USDA Agricultural Marketing Service

1400 Independence Avenue, S.W.
Room 2646-South, STOP 0268
Washington, DC 20250-0201

USDA REVIEW OF CANADA: U.S. – CANADA EQUIVALENCY AGREEMENT

DATES OF ONSITE REVIEW:

- Canada: October 23 – 27, 2017
- Thailand: May 7 – 12, 2018

REVIEW TEAM:

- Cheri Courtney, Director, Accreditation and International Activities Division, USDA-AMS NOP
- Robert Yang, Assistant Director, Accreditation and International Activities Division, USDA-AMS NOP

INTRODUCTION

On June 17, 2009, the U.S. Department of Agriculture (USDA), Agricultural Marketing Service (AMS) established an equivalency arrangement with Canada. The arrangement allows for agricultural products produced and handled in conformity with the Canadian Organic Products Regulations, subject to the terms of the arrangement (January 20, 2012 revision), to be sold, labeled or represented in the United States as organically produced, including by display of the USDA organic seal as well as the Canadian organic seal. On October 23 – 2017, 2017 and May 7 – 12, 2018 the USDA-AMS National Organic Program (NOP) conducted an onsite review of Canada's organic certification program in Canada and Thailand, respectively. This report is an account of those activities and observations of the review.

I. REVIEW OBJECTIVES

The objectives of the review were the following:

1. To verify that the Canadian Food Inspection Agency (CFIA), Conformity Verification Bodies, and accredited certification bodies are carrying out the requirements of the Organic Products Regulations (2009), including the Canadian Organic Standards.
2. To verify CFIA's, its Conformity Verification Bodies', and accredited certification

3. bodies' continuing adherence with the provisions of the U.S. – Canada Equivalency Arrangement.
4. To verify the implementation of actions taken by CFIA in response to USDA AMS-NOP's 2013 onsite peer review.

II. REVIEW SCOPE

The scope of the review included activities related to the following:

1. CFIA's assessment and oversight of its designated Conformity Verification Bodies
2. CFIA's accreditation and oversight of certification bodies accredited under the Canada Organic Regime (COR)
3. The Conformity Verification Bodies' accreditation and oversight of certification bodies accredited to ISO 17065
4. CFIA's investigation of, including enforcement actions taken against, violations of the terms of the U.S. – Canada Equivalency Arrangement by certified operations or certification bodies.
5. Certification and oversight of domestic and foreign operations certified under the COR, including operations verified to be meeting the terms of the U.S. – Canada Equivalency Arrangement.

III. LEGAL BASIS FOR THE REVIEW

The January 2009 U.S. – Canada Equivalency Arrangement (USCOEA) provides for representatives of USDA, following advance notice, to conduct onsite evaluations to verify whether CFIA's certifying agents are carrying out the requirements of Canada's organic certification program, including visits to agent facilities and to product facilities and farms that agents have certified. On August 22, 2017, AMS-NOP informed CFIA of its intent to conduct onsite reviews of Canada's organic certification program both in and outside of Canada as part of the ongoing requirements of the USCOEA. Equivalency arrangements are provided for pursuant to USDA organic regulations at 7 CFR 205.500(c)(1).

The following regulations, standards, and criteria were considered in the review:

- Provisions of the 2009 U.S. – Canada Equivalency Arrangement
- Organic Products Regulations (2009)
- Canadian Organic Standards
- ISO/IEC 17011:2004
- ISO/IEC 17065:2012
- USDA-AMS NOP 2013 Peer Review Report

PROTOCOL

The review was accomplished in five parts in Canada and Thailand: a review of CFIA's organic program known as the Canada Organic Regime (COR); a review of two CFIA-designated conformity verification bodies (CVB); a review of certification and oversight activities of two certification bodies (CB) accredited by CFIA under COR; an observation of a witness audit of a CVB witness audit conducted by a CFIA auditor; and observations of three witness audits conducted by the two CVBs. In selecting the CVBs, CBs, and organic operations for the witness audits, the AMS-NOP review team worked with CFIA staff to select both domestic and foreign CVBs, CBs, and organic operations certified under COR and verified to have met the terms of the U.S. – Canada Equivalency Arrangement.

