



United States
Department of
Agriculture

Agricultural
Marketing
Service

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USDA/AMS PEER REVIEW REPORT [Final: August 15, 2011]

**ORGANIC EQUIVALENCE ARRANGEMENT
BETWEEN THE UNITED STATES AND CANADA**

DATES OF REVIEW – SEPTEMBER 23-30, 2010

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1. INTRODUCTION AND BACKGROUND

In June 2009, the governments of the United States and Canada exchanged letters agreeing to a determination of equivalence of organic standards between the two countries. These letters provided for products produced under one country's organic standards to be accepted for sale as organic in the other country. Exceptions or "critical variances" to the agreement were noted in attachments to the letters.

The two countries agreed to establish a working group of technical experts from each country to work out details of the implementation of the arrangement. One of the first tasks of the working group was to establish a peer review process to provide confidence to industry stakeholders that the arrangement was being fairly enforced. The working group determined that after approximately one year of operation, each country would conduct a peer review of the other country to evaluate the effectiveness of the arrangement. After the first round of reviews, the countries would alternate years for conducting subsequent onsite reviews. The initial review, described in this report, was the first of the reviews scheduled as recommended by the working group.

At a December 1-2, 2009 meeting, the US and Canadian officials agreed to conduct assessments of each respective program in 2010. The following references would be used in developing the assessment procedures:

- ISO 17040 – Conformity assessment general requirements for peer assessment bodies

and accreditation bodies.

- ISO/IEC Guide 68:2002 – Arrangements for the recognition and acceptance of conformity assessment results.
- National Organic Program (NOP) procedures for assessment of foreign recognition agreements.

At the time of the review, the United States and Canada were continuing to meet to clarify certain aspects of the arrangement. There was an expectation that information gathered during the peer review process would continue to inform the ongoing discussions and facilitate efforts to clarify functional aspects of the arrangement.

2. OBJECTIVES OF REVIEW

The United States' objective in conducting the review was to observe the Canadian organic program in operation within the context of the US-Canada Organic Equivalence Arrangement. Although teams from both countries had explored and compared virtually every aspect of the written standards, because the Canadian organic standards had not entered into effect at the time of the agreement, there had been no onsite review conducted in Canada to assess the level of implementation and rigor of controls related to the new regulations. By conducting the review, the United States expected to:

- Gain a better understanding of the structure and functions of the Canadian program.
- Assess the method and rigor of controls associated with the overall program, but particularly with regard to the controls associated with the critical variances on both sides.
- Evaluate the regulatory authority and capacity of Canadian authorities to investigate complaints against products produced under the Canadian Organic Regulations (COR) and sold in the United States as organic.
- Obtain specific information needed to inform further discussions between the two countries.

3. LEGAL BASIS FOR THE REVIEW

The peer review was conducted by mutual agreement between the US and Canadian

Government competent authorities. As prescribed in Appendix 2, paragraph 2 of the letter from the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS) to the Canadian Food Inspection Agency (CFIA), following advance notice from USDA, the CFIA shall permit USDA to conduct on-site evaluations in Canada to verify that the CFIA's certifying agents are carrying out the requirements of Canada's organic certification program, including through visits to agent facilities and to production facilities and farms that agents have certified. CFIA shall cooperate and assist USDA, to the extent permitted under domestic law, in carrying out such evaluations.

4. REVIEW ACTIVITIES

The peer review included onsite visits to the:

- CFIA, Canada Organic Office (COO), Ottawa, ON
- Standards Council of Canada (SCC), Ottawa, ON
- Main Office and organic operations certified by OCCP/Pro-Cert, Saskatoon, SK
- Organic operations certified by OCCP/Pro-Cert, Alfred/ St. Eugene, ON
- Certified Organic Associations of British Columbia (COABC), Vernon, BC
- Main Office and organic operations certified by the Pacific Agricultural Certification Services (PACS), Vernon, BC

Prior to the onsite portion of the review, the NOP requested and the COO provided copies of the most current version of the COO Operating Manual and Quality Manual.

The review team was accompanied by a COO representative through each step of the review. At each of the certified organic operations visited, the team was accompanied by at least one representative of the respective certifying body (CB). Any issues of concern or perceived noncompliances were immediately brought to the attention of the accompanying official or representative.

September 23, 2010 – CFIA Offices in Ottawa, ON

The US team began the peer review with an opening meeting at the CFIA offices in Ottawa, ON, on the morning of September 23, 2010. The US team was provided with a

detailed overview of the COO functions and interviewed members of the COO staff.

Standards Council of Canada. The review continued in the afternoon with a visit to the Standards Council of Canada (SCC). The SCC is the Canadian equivalent of the American National Standards Institute (ANSI) in the US, serving as Canada's representative to the International Organization for Standardization (ISO). SCC is a recognized conformity verification body (CVB) under the COR and at the time of the review and had recommended 3 certifying bodies for accreditation under the COR. It is noted that CVBs are not considered *accreditation bodies* because they only *recommend* bodies for accreditation; actual accreditation decisions are made by the COO. SCC performs accreditation functions under a number of industry sectors, with organic agriculture accreditation being only a small part of its overall program. SCC has permanent staff assigned to manage the organic accreditation services and uses industry technical experts as part of the accreditation review team. The AMS team requested and reviewed qualification and conflict of interest statements for personnel associated with the SCC organic services. The AMS team met with and interviewed the SCC's organic program manager and observed files for CBs scheduled to be visited later in the review.

All CVBs receive an annual onsite inspection from the COO. The AMS team was provided with and reviewed a copy of the COO's most recent inspection report of the SCC.

September 24, 2010 – Ottawa, ON

The AMS team continued its review of the COO with interviews of staff and review of files for accreditation and training activities. The review team evaluated each phase of the Canadian standards and conformity assessment system to determine if the competent authority had the necessary controls in place to ensure traceability and compliance with the COR and the terms of the US-Canadian organic equivalence arrangement.

The COO officials provided a detailed explanation of the COO processes for conducting investigations of fraud and noncompliances under the new program. The AMS team was interested in details and regulatory authority for COO officials to conduct direct reviews of certified operations that may be in noncompliance with the COR or the terms of the equivalence arrangement. The COO provided additional regulatory references regarding the

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overall authority of the CFIA to gain access to operations regulated by CFIA programs. The AMS team examined processes used to evaluate the competence of the CVBs. The team requested and reviewed files of evaluation of CVBs, including witness audits conducted as a part of the approval process.

Saturday, September 25, 2010 – Ottawa/Gatineau area

The team visited a small organic dairy operation located in Alfred, ON, and a small organic dairy/processing operation near St. Eugene, ON.

Monday, September 27, 2010 – Saskatoon, SK

The team met with officials from OCCP/Pro-Cert, one of the larger organic certifying bodies in Canada. OCCP/Pro-Cert is accredited by the SCC and the National Organic Program. The team interviewed CB personnel to determine their ability to provide organic certification services, their knowledge of the terms of the US-Canadian arrangement and their qualifications with respect to their duties and responsibilities. The team also cross-checked documents reviewed at the Alfred and St. Eugene operations to discuss observations from those farms and compared information reviewed at SCC with regard to their accreditation.

In the afternoon, the team visited an organic oilseed processing facility in Saskatoon, SK. The facility was certified organic by OCCP/Pro-Cert.

Tuesday, September 28, 2010 – Saskatoon, SK

In the morning, the team visited an organic farm certified by OCCP/Pro-Cert southeast of Saskatoon, SK. The team reviewed storage and production areas and production plans and records provided by the farmer.

On Tuesday afternoon, the team held an interim conference with the COO representative to discuss observations up to that time.

Wednesday, September 29, 2010 – Vernon, BC

The team met with officials from the Certified Organic Associations of British Columbia (COABC), Vernon, BC. COABC is recognized to accredit CBs to certify to the COR. COABC is also one of three organizations in Canada recognized as an accrediting body by the NOP. The team discussed accreditation processes and reviewed documents related to the

accreditation of the Pacific Agricultural Certification Society (PACS), which is accredited to certify to the COR by COABC.

On Wednesday afternoon, the team met with officials from PACS, also in Vernon, BC. PACS officials described their experiences as a COABC-accredited CB and provided organic system plans and reports for operations to be observed later in the review. The team interviewed PACS staff present at the meeting to determine their knowledge and understanding of the terms of the US-Canadian arrangement.

Thursday, September 30, 2010

On Thursday morning, the team visited a mid-sized organic dairy farm certified by PACS near Salmon Arm, BC. The team reviewed operations on the farm and the organic production plans and records which were readily available onsite.

5. CLOSING MEETING

The review team conducted a closing meeting with USDA and CFIA officials by way of a telephone conference call from Vernon, British Columbia on the afternoon of September 30, 2010. At the meeting, the NOP review team provided a complete summary and discussion of all observations from the review.

6. SUMMARY OF PREVIOUS REVIEWS

This was the first peer review of the US-Canadian Organic Equivalence Arrangement. There were no previous onsite review findings to consider for follow-up actions.

7. OBSERVATIONS

Stream of Commerce Policy. The Canadian program provided for a two-year stream of commerce policy to allow time for producers to come into compliance with the new regulations. At the time of the review, the Canadian organic program was approximately 15 months into this “soft enforcement” period. All products sold as organic in Canada after June 30, 2011, must be in full compliance with the COR or certified under an established equivalence arrangement. Throughout the review, COO representatives clarified that the regulations are in effect and that certifiers and certified operation are required to comply with the regulations. However, actions taken when noncompliances are detected are designed to be

educational in nature.¹ Certified operations are expected to correct noncompliances when they are identified by CBs.

Document Control and Records Management. While most of the focus of the AMS team was dedicated to technical implementation and enforcement of critical variances, some attention was paid to quality management within the COO program. During the review, there were no overt system-based deficiencies identified. COO officials were consistently able to demonstrate excellent document control and records management practices. Documented processes were closely followed and records demonstrating the basis for recognition decisions fully supported such decisions. When COO lead auditors were asked to provide records from a particular review or training event, the responsible person was quickly able to retrieve all documents requested.

Communicating Requirements to CVBs and CBs. Throughout the review, CVB and CB representatives interviewed commented that the COO was very good at communicating program requirements and updates to organizations and persons responsible for implementing the program in the field. The COO holds regular meetings and trainings with CVBs and CBs.

Stocking Rate Enforcement . The stream of commerce policy was apparent when interviewing certifiers regarding stocking rate enforcement. One certifier stated that if there was a noncompliance with the COR stocking rate requirements during an onsite inspection, the CB would not propose suspension or revocation of the operation. Rather, it would be identified as a noncompliance and the operator would be allowed to continue to sell products as organic.²

¹ Canada Comment: The Stream of Commerce Policy was established on June 30, 2009, as strategy for managing the transition from a voluntary organic certification system to a mandatory certification system. The Policy came into effect on June 30, 2009 and is expected to be revoked on June 30, 2011. Please note that when the Organic Products Regulation came into force, all organic products produced after the coming into force had to be certified in accordance to the Canadian Organic Standards by a CFIA accredited Certification Body, unless the products were imported from a country with which the CFIA had entered into an import/export arrangement with and were certified according to the conditions of the arrangement. During the period of the Stream of Commerce Policy organic products must comply with the Regulatory requirements, operators must be advised of the issues of non-compliance and enforcement based on what is outlined in the Policy. This Policy is not a transition period, as some people interpret it; it is an enforcement strategy. Please be advised that a CFIA accredited Certifying Body using this as an excuse could be subject to the suspension and cancellation of its accreditation.

² Canada Comment: Again, please be advised that a Certification Body using the Stream of Commerce Policy as an excuse for not following up on noncompliant products is not acceptable in Canada. Point of Clarification: Canada highlights that this is a scenario-based question not an actual incident. Section 20 (1) and (2) from the

Supply Management System. The marketing of dairy, poultry and egg products in Canada is subject to the supply management system. The system is designed to match domestic production to domestic requirements, while ensuring a reasonable return to producers and stable prices to consumers. Organic products are included under these controls. Very little organic milk or processed organic poultry or egg products are traded between the US and Canada.

Control of Milk Produced with Antibiotics. While the COR only allows the use of antibiotics as a treatment of last resort for organic livestock producers, it is not uncommon for dairy animals to be treated with antibiotics at some point in their lives. The most common uses of antibiotics on organic operations as stated by producers interviewed was for pneumonia and foot rot, but treatment with antibiotics is standard for livestock that have some sort of surgical procedure such as a Caesarian section.

Dairies observed during the review had only a single stream for handling milk; persons interviewed stated that there was no practical method for segregating the milk from cows that had been treated with antibiotics at some point in their lifetime from milk from cows which had never been treated with antibiotics. Absent the ability to segregate milk in compliance with the critical variance for the NOP regarding non-treatment of livestock with antibiotics, the dairy farm would essentially have to be antibiotic-free or cull any cow treated with antibiotics at any point in her life in order to be eligible to ship milk products to the United States.³

Organic Products Regulations (OPR) outlines the steps that are taken in cases of suspension or cancellation of organic certification. All the CFIA accredited CBs are required to comply with the OPR. To ensure that the CBs understand and correctly apply section 20 (1) and (2), the Canada Organic Office has prepared training for CFIA accredited Certification Bodies covering issues of non-compliance and actions required. The COO will have held four (4) training sessions for Certification Bodies by the end of March 2011. In addition, the Canada Organic Office will continue to educate Certification Bodies on the procedures on how to deal with non-compliance with the COR.

³ Canada Comment: As mentioned, the dairies observed during the review had only a single stream of handling of milk. In preparation for the peer review, Canada attempted to find shippers of milk to the US: however, it was not possible to visit these producers. It was communicated to the review team that the only shippers of milk and milk products at the time of the US visit were located in Quebec. These shippers had been accredited under the US National Organic Program for several years and had established a separate stream for segregating the milk that is shipped to the US. The heifers/cows that are treated with antibiotics in Canadian organic operations would not be able to supply milk to the US. In fact, these Quebec milk producers have been excluding antibiotic use for some time. Canada agrees to draft a paper for discussion at the next Technical Working Group meeting.

Certification to the NOP. One certifying agent interviewed stated that certifying agents in Canada are still certifying Canadian operations to the NOP standards.⁴ These certifiers are directly accredited by the NOP as well as the COR so that they may certify US organic operations to the NOP. During the review, the certifier explained that NOP certification is still requested by some US clients due to uncertainty surrounding the organic equivalence arrangement. Even though the arrangement clearly states that products produced to the Canadian standards may be sold as organic in the US, Canadian certifiers interviewed stated that it would be helpful if the NOP would issue a statement to the effect that certification of Canadian products to the NOP is no longer necessary and should be discontinued. Persons interviewed said that a statement from the US side to the effect that Canadian products certified to the COR are guaranteed to be accepted as organic in the US would help reduce or eliminate requests for NOP certification in Canada.

Ability to Directly Investigate Complaints. The NOP, through its Compliance and Enforcement Division, has dedicated significant resources to investigate complaints regarding the integrity of products certified to the NOP regulations throughout the world. During the review, the AMS team dedicated a significant portion of the time allowed to determine whether the COO had similar investigative enforcement resources and capabilities.

Initial review of the COO operations manual did not reveal clear regulatory authority for direct onsite investigative inspections of organic producers and handlers by Canadian Government officials; investigative responsibilities were delegated through the CVBs and on to the CBs. When asked how the COO would investigate situations where it is suspected that the CB is possibly involved in fraudulent activities of the certified operation, the COO responded that they would investigate the violation directly. While the COO was able to identify CFIA regulatory policies that provide for broad access to certified operations to investigate violations, such broad authority and investigative processes were not clarified in

The paper will clearly describe what the US NOP does and what the COR does to restrict the use of antibiotics in calves, replacement heifers, and cows in the production of organic milk and, in the case of Quebec shippers, how they exclude antibiotics.

⁴ Canada Comment: At the October 2011 US-Canada Steering Committee meeting the Technical Working Group was to further discuss this issue so that further clarity can be provided. There is a lot of confusion in Canada around this and Canada needs to clarify this issue. It is essential that a communication plan be developed to address/eliminate confusion.

functional documents at the COO level.⁵ Currently, Part C Certification of Organic Product and CB Requirements paragraph C.2.9.2 of the COO Operating Manual most closely addresses this authority by saying: “The CB shall comply with any requests from the Canada Organic Office or the CVB that additional inspection be conducted by the CB when the compliance of the operation is in doubt or for other valid reasons.”

CFIA Cooperative Enforcement. The CFIA has a broad-based enforcement team consisting of cross-utilized CFIA inspectors. CFIA is well on its way toward networking its 14 commodity programs to provide front line enforcement of the organic labeling requirements. Some personnel in all program areas have already been trained to some degree. The team reviewed documented procedures showing that processes had already been incorporated into Program – level procedures for various processed commodities. Some overlapping responsibilities were noted which may add depth to the CFIA organic enforcement program.

Differences in Points of Enforcement. During the review, the AMS team identified a possible disparity between government regulatory oversight for products produced under the Terms of the Arrangement due to differences in the methods of enforcement in the US and Canada. NOP standards are process-based, with the principal level of enforcement occurring on the farm or at the processing (handling) facilities. Products certified to the NOP in the US and sold as organic in Canada are subject to regulatory enforcement activities twice; once during production or handling in the US and again via CFIA product-based enforcement at the border when entering Canada.⁶

⁵ Canada Comment: COO’s Operating Manual and COO’s Quality Manual outlines procedures for handling complaints against CVBs, CBs, Suppliers, Consumer and Trade complaints. Section 9 of the COO Quality Manual outlines the policy and the procedure in place to deal with complaints. Consumer and trade complaints regarding organic product claims are to be reported to the CFIA. CFIA inspection staff responds to organic claim complaints following the procedures established in their office or that has been developed by each DFIA commodity Inspection Program. Complaints concerning the validity of the organic certification or compliance of a product to the CAN/CGSB32.310 and CAN/CGSB 32.311 are directed to the COO and are forwarded by the CVB to the CB that certifies the products together with all supporting evidence. ISO Guide 65 requires that the CB as procedures to deal with complaints. The COO may at any time during the CB investigation request update on the complaint directly from the CB or through the CVB.

⁶ Canada Comment: In Canada, consumers want assurances that the products that claim to be organic are and that these products comply with the same principles, standards and controls set out in the Organic Products Regulations and referenced standards. The CFIA ensures that the certification activities are delivered in a uniform and consistent way and that all organic products are subject to the same monitoring and enforcement actions.

Conversely, with Canadian product-based certification, CFIA ensures compliance by reviewing products in stores and by inspecting imported finished products at the border. Canadian products sold as organic in the US are not normally subject to CFIA oversight at the production/handling level in the same way US products are and are not subject to in-store oversight in the US due to different enforcement strategies between the two countries.

Given the different regulatory oversight strategies taken by the two countries, products exported from Canada to the US under the US-Canadian agreement would not be subject to direct, regulatory oversight. However, products exported from the US to Canada would be subject to regulatory oversight twice: once at the time of production and again upon arrival in Canada.

Control of Canadian Organic Mark. The COR requires that persons applying the Canadian organic seal must have advance written approval. COO representatives explained that while the approval step may create a burden at some point, the controls in place have been effective in preventing misuse.

Availability of Organic Systems Plans. With the exception of two farms visited on Saturday, the farms and handling operations visited during the review had current copies of their organic production or handling plans available for review by the AMS team.⁷

8. CONCLUSIONS AND RECOMMENDATIONS

- a. In general, the AMS team found objective evidence that the COO was competent as a regulatory control body in support of the terms of the US-Canadian organic equivalence arrangement.
- b. While the COO was able to identify general authorities to access operations certified under

To support the CFIA's monitoring and enforcement activities relating to organic claims, all CFIA inspection programs have integrated organic label verification within their operation and inspection activities. In addition, over 350 CFIA inspectors have successfully followed and completed the Organic Label Review Training. These CFIA inspectors verify organic labels and take appropriate enforcement actions when required. This issue should be discussed at our next working group meeting.

⁷ Canada Comment: This is a requirement of the operators and was emphasized at the recent COO CB training sessions.

the COO, the AMS team was not able to identify clear program-level authority and procedures for conducting direct investigations of complaints against organic producers and handlers. The AMS team recommends clarifying the authority and procedures of the COO to conduct direct, unannounced onsite reviews of organic operations during normal business hours in order to investigate complaints and ensure compliance with the COR. Such authority should extend to anywhere products are produced to the COR for export to the US under the Terms of the Arrangement.⁸

⁸ Canada Comment: One of the three (3) objectives of Canada's Organic Products Regulations was to protect against fraudulent and misleading organic claims. This is accomplished in two ways: by active involvement of CFIA inspectors and by efficient oversight of the accreditation and certification activities of organic products in Canada, or organic products destined for Canadian markets. The COO is the CFIA primary contact regarding organic claims requirements. Communication between the COO and CFIA operations (inspectors) is ongoing. In 2011, the COO will be giving additional training sessions for inspectors across Canada.

In general terms, CFIA has developed a comprehensive enforcement policy and strategy to support its integrated inspection system (which includes CFIA inspectors taking the appropriate enforcement actions when required on organic products). The policy establishes uniform policies and procedures for monitoring compliance, carrying out inspections and conducting investigations.

The authority to conduct these types of investigations is pursuant to section 11 of the Canadian Food Inspection Agency Act. CFIA is also responsible for the administration and enforcement of the Agriculture and 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 Labeling Act as it relates to food.

As mentioned earlier, the Canada Organic Office is the primary contact regarding organic and organic complaints originating inside the CFIA or outside the CFIA. It is responsible for receiving all complaints and determines how these complaints are investigated.

Inside the CFIA, CFIA inspectors will conduct regulatory inspection activities to assess industry compliance with the Organic products Regulations, in accordance with the established policies and procedures. With respect to organic products, these activities include:

An example of a CFIA product inspection activity is: the inspection of organic fresh fruits and vegetables for grade/condition requirements. During these inspections, the inspector verifies whether the fresh fruit and vegetable meets the organic requirements: the CFIA inspectors ask the operator to see the organic certification/paperwork in the case of an imported product a copy of documents (attestation statement) and finally the inspector examines the labels to identify the name of the certification body. The CFIA inspector then verifies that the certification body is listed in the COO's list of accredited certification bodies under the Canadian Organic Regime. A list of CBs is made available to the CFIA inspectors.

Corrective action is taken if problems are found. The CFIA inspector informs the operator and the COO of any deviations observed; the COO contacts the certification body which certified the product; depending on violation the product may be seized, detained, relabeled, destroyed or re-exported out of Canada. Corrective actions are taken in accordance with the enforcement policy guidelines of the CFIA.

- c. The working group should review the observations of this report to inform further discussions regarding the implementation of the US-Canadian Organic Equivalence Arrangement.

END OF REPORT

Examples of actions taken are: the label used fails to meet all of the organic labeling requirements; this could include actions such as information letters, notices of noncompliance, warnings(s) and detentions. Inspectors must follow the procedures outlined by the enforcement and compliance policy. Serious offenses are defined as a consistent deviation from the Organic Products Regulations or associated documented requirements such that the organic program integrity or compliance with the requirements is absent. An example of this would be that an operator does not demonstrate willingness to achieve compliance after being notified of a deviation by the CFIA. The enforcement actions that result from serious noncompliance are revocation of certification, prosecutions or depending on the commodity administrative penalties.

In response to the US's recommendation that Canada should clarify the authority and procedures of the COO to conduct direct, unannounced onsite reviews of organic operations during normal business hours in order to investigate complaints and ensure compliance with the COR. Such authority should extend to anywhere products are produced to the COR for export to the US under the Terms of the Agreement.

Canada's Response: Again the role of the CFIA inspectors is described in detail above. COO's Operating Manual and COO's Quality Manual outlines procedures for handling complaints against CVBs; CBs; Suppliers; Consumer and Trade complaints. Section 9 from the COO Quality Manual outlines the policy and the procedure in place to deal with complaints.

Complaints concerning the validity of the organic certification or compliance of a product to the CAN/CGSB 32.310 and CAN/CGSB 32.311 are directed to the COO and are forwarded by the CVB to the CB that certified the product together with all supporting evidence. ISO Guide 65 requires that the CB has procedures to deal with complaints. The COO may at any time during the CB investigation request update on the complaint directly from the CB or through the CVB.