guide 65

A2.3 The IOAS is the legal entity responsible for all accreditations and operates quite separately from IFOAM.

A2.4 As a nonprofit organisation the IOAS has a membership structure rather than shareholders. IFOAM is the sole member of the IOAS.

A2.5 As the sole member of the IOAS IFOAM's role is restricted to appointing the IOAS Board of Directors. The procedure requires that the IOAS board vet applications and make recommendations to IFOAM.

A2.6 The activities of the IOAS member IFOAM does not effect the confidentiality, objectivity or impartiality of its accreditations. (PL0902)

A3 Accreditation under the COR

A3.1 IOAS Accreditation Programme under the COR

On December 21, 2006 the Organic Products Regulations were published in Canada. The regulation is to be implemented from December 14th, 2008.

A3.2 There are three main players in the implementation of the regulation:

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 should 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).

A3.3 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.

A3.4 These are the reference documents against which IOAS will judge certification bodies applying for accreditation under the COR. All are available via the IOAS web site at www.ioas.org/cor.htm

A3.5 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 Annex 3 of the COO QMS Manual.

A3.6 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.

A3.7 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 programme 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.

A3.8 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.

Section B: Scope and Structure of the Accreditation Programme

B1 Scope of Accreditation

B1.1 IOAS accreditation under the COR is open to applications from certification bodies engaged in the inspection and certification of organic production and/or processing operations.

B1.2 The Organic Products Regulations (OPR) apply to:

- Livestock, plants or livestock or plant products. This includes seed and planting stock and nursery products including sod;
- 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;
- Livestock feed;
- 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 aquacultural products).

B1.3 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.

B1.4 The products listed above must adhere to the labelling requirements of the OPR if they bear indications referring to organic production methods.

B1.5 Certification bodies must agree to conform with all applicable requirements, structures, and operating procedures as set down in the COO QMS and provide all required information.

B1.6 IOAS accreditation under the COR is implemented and awarded against 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. No assessment of standards is performed as with IFOAM Accreditation although implementation is evaluated.

B1.7 Certification bodies that contract out part of their services may apply for accreditation providing the certification body takes full responsibility for subcontracted work and provided the certification decision itself is not subcontracted. This is relevant to certification bodies that subcontract their inspection service and those that operate a regional structure. Where there is

uncertainty on which body should apply for accreditation, it is the decision making body that should apply.

B2 Structure of the IOAS

(PL0101, PL0104, PL0204, PL0902)

B2.1 The management and operation of the IOAS accreditation under the COR is the responsibility of the IOAS. The IOAS and its Board of Directors operate independently from IFOAM the organisation that established the IOAS in 1997.

B2.2 The Board of Directors of the IOAS is appointed by the IFOAM World Board of Directors based on an open nomination process (PL0204). The Board is constituted with a balance of interests taking into account geographical and gender spread. Normal length of tenure is three years. A current list of Board Members is available on the IOAS website (www.ioas.org/who.htm)

B2.3 The International Organic Accreditation Service Inc. is a non-profit corporation registered in the United States. It was founded in 1997 with the sole member being IFOAM. The aims of the IOAS include the following;

- To provide a means whereby certification bodies involved in the certification of organic agriculture and the products thereof can submit themselves for evaluation against internationally agreed criteria, thereby enabling them to gain accreditation status;
- To improve the certification of organic products, thereby facilitating international trade in organic products on an equitable basis;
- To make its services available to outside interested parties, thereby facilitating international trade in organic products on an equitable basis.

B2.4 The structure of the IOAS and procedures for accreditation under the COR are laid down in the IOAS Quality Manual. Individual policies may be obtained from the IOAS head office.

B2.5 The Accreditation Committee (PL0205, LS0202)

The Accreditation Committee is responsible for making accreditation recommendations to the COO and for monitoring the continued compliance of accredited certification bodies. Members are appointed by the IOAS Board on the basis of experience. It is constituted with a balance of interests. The Accreditation Committee is governed by its terms of reference and answerable to the IOAS Board. A current list of Accreditation Committee members is available on the IOAS website (www.ioas.org/who.htm).

B2.6 IOAS Staff Members

In January 2008, there are currently six full-time professional staff members responsible for the day to day management of the accreditation programme; Executive Director(ED), Assistant Executive Director and Programme Manager (PM) and three Client Managers with offices in the USA, UK, Spain and Australia respectively. The ED is responsible for the overall operation of the IOAS and the PM is responsible for the administration of the accreditation process. An Office Manager supports the team of professional staff. A current staff list can be found at www.ioas.org/who.htm

B2.7 Accreditation Management Committee (PL0304)

A staff Accreditation Management Committee is appointed to make procedural decisions concerning the need for Accreditation Committee review of a certification body file at certain stages of evaluation.

B2.8 Evaluators (PL0402)

Evaluation visits are undertaken by evaluators who have reached a required degree of professional competence. This includes a formal degree in agricultural science or equivalent education plus knowledge of, and experience in, organic inspection and certification. Evaluators serve an apprenticeship period before conducting evaluations. Most evaluation visits are performed by in-house professional staff. Any allocated evaluators should not have been employed by a Certification Body in a position or within a period of time that might reduce their impartiality. The criteria relative to an evaluator's expertise includes, among others:

- Knowledge and understanding of the COR's accreditation program (accreditation criteria and procedures);
- Knowledge of Canada's national organic standard and generally accepted experience (practical experience in production, processing, inspection or certification management) relative to conformity assessments;
- Knowledge of evaluation methods including, among others, interviewing techniques and an ability to draft reports;
- No current involvement in certification management or certification inspection activities.

B3 IOAS Policy

B3.1 The IOAS has a comprehensive quality manual in which all its policies are laid down. The following policies are of particular importance.

B3.2 Confidentiality(PL0203)

Members of the IOAS board, the Accreditation Committee, the staff, evaluators and other relevant personnel are required to sign a confidentiality agreement that is based on a comprehensive Confidentiality Policy. Full confidentiality is maintained regarding evaluation reports, application forms and any information which is regarded as commercially sensitive. Except for confidentiality restrictions, the IOAS principle is one of transparency, and the names of all evaluators are published (www.ioas.org/who.htm) A list of approved certification bodies under the COR is published on the COO web site.

B3.3 Conflicts of Interest (PL0202, PL0305, PL0401)

The IOAS is committed to a policy of neutrality in carrying out the Accreditation Programme. Among other measures, the following procedures and policies are adhered to.

- Members of the IOAS Board and Accreditation Committee are drawn from all sectors with an interest in organic accreditation but with no single interest predominant.
- The interests of all IOAS Board and Accreditation Committee members are on file, are updated regularly, and are formally reviewed once a year. Failure to declare an interest is sufficient cause for dismissal.

- Applicant certification bodies are informed of the current membership of the Accreditation Committee. The certification body may request that a committee member not take part in discussions regarding their application or accreditation if they perceive that member to have a conflict of interest. The IOAS will decide the validity of such a request.
- All Board and Accreditation Committee members are obliged to declare any perceived conflict of interest and to absent themselves from the meeting before deliberations commence regarding an applicant or accredited body.
- The interests of all evaluators are on file in the IOAS office and are consulted in the assignment of evaluators. Failure to declare an interest is sufficient cause for removal of the evaluator from the approved evaluator list.
- Applicant bodies have the opportunity to object to the assignment of an evaluator.

B4 Review of the Accreditation Programme

(PL0106)

B4.1 The IOAS Accreditation Programme under the COR is subject to periodic internal review in line with its Internal Review Policy. It entails an assessment of its structure, criteria, and procedures and results in a revision of those areas where a need for improvement is noted.

B4.2 In August 2004, the IOAS was recognised by the National Institute of Standards and Technology (a technical institute which forms part of the United States Department of Commerce) as compliant with ISO17011. The NIST evaluation included document review of the IOAS quality system, an office visit and a witness audit of an IOAS evaluation visit. The NIST recognition covers both IFOAM and ISO65 accreditation programmes and the recognition is subject to continuous surveillance. The current NIST certificate is available to view at www.ioas.org/xnistcer.pdf

B4.3 The IOAS is also subject to periodic audits by the Canadian Organic Office in order to maintain its status as an Approved Accreditation Advisory Body under the Canadian Organic Regime

Section C: The Accreditation Process

The procedures for attaining and maintaining Accreditation under the Canada Organic Regime involves six phases;

- Application and screening of documentation
- Assessment of certification body performance
- IOAS recommends accreditation to the CFIA
- CFIA grants accreditation
- Surveillance
- Re-evaluation

C1 Application and Screening Procedures

(PR0501, PR0502)

C1.1 Following inquiry the IOAS forwards to the certification body an application pack which contains full details of the procedures of application. Potential applicants must assure they have consulted the documents referred to under A3 above.

C1.2 The applicant returns the completed application form and the required documentation together with the application and assessment fee. The applicant must provide its Quality Management System Manual, and any additional documents deemed essential to the assessment to the IOAS (see Appendix B of Annex 2 of the COO QMS for a complete list of documents to submit along with application) .

C1.3 The IOAS sends acknowledgement of receipt within five working days after reception of the application and proceeds with the assessment.

C1.4 The documentation is reviewed for completeness. Where documentation is manifestly incomplete the IOAS informs the applicant of the necessary additional documentation before further processing the application.

C1.5 The IOAS has the obligation to notify COO, of any certification body, located outside Canada, prior to proceeding with its accreditation under COR.

C1.6 Upon completion of the steps above, the IOAS is required to record in the COR's informatics' system of its intention to proceed with the analysis and the assessment. The applicant's name will be published on the CFIA web site.

C1.7 The IOAS screens the documentation against the Annex 3 of the COO QMS and prepares a screening report. This screening report is peer reviewed by another member of IOAS staff.

C1.8 A non-compliance report is prepared by the IOAS, which indicates any non-conformities and deficiencies with the standards and criteria and requests for further information where necessary. This is sent to the applicant programme requiring it, within a set time limit, to take the necessary actions to come into conformity with the requirements.

C1.9 Applicants may wish to seek review of specific conditions without officially appealing the overall decision. Such requests must include substantive reasons why the condition imposed is considered inappropriate or unjustified.

C1.10 Once the submitted information and standards or policy/procedure amendments have been accepted by the IOAS, to the effect that there are no outstanding non-conformities and the deficiencies have been reduced to a defined number, an evaluation visit is arranged.

C1.11 In order to complete its evaluation, the IOAS 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 IOAS under the condition that this report is about an on-site evaluation visit that took place within the last 12 months.

C2 Assessment of certification body performance

(PR0503, PR0504)

C2.1 The evaluation visit is assigned to an approved evaluator. Evaluators must not have, or have had during the past five years, any interest in the organisation to be evaluated. A certification body shall not be evaluated by the same person for more than two consecutive evaluations.

C2.2 The certification body may challenge the appropriateness of an assigned evaluator.

C2.3 The evaluator is briefed and provided with the screening report and any necessary documentation.

C2.4 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:

- An obligatory visit to the main office, then
- The two offices handling most of the Certification Body's clients, or
- The two offices carrying out the most important tasks concerning the certification process.

C2.5 The IOAS sends 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.

C2.6 The evaluation visit is made up of the following stages:

- Initial meeting with officers of the applicant body at the central office
- Interviews with managers and employees
- A detailed inspection of the certification office files in line with requirements of the COR.
- Physical review audits of operators
- Post audit (review audit) operator inspections according to the requirements of the COR
- At least one witness audit

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- Exit interview held in the central office with opportunity for questions

C2.7 The evaluator requires access to all previous inspection documentation and may request an inspector or officer of the certification body to accompany him/her on the review audits.

C2.8 The evaluator(s) will check, among other things, that:

- all documentation is complete and up to date and that there are no forms, inspection reports, or certification decisions missing;
- the inspection reports are comprehensive and enable sound certification decisions to be taken on the basis of the information provided;
- the certification decisions are consistent with the degree of compliance recorded in the inspection reports;
- where conditions or requirements for corrective action have been imposed on the operators by the certification body, that their implementation has been adequately monitored and documented;
- where relevant verification of Export Certification at CB level.
- the body is operating in accordance with the COR;
- in the case of re-evaluations, conditions of accreditation have been fulfilled;
- in the case of operator audits, that the practices of the operators conform to the standards of the certification body and that the inspection files accurately record the production system.
- Where certification bodies operate in countries outside of their home territory, the evaluation will normally include office and/or operator visits in a sample of the countries concerned.

C2.9 The evaluator will record the findings of the visit in the evaluation report. The evaluation report follows a set format and includes the findings of the office file checks and the operator visits.

C2.10 The IOAS submits a draft evaluation report to the applicant body. 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.

C2.11 When the report is finalised, if no major problems are uncovered, the IOAS will send a final copy to the evaluated applicant body. The report may be referred to the Accreditation Management Committee and subsequently to the Accreditation Committee where serious deficiencies are uncovered.

C2.12 Following the visit, the IOAS identifies any additional non-conformities and deficiencies resulting from the visit. The applicant body is informed of these and is allowed a time period for taking the necessary corrective actions.

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C2.13 The IOAS Accreditation Committee (AC) reviews the file at critical points in the process. The AC may determine that the applicant body's functional performance has been revealed by the evaluation visit to be inadequate and terminate the evaluation process. Alternatively, the AC may withhold accreditation pending the outcome of an additional visit to verify the effective implementation of corrective actions related to the functional performance of the certification body.

C2.14 Failure to meet the deadlines for the required corrective actions specified in C1.5 or in C2.12 may result in the IOAS recommending to the COO the termination of the evaluation process.

C2.15 The COO Lead Auditor may accompany the IOAS assessor team to observe the accreditation process for CBs

C3 IOAS recommendation for Accreditation

(PR0506, PR0511)

C3.1 Under the COR, it is the role of the IOAS to submit a recommendation report to the COO. The options are:

- accreditation granted or renewed,
- accreditation with programme amendment requirements,
- accreditation refused.

C3.2 The IOAS will only submit a recommendation for accreditation if:

- All identified non-conformities have been adequately addressed by the applicant body.
- Identified deficiencies have been reduced to a specified number.
- The certification body has agreed to take the necessary corrective actions regarding the remaining deficiencies within a set time period not to exceed 2 years.
- The IOAS is satisfied that the functional operation of the certification body is effective.

C3.3 When the IOAS accreditation committee is satisfied that the applicant body meets the requirements, a recommendation for accreditation status will be sent to the COO.

C4 CFIA grants accreditation

(PR0506, PR0511)

C4.1 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 the accreditation programme.
- 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.

C4.2 Deficiencies remaining to be rectified following accreditation are included in the accreditation contract as conditions of accreditation together with the deadlines for associated corrective actions.

C4.3 Once the applicant body has agreed to the conditions imposed and the timetable for compliance, it is sent an accreditation contract binding which commits them to comply with the requirements submitted. Under the COR the accreditation granted by the IOAS is valid for a period of one year, beginning on the date the accreditation agreement is signed. The accreditation contract must be signed and returned with the annual fee. The contract permits the body to use its accreditation status subject to the terms stated in the contract.

C4.4 Once the contract has been signed, the IOAS issues a Certificate of Accreditation. Among other details, the certificate identifies the scope of accreditation including the activities and programmes of the certification body that are, and are not, covered by the accreditation.

C4.5 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.

C4.7 The certification program shall only be accredited for product classes covered by the *Organic Products Regulations*.

C4.8 The accredited Certification Bodies must automatically and unconditionally accept the certification decisions made by any other accredited certifier under the COR.

C5 Surveillance

(PR0508)

C5.1 The IOAS is responsible for monitoring the compliance of accredited certification bodies on an ongoing basis. Certification bodies are required to submit an annual update report and to undergo short surveillance visits to a specified schedule. After initial accreditation the certification body will normally receive surveillance visits in year 1 and year 3 of their first 4 year contract. In subsequent contract periods, the certification body will normally receive one surveillance visit in year 2 of the contract period. This surveillance model depends on continued good performance of the certification body, the details of which are available in document PR0508.

C5.2 At any time, and upon its own initiative, the IOAS may carry out a supervision visit for any major non-conformance with the Canada Organic Regime. The IOAS may conduct unscheduled assessments as a result of valid complaints or changes that have affected corporate structure and directors, the administrative structure, etc.

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C5.3 Detailed instructions for both the report and the visit are sent to accredited certifiers in advance.

C5.4 The purpose of the update report is to enable the IOAS to monitor the general changes undergone by the certification body over the previous year. Under the accreditation contract, substantial changes which may effect the accreditation status of the certification body are required to be reported at the time they are being made. In addition the COO requires

- An update of documents required to obtain accreditation and included on the list the Accreditation Advisory Body transmits to Certification Bodies each year,
- 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 certification system,
- 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),
- List of all appeals filed pertaining to certification decisions handed down by the organization and regarding products that originated from Canadian operators,
- Copy of the files containing complaints against the organization and complaints about operators certified to do interprovincial or international trade,
- 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.

C5.5 The Certification Body's annual audit report must be signed by authorized personnel.

C5.6 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.

C5.7 Surveillance visits are conducted following review of the update report. At the surveillance visits the IOAS will:

- examine any additional material related to the update report;
- review the evidence related to compliance with contract conditions. The evaluator will give the accredited certification body an assessment of whether the condition has been adequately fulfilled and, if not, explain the deficiency and what is expected;
- review both general files and operator files. Particular attention will be paid to whether the accredited certification body has effectively implemented conditions that have previously been considered fulfilled;
- as deemed necessary the surveillance visit may include a witness audit of a scheduled inspection.

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- conduct an exit interview during which the evaluator will inform the accredited certification body of any findings;
- complete a report of the visit and its conclusions and send a copy to the accredited certification body.

C5.8 The Accreditation Committee shall review the results of the surveillance visit. The certification body is informed of the outcome and of any additional conditions of accreditation.

C5.9 If the certification body has failed to meet the deadlines for contractual conditions or where the visit reveals that the certification body has failed to effectively implement the corrective actions related to conditions that have previously been considered fulfilled, the IOAS may impose sanctions.

C5.10 Failure to meet any of the terms of the accreditation contract may result in the suspension or withdrawal of the accreditation contract or in the imposition of other sanctions in accordance with the IOAS policies and procedures. The action taken will be in accordance with the severity of the infringement.

C5.11 The COO may conduct unscheduled assessments of CBs as a result of valid complaints or changes that have affected the CBs.

C6 Re-Evaluations

(PR0510)

C6.1 The COR requires regular review evaluations at least every fifth year. Certification bodies accredited under IOAS programmes will work on a 4 year cycle. Procedures for the review evaluation are similar to those of the initial evaluation and include resubmission of all required documentation and a full evaluation visit.

C7 Timeframe for the accreditation process

C7.1 The time period from receipt of an application by the IOAS to signing an accreditation contract will vary depending on the initial level of non-compliance of the certification body and the intensity of work done to rectify nonconformities. The time period can be expected to be 9 to 12 months.

C8 Fees

(LS0503, PL0312)

C8.1 The IOAS is a not for profit company and the Accreditation under the Canadian Organic Regime is run on a non profit basis. Charges are set to cover the operating and continued development costs of the programme. A current fee schedule is available from IOAS offices and www.ioas.org/fees.htm

C9 IOAS records

The IOAS maintains and provides to COO upon request the following:

- Number of applications,
- Number of acknowledgement of receipt sent within five (5) working days;

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- Number of planned audits,
- Number of audits completed,
- Number of accredited applicants,
- Number of nonconformities
- Number of complaints/appeals on the evaluation process.

Section D: Rights and Responsibilities

The rights and duties of accredited bodies are documented in the Contract for Accreditation under the Canada Organic Regime, document number PL 0502-can, a sample of which is sent out as part of the application pack and is available from IOAS offices and from www.ioas.org/cancon.htm

D1 Accreditation Contract Period

(PL0518)

D1.1 The accreditation cycle is 5 years following which re-evaluation must take place. Certification bodies additionally accredited under IOAS programmes other than the COR will work on a 4 year cycle. Accreditation is a continuous status, subject to the certification body's compliance with the relevant Norms, as well as the terms of the contract including any specific conditions set by the IOAS. IOAS retains the right to recommend to the COO the withdrawal of the accreditation contract in the event that the accredited body does not fulfill its obligations.

D2 Use of Accreditation Status

(PL0503)

D2.1 The accreditation contract includes the following provisions regarding the use of the accreditation status:

- Accredited programmes may refer to their accredited status in writing, either on letterheads or in written documents and reports and other information related to the programme. The IOAS has formulated detailed instructions for such use.
- Reference to IOAS accreditation under the COR may only be made in conjunction with the categories for which accreditation applies, as stated in the contract.
- The right to the use of accreditation designation is not transferable.
- 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. See section 2.12 of the COO QMS.
- Unless the certification body is also accredited against IFOAM Norms, no use or reference to IFOAM accreditation or the IFOAM logo may be made in promotional materials or by its operators.

D3 Notification of Changes and Extension of Certification Scope

(PR0512)

D3.1 Accredited certification bodies are required to inform the IOAS of any changes which may impact their accreditation and of any changes which effect the scope of their accreditation as stated on the accreditation certificate.

D3.2 Where the certification body is introducing a category of certification not previously included in its accreditation scope (see B1.2), a request for extension of scope must be filed with the IOAS. Appropriate standards of production and evidence of competence in this field must be submitted to IOAS for screening and evaluation. Any corrective actions must be taken before the commencement of the first certification decision.

D3.3 The Certification Body must state the objectives and the reasons associated with the request for an extension of scope.

D3.4 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.

D4 Appeals, Complaints and Sanctions

D4.1 Appeals

(PL0504)

Accreditation decisions of the IOAS may be appealed by the CB. Appeals must be directed to the IOAS and lodged within 30 days of notification of the disputed decision.

D4.2 Initial appeals are considered by the Accreditation Committee but may be further appealed to the Appeals Committee of the IOAS. The Appeals Committee is a 3 person committee established by the President of the IOAS on an ad hoc basis. The decision of the Appeals Committee will be sent to the appellant.

D4.3 In addition, certification bodies may request a hearing on decisions made by COO or the IOAS impacting their operations. Where appropriate the appeal flows from operator to CB to AB. The COO is the final level of appeal. Requests must follow the conditions outlined below:

- Any request must be submitted, in writing, to the manager of the COO within 30 days of the original accreditation (or revocation of accreditation) recommendation/decision;
- The original accreditation (or revocation of accreditation) recommendation/decision must not have been the subject of a previous hearing.
- 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.
- If the COO rejects a hearing, it shall inform the applicant of its decision.
- 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.
- The decision of the manager shall be sent in writing to the appellant within 5 working days after the end of the hearing.
- The decision of the national Manager of the COO is final in all hearings.

D4.4 Complaints

(PL0511)

The IOAS has formulated a detailed complaints policy which is available to interested parties on request and at www.ioas.org/complain.htm

D4.5 Complaints against IOAS

Complaints concerning the functioning of the IOAS Accreditation Programme under the COR and its personnel should be addressed in writing to the IOAS office. Complainants will be informed of the decision.

D4.6 Complaints regarding accredited programmes

Under the COR 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.

D4.7 As part of the above process the IOAS will investigate the complaint. Where the IOAS considers the complaint to be sufficiently substantiated, it will inform the body concerned and invite a response. The matter will then be referred to the IOAS Board to formulate a complaint resolution. The complainant is informed of the complaint resolution. If the complaint is upheld, the IOAS may impose appropriate sanctions against the CB.

D4.8 Sanctions

(PL0505)

In event of non-compliance with the accreditation contract, failure to fulfill conditions or gross breaches of the requirements of the accreditation criteria and basic standards, the IOAS may apply one or more of the following sanctions:

- issue a warning letter or letter of reprimand;
- impose additional conditions and insist on corrective action according to a timetable;
- require the certification body to undergo a re-evaluation within a certain period;
- recommend to the COO suspension of accreditation;
- recommend to the COO withdrawal of accreditation.

D4.9 The IOAS has procedures for identification and management of nonconformities.

D4.10 The IOAS communicates 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 IOAS to begin the analysis of the application.
- Accreditation requirements of Annex 2 not met:
 - The IOAS shall communicate to the applicant the list of deviations,
 - The IOAS 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 IOAS recommendations.
- Suspension or cancellation of accreditation:

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- The IOAS 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.

D4.11 Only the COO can revoke the accreditation number of the certification body.

ANNEX 1: Addresses

IOAS Administrative Office

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Contact: Ken Commins

National Institute of Standards & Technology

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USA

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Web: www.nist.gov

Canada Organic Office

Canada Food Inspection Agency
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Ottawa, ON

Web: www.inspection.gc.ca