At the CFIA head office in Ottawa, an opening meeting was conducted with CFIA representatives. The AMS-NOP review team reviewed all phases of CFIA's CVB designation and certification body accreditation processes, including CVB surveillance scheduling and procedures; process for managing complaints under the COR; import/export oversight measures; COR standards development, maintenance and interpretation; and chemical residue sampling and testing program. The review team also conducted a sample review of CVB assessment records maintained electronically by CFIA.

The AMS-NOP review team conducted the onsite review of one CVB at the CVB's office in Canada. The review of the second CVB, whose head office is located in the U.S., was conducted in Thailand with the CVB's representative. The CVB's records were maintained electronically and accessible remotely. The AMS-NOP review team reviewed each CVB's policies and process for monitoring and assessing certification bodies under the COR, including complaint/residue testing investigation and handling process; internal audit and management review policies and processes; and personnel training and evaluation policies. The review team conducted a sample review of CB assessment records maintained by each CVB.

The AMS-NOP review team conducted onsite reviews of two CBs at each CB's office, which were located in Canada and Thailand respectively. The review team reviewed each CB's policies and procedures for certification under the COR, including each CB's process for verifying an operation's compliance with the terms of the U.S. – Canada Equivalency Arrangement; complaint/residue testing investigation and handling process; internal audit and management review policies and processes; and personnel training and evaluation policies. The review team conducted a sample review of certification; complaint investigation; sample collection/residue testing; and staff training files. The review team also verified the CBs' implementation of the CFIA's response to AMS-NOP's 2013 onsite review observations.

In Canada, the AMS-NOP review team also observed a CFIA auditor conduct a witness audit of the Canadian CVB's witness audit of an annual inspection of a handling operation. The review team additionally observed the same CVB conduct a witness audit of an annual onsite inspection of a crops operation. In Thailand, the AMS-NOP review team observed the second CVB conduct witness audits of a handler/processor annual inspection and a crops grower group annual inspection.

The AMS-NOP review team was accompanied by representatives of CFIA throughout the audit in Canada. A closing meeting of the onsite audit in Canada was conducted with CFIA officials and the Canadian CVB representative at the CFIA office in Saskatoon on October 27, 2017. A closing meeting of the onsite audit in Thailand was conducted with CFIA officials via teleconference on June 6, 2018.

GENERAL OVERVIEW OF CFIA AND COR

The CFIA is the regulatory agency responsible for delivering Canada's federal food safety, animal health and plant health regulatory programs. CFIA administers the Organic Products Regulations, 2009 under the authority of the Canada Agricultural Products Act. The regulations require agricultural products to be certified to the Canadian Organic Standards (or to the terms of equivalency arrangements) if the products are represented as organic when imported into Canada, or interprovincially traded, or display the Canada organic logo. As of January 15, 2019, the Organic Product Regulations have been consolidated into the Safe Food for Canadians Regulations, which require any food, seed, or animal feed that is labelled organic to be regulated by CFIA and certified under the Canadian Organic Standards.

The COR is Canada's organic certification system, which is comprised of six elements: regulations; standards; administration (i.e. designation of CVBs); accreditation of certification bodies; certification of products; and monitoring and enforcement. Under the COR, agriculture products must comply with the Canadian Organic Standards (COS). The COS comprises of two documents – CAN/CGSB 32.310 Organic Production Systems, General Principle and Management Standards and CAN/CGSB 32.311 Organic Production Systems, Permitted Substances Lists. The standards are developed and reviewed by the Committee on Organic Agriculture, a volunteer committee of experts in organic agriculture who represent the public and private sector stakeholders. The development and review process is managed by the Canadian General Standards Board, a federal government organization that provides standards development services. The standards are updated every five years. The COS was last updated in 2015 and amended in March 2018.

The CFIA is the competent authority responsible for designating and auditing CVBs to assess and monitor certification bodies; accrediting CBs to certify organic products; and overseeing, monitoring, and enforcing the requirements of the COR. The Canada Organic Regime team is comprised of experts within the Food Import and Export Division of the Food Import/Export and Consumer Protection Directorate. The team is responsible for implementing the COR and the roles and responsibilities are clearly defined. The COR team that is part of the Food Import and Export Division is responsible for overseeing the implementation and the enforcement of the 3rd party delivery system, maintenance of the organic equivalency arrangements, complaints managements, the follow up on the chemical residues and the day to day work related to the maintenance of the COR. The COR team is comprised of one National Manager, one Lead Auditor, one Policy and Programs Specialist, one Policy and Program Analyst, and the colleagues from the Consumer Protection and Market Fairness Division. The interpretation of the Organic Products Regulations as it relates to organic labelling and claims as well as the maintenance and the interpretation of the Canadian Organic Standard is within the responsibilities of the CFIA Consumer Protection and Market Fairness Division.

The COR-related complaints are managed by the COR team. Complaints against certification bodies are referred to the appropriate CVB for further investigation and resolution. Complaints against operators with certified products are referred to the appropriate CB for investigation via their CVB. Complaints regarding organic products at the retail level are forwarded to the CFIA inspectorate.

In order to become a designated CVB, an entity must apply to and undergo an on-site audit by CFIA. CVBs must meet both the requirements of ISO/IEC 17011 and additional CFIA requirements outlined in the COR Operating Manual. CVBs enter into a five-year agreement with CFIA to assess and recommend CBs for accreditation. CVBs are also responsible for the monitoring of the CFIA-accredited CBs through onsite audits. CFIA conducts on-site assessments of its CVBs in the first, third, and fifth years. In the second and fourth years, the surveillance assessment consists of a document review. A witness audit of the CVB is conducted every year, and the fifth year is the re-assessment year. CFIA may conduct unscheduled assessments or visits as a result of valid complaints against the CVB. At the time of the audit, there were three designated CVBs – two in Canada and one international CVB with physical office in the U.S.

An entity seeking to become a CFIA-accredited CB to certify agricultural products and organic product packaging and labeling under the COR must apply to a designated CVB. Accreditation applicants undergo a document review and onsite assessment conducted by the CVB to verify compliance with the COR requirements, which includes conformity with the requirements of ISO/IEC 17065. CFIA makes the decision to grant the CB accreditation based on the

recommendation and information provided by the CVB. Accreditation is granted for five years. At the time of the audit, there were thirty-six accredited CBs, eighteen of which offer certification services in Canada.

An operation seeking certification of its products or packaging and labeling activity under the COR applies to a CFIA-accredited CB. The CB conducts an initial onsite inspection to verify the operation's compliance with the COS and COR requirements, and grants certification of the product or packaging and labeling activity if the operation is determined to be compliant. Verification of whether the product meets the terms of the U.S. – Canada Equivalency Arrangement is also conducted by the CB upon request of the operation. Once certified, the certification of the product remains valid unless suspended or cancelled by the CB. In order to continue certification, an operation must submit its intent to maintain certification to the CB and undergo an onsite inspection annually. In addition to annual inspections, operations may be subjected to unannounced inspections and sampling and testing. CBs are required to conduct unannounced inspections representing 3% of primary producers (minimum one) and 5% of other operators (minimum one) to which it grants certificates for products under the Canada Organic Regime. CBs may conduct sampling and testing when there is reason to suspect that the organic product has come into contact with a prohibited substance, method or ingredient in the production and handling of the product. At the time of the audit, CFIA reported that there were a total number of 5,393 COR-certified operations (5,063 domestic, 330 international) in 2016.

SUMMARY OF PREVIOUS REVIEW OBSERVATIONS AND VERIFICATION OF CFIA RESPONSES

AMS-NOP's previous onsite audit conducted in June 2013 resulted in eight observations. In response to the findings, CFIA submitted responses to USDA-AMS NOP on October 30, 2013. AMS-NOP's 2017 - 2018 onsite review verified the implementation of CFIA's responses.

A previous observation labeled as "Cleared," indicates that the responses are determined to be implemented and effective. A previous observation labeled as "Outstanding" indicates that either the auditors could not verify implementation of the response or that records reviewed and audit observations did not demonstrate that the responses were implemented. The following are the results of the verification:

OBSERVATION 1 – Accepted. Certification Body 1: During discussion with the certification body (CB) and in review of communication between the CB and a certified operation (CO), it was found that the CB does not accept attestations from NOP operators that are compliant with the NOP Policy Memo, PM 10-3, in order to demonstrate compliance with the USCOEA, specifically if the attestation is provided by a party other than the operation's certifier (i.e. by the producer). The CB only accepts USCOEA compliance documents from a certifier. In review of a particular situation with the CB's client, the CB prohibited the client from using sugar from Peru that was certified by an NOP-accredited certifier in Guatemala because the attestation was not provided by the certifier directly. It was noted that the sugar operation and certifier in Guatemala are unilingual Spanish-speaking operations, making obtaining an attestation difficult for the CB and its operator.

CFIA/COR Response:

Certification Body 1 has clarified what is required as an attestation of COR equivalency for NOP-certified products with its clients, verification officers and staff. Form ORG_36 has been updated to reflect the requirements for attestations of equivalency to COR. ORG_36_Canada-US equivalence has been amended to require an attestation only from a supplier, and not the supplier's certification body. An "Equivalency Fact Sheet" has been prepared for distribution to the CB's clients, applicants and verification officers. Equivalency requirements shall be reviewed with verification officers (at training sessions planned for October 31 and November 4, 2013) and with staff (meeting planned for September 30, 2013).

AMS-NOP Verification:

The auditors' review of CFIA's website found that information posted by CFIA regarding the USCOEA included the following appropriate information: "The attestation statement may be included on the organic certificate, transaction certificate, bill of lading, purchase order, or any other affirmative attestation. The operator may provide this attestation, or may request that a certifier do so." However, the auditors' interviews with certification staff at the Canada and Thailand CBs found that CBs were not accepting attestation statements provided by operators. The Canada CB staff stated that for product imported to Canada under the USCOEA, either an official statement from the certifier of the product or an organic certificate with the compliance statement would be required for the Canada CB to allow its certified operation to use the imported product. Thailand CB staff stated that a certifier-issued organic certificate, transaction certificate, or confirmation letter that includes the attestation statement would be acceptable, but not an attestation provided by the operator.

CFIA/COR Team Response:

The NOP Policy Memo dated January 27, 2012 was sent to all the CFIA accredited CBs and discussed at both the CVB annual meeting in November 2018 and at the CB Working Group on January 10, 2019. The Memo is publically available on the CFIA web site at:

http://www.inspection.gc.ca/food/requirements-and-guidance/organic-products/equivalence-arrangements/uscoea-overview/eng/1328068925158/1328069012553

With the SFCR in place the CFIA has initiated the process of incorporating the organic import requirements of Part 13 of the SFCR into the CFIA's Automated Import Reference System (AIRS);

- Any person who imports organic products must be able to present at any time, including at the time of import a valid organic certificate when requested.
- The organic certificate must be issued by a certification body that is accredited by the CFIA, or by an accredited certification body recognized under an existing organic equivalency agreement between Canada and a foreign country.
- The imported organic product must be certified as organic, in accordance with the arrangement, by an entity that is accredited by that foreign state.

This process will eliminate the need for the operators to provide an attestation confirming that the product is "certified in compliance with the terms of the US-Canada organic equivalency arrangement" and the issue with the CFIA accredited CBs requesting an attestation issued only by the NOP accredited CBs.

OBSERVATION 2 – Cleared. Certification Body 1: During the office visit at the CB the certification process was discussed, along with the inspector selection process. The CB indicated that inspectors are allowed to inspect at the same operation for only 3 years in a row, after which a new inspector would be selected. At the first certified operation visited, however, it was found that the same inspector has visited the operation for the previous four years of organic certification and was also selected for the current – and fifth – year in 2013, which is not in line with the CB's own policies for inspector selection.

CFIA/COR Response:

Certification Body 1 is in a process of developing an internal process which will identify the verification officer (VO) who has done the previous three inspections for any of its clients. This will enable the CB's Compliance Evaluators to assign VOs in accordance with section 2.2 of ORG-SWI 10.1.1. This report will be issued in February 2014 when assignments are established. Target completion date is October 31, 2013.

AMS-NOP Verification:

The auditors' review of the two CB's inspector selection policies and observations during the witness audits indicated that all inspectors were conducting inspections in accordance with their CB's policies for inspector selection.

OBSERVATION 3 – Cleared. Certification Body 1: During a visit to the second certified operation, it was found some seed used to plant crops had seed tags showing certification by an NOP-certifier, and also displayed the USDA organic seal. There was no certificate on file for the seed, and no attestation for the incoming product. It was found that this was not caught by the inspector at the previous year's inspection (to which the purchase of this seed applied).

CFIA/COR Response:

Although verification officers have been trained on requirements under equivalency arrangements, and Certification Body 1 staff has been trained to review files for equivalency requirements when requested by a client, the CB's farm system plan (ORG_FAR_04 and ORG_FAR_03) and seed listing (ORG_FAR_06) do not explicitly mention equivalency or the requirement for an attestation. This requirement will be included in the verification officers training planned for October 31 and November 4, 2013. The CB's farm forms (ORG_FAR_04; ORG_FAR_03; and ORG_FAR_06) will be updated to reflect the requirement for a certificate and attestation for NOP-certified seed. The issue of equivalency and attestations for seed will be included in the "Equivalency Fact Sheet" to be prepared by the CB for distribution to its clients. Target completion date is November 4, 2013.

AMS-NOP Verification:

During the witness audits, the auditors observed that inspectors verified whether certificates were on-file and attestation statements were available for all incoming products.

OBSERVATION 4 – Cleared. Certification Body 1: During review of certificates for clients certified to the USCOEA, it was found that the CB does not include the specified and required statement on the organic certificate, per COO's Directive 09-01 amended June 18, 2010.

CFIA/COR Response:

The CB's certificates (for farms, livestock and processors) have been amended to use the correct statement "certified to the terms of the US-Canada organic equivalency arrangement" according to Directive 09-01 as of September 27, 2013. The three certificates (farm, livestock and processor) have been changed in the CB's database to use the correct statement. A copy of the new certificate is attached.

AMS-NOP Verification:

The auditors' sample review of organic certificates issued by the two CBs indicated that the certificates included the statement specified and required by CFIA Directive 09-01.

OBSERVATION 5 – Cleared. Certification Body 2: In reviewing a file for a certified operation, it was found that the CB's inspector cited an issue on the operator's inspection report specific to the USCOEA that was not also identified on the inspection exit interview. Per the CB, this is out of compliance with their policies – all issues on the inspection report must be reflected on the exit interview. This discrepancy was not caught by the CB's review staff or certification decision-maker.

CFIA/COR Response:

Specific instructions were given to all verification officers and certification officers with regards to issues found during inspection. All issues related to the standard being inspected must be indicated on the exit interview and report. A reminder regarding non-compliances that need to be listed in the 2 documents: exit interview and inspection report has been sent out. Training for both certification officers and verification officers is planned for December 2013. A copy of the applicable sections of the training is attached.

AMS-NOP Verification:

The auditors' sample review of inspection reports of the two CBs and observations during the witness audits indicated that the CBs inspectors recorded issues identified in the inspection report on exit interview forms.

OBSERVATION 6 – Cleared. Certification Body 2: The specific USCOEA issue referenced in Observation 5 above was that the inspector required in the inspection report that a certificate be on file for incoming NOP-certified ingredients, which is not in line with NOP PM 10-3. This memo specifies that the attestation may be issued an organic certificate, a transaction certificate, bill of lading or any other affirmative attestation. As noted in Observation 5, there was no mention of the issue in the exit interview; further, the inspection report did not have any additional details on the topic – such as whether an attestation statement in another form was available.

CFIA/COR Response:

The CFIA accredited CBs are not expected to be in line with the NOP Policy Memos. The CBs should follow the CFIA requirements and directives. The COO suggests that this observation is revised to reflect this comment. The Certification Body 2 certification officers and verification officers were reminded of this issue during the training sessions that took place on June 14, 2013, and June 20, 2013.

AMS-NOP Verification:

The auditors' sample review of certification files indicated that both CBs were following CFIA requirements and directives.

OBSERVATION 7 – Accepted. Certified Operation: The processor repackages pasta products into packaging for the US market that are listed on the certificate as "certified to the terms of the US-Canada Organic Equivalency Arrangement," though product is not always sold to the US. Packages display the USDA organic seal and an ingredient statement compliant with the NOP labeling requirements; however, the "certified organic by…" required statement was not properly displayed. Additionally, the CB's logo was displayed more prominently (on the same panel in a larger size) than the USDA organic logo. COO Directive 10-5 for "Labeling of organic products under the Canada Organic Regime," under section 3.0 and "Labeling Requirements related to import/export arrangements" states, "Organic products shall meet the labeling requirements of the importing country; that is, the country where it is marketed and sold." The Directive is noted at the top as "Intended for: CFIA designated CVBs, CFIA accredited CBs, and all operations under the COR." It was found that neither issue was caught by the inspector or the certifier.

CFIA/COR Response:

The client has been informed that his labels used for sales in the USA are non-compliant and needed to be corrected. The client sent all labels bearing the USDA logo for verification on September 24, 2013. The CB's label approval manager has reviewed all labels and informed the client on all necessary changes on September 30, 2013. The Certification Body 2 label verification approval document has been amended in July 2013 to include the specific requirements for the countries with which Canada has an equivalency arrangement. A reminder was sent to the verification officers and certification officers in regards to the equivalency arrangement on October 2, 2013. A copy of the CB's label approval form is attached.

AMS-NOP Verification:

The auditors' sample review of labels approved by the Thailand CB found that the labels did not comply with NOP requirements in the following manner: (1) labels on four tea products displayed "Certified by " instead of "Certified Organic by"; (2) the displayed statement was not placed below the information identifying the handler of the product on the labels of the four tea products and two additional rice products. Additionally, the auditors' interviews with the representative of the Thailand CB's CVB indicated that the CVB was not verifying during its onsite assessment whether the CB reviews and appropriately approves labeling on product exported under the USCOEA for compliance with NOP labeling requirements.

CFIA/COR Response:

CFIA covered USDA labeling under the USCOEA during a CB Working Group Call in June 2019 and at a CVB face to face meeting in November 2018. In 2018 and 2019, as part of CFIA's office and witness audits, the CFIA confirmed that the CBs review and approve all the labels. The US labelling requirements are publicly available on the CFIA web site at: http://www.inspection.gc.ca/food/general-food-requirements-and-guidance/organic-products/equivalence-arrangements/uscoea-overview/eng/1328068925158/1328069012553.

OBSERVATION 8 – Cleared. Certified Operation: At the processor, audit trail documents were reviewed for two randomly selected production runs of product qualifying for the USCOEA certification. It was found that a certificate for organic cheese and butter, which is used in an Alfredo sauce labeled with the USDA Organic seal that is certified under the USCOEA, did not contain the required certification statement for USCOEA products/ingredients, per COO Directive 09-01 amended June 18, 2010. Under this Directive, "Products imported or exported under the terms of this arrangement must be accompanied by documents which would have the following attestation added to the product by the Certification body verified the product: certified to the terms of the US-Canada Organic equivalence arrangement." The certificate from the CB for the supplier of cheese and butter stated only, "Equivalency Arrangement Etats-Unis-Canada." As these are dairy products, which have a restrictive critical variance under the terms of the USCOEA, being used in a product labeled with the USDA organic seal and certified for sale to the US under the USCOEA, incoming ingredient documents must properly demonstrate compliance, per COO's own Directive. It was found that the inspector did not catch this issue at the processor's most recent inspection conducted prior to the peer review.

CFIA/COR Response:

A reminder was sent to the Certification Body 2 staff in regard to the equivalency arrangement on September 20, 2013. A copy of the CB's Internal Note is attached.

AMS-NOP Verification:

The auditors' sample review of certification files indicated that the certification files included documentation with the appropriate attestation statement. During the witness audits, the auditors observed that inspectors were verifying whether an operation's documentation included the appropriate attestation statement.

SUMMARY OF REVIEW OBSERVATIONS

The 2017 - 2018 onsite review identified the following observations:

OBSERVATION 1 – Accepted. ISO 17011 7.2.1.c states, "The accreditation body shall require a duly authorized representative of the applicant CAB to make a formal application that includes the following: a clearly defined, requested, scope of accreditation; …." *The auditors review of CFIA agreement letters issued to the two CVBs and one CVB's CB accreditation recommendation letter to CFIA found that the letters do not refer to specific scopes (i.e. crops, livestock, processing, etc.) for accreditation. Additionally, the auditor's interviews with CVB staff and review of both CVBs' application forms from found that the CVBs are not consistent with each other in the types of scopes CB applicants may apply for.*

CFIA/COR response:
The CFIA has amended the CVB recommendation letter template. The amended template includes detailed information on both the accreditation and the geographical scope.

OBSERVATION 2 – Accepted. ISO 17011 8.2.1.b – c states, "The accreditation body shall make publicly available information about the current status of the accreditations that it has granted to CABs … The information shall include the following: dates of granting accreditation and expiry dates, as applicable; scopes of accreditation, condensed and/or in full. If only condensed scopes are provided, information shall be given on how to obtain full scopes." *The auditors' review of information publicly available on CFIA's website found that CFIA only posts a list of approved CVBs and CBs, which does not include all the information required by ISO 17011 8.2.1.b - c.*

CFIA/COR response:
The accreditation status of each CB is publicly available on the CFIA website at: http://www.inspection.gc.ca/food/general-food-requirements-and-guidance/organic-products/certification-bodies/in-canada/eng/1327861534754/1327861629954. The accreditation status provides information such as the CB's accreditation number, name of the CVB, effective and expiration date of accreditation, accreditation scope and geographical scope.

OBSERVATION 3 – Accepted. ISO 17011 7.8.6 e - h states, "The information provided to the accreditation decision-maker(s) shall include the following, as a minimum: proposed scope of accreditation that was assessed; the assessment report; information on the resolution of all nonconformities;" *The auditors' review of CFIA's CB accreditation process found that CFIA does not always require CVBs to provide CFIA with the information required by ISO 17011 7.8.6 e - h for CFIA to make its accreditation decision. Interviews with CFIA staff indicated that the information may be requested from the CVB on a case-by-case basis.*

CFIA/COR response:
In March 2018, the CFIA revised the COR Operating Manual V14 and published the amended V15 of the COR Operating Manual. The NOP observation was addressed by clause B.2.3.5,

which requires the CVB to send to the CFIA the recommendation decision in writing and provide to the CFIA a copy of the CVB evaluation report on the applicant CB and any other relevant information to support the accreditation recommendation. This requirement remains unchanged in the current V16 dated January 15, 2019 Copy of the manual can be found on the CFIA website at: http://www.inspection.gc.ca/food/general-food-requirements-and-guidance/organic-products/operating-manual/eng/1389199079075/1544800597955?chap=4#s16c4

OBSERVATION 4 – Accepted. ISO 17011 4.2.1 states, "The structure and operation of an accreditation body shall be such as to give confidence in its accreditations." *The auditors' review of the Thailand CB's list of certified operations submitted to its CVB prior to its assessment of the CB found that the submission did not meet CFIA's requirements. CFIA requires CVB's to request from its CB prior to conducting an on-site assessment updated information that includes a complete list of operations certified to the terms of Canada's organic equivalence arrangements, including name, address and phone number of the certified entity, the scope of certification and their locations. If provided through a directory on the internet, it is acceptable to provide the URL to the directory instead. The list (i.e. URL to website list) the CB provided its CVB with included a list of COR-certified operations. However, the list did not identify which operations were certified to the terms of the USCOEA. Additionally, the list incorrectly included operations with an "in-conversion" status.*

CFIA/COR response:
This NOP observation triggered a nonconformity that was issued to the CVB by the CFIA. The CVB was given 30 days to address the NC and to provide a corrective action plan to the CFIA for review.

CONCLUSIONS AND RECOMMENDATIONS

The implementation of CFIA's response to any finding noted as "Accepted" will be verified by USDA AMS NOP during its next onsite review of Canada's organic certification program.

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Agricultural Marketing Service
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USDA/AMS PEER REVIEW REPORT [Final: December 18, 2013]

ORGANIC EQUIVALENCE ARRANGEMENT

BETWEEN THE UNITED STATES AND CANADA

DATES OF REVIEW – JUNE 10-14, 2013

REVIEWER: Meg Kuhn, National Organic Program

1. INTRODUCTION

1.1. The U.S. Department of Agriculture (USDA) is engaged in an equivalence arrangement with the Canadian Food Inspection Agency (CFIA). This arrangement includes periodic peer review assessments of the USDA/National Organic Program and CFIA/Canada Organic Office (COO). The previous peer review assessment of the CFIA/COO was in June 2011.

1.2. On June 10-14, 2013, a representative of the USDA Agricultural Marketing Service (AMS) reviewed organic accreditation and certification activities in the Quebec province of Canada, which represented the Canada Organic Regime (COR) activities. This report is an account of those activities and observations of the review.

1.3. Review team was comprised of:

1.3.1. Meg Kuhn, Agricultural Marketing Specialist – Regulatory, AMS – National Organic Program (NOP)

1.4. Additional participants included:

1.4.1. Cheri Courtney, Director of Accreditation and International Activities, AMS – NOP; Peer review evaluator

1.4.2. Bernd Winkler, Auditor with Food and Veterinary Office for the European Union; Observer

2. OBJECTIVES OF REVIEW

2.1. The objective of the review was to evaluate the system capabilities and performance of CFIA authorities in controlling the proper application and enforcement of the Organic Products Regulations (OPR) and oversight of the US/CAN Organic Equivalency Arrangement (USCOEA) for organic products.

3. LEGAL BASIS FOR THE REVIEW

3.1. The review was conducted based on USCOEA conditions of periodic peer review assessments.

3.2. The following statutes, regulations, and standards were considered in the review:

3.2.1. U.S. Organic Foods Production Act of 1990

3.2.2. U.S. Code of Federal Regulations (CFR) Part 205, National Organic Program

3.2.3. Organic Product Regulations, 2009

3.2.4. US/CAN Equivalence Arrangement (USCOEA), Appendices 1 and 2

3.2.5. ISO/IEC 17011:2004(E) Conformity assessment — General requirements for accreditation bodies (identified as Conformity Verification Bodies (CVBs) within the COR) accrediting conformity assessment bodies (identified as Certification Bodies (CB) within the COR)

3.2.6. ISO/IEC 17040:2005 Conformity assessment – General requirements for peer assessment of conformity assessment bodies and accreditation bodies

4. PROTOCOL

4.1. The review was accomplished by observing the competent authority Canada Organic Office (COO), a Conformity Verification Body (CVB), two (2) certification bodies (CBs), and four (4) certified organic operations (CO) in the Canadian provinces of Ontario and Quebec. In selecting the CVB, CB, and COs to be reviewed, the reviewer worked with representatives of the COO to select operations representative of organic products produced in Canada.

4.2. The reviewer included each phase of the organic production, certification, and accreditation system in the review to determine if the responsible authorities had the necessary controls in place to ensure compliance and traceability with the referenced organic standards.

4.3. At the CVB office reviewed, the reviewer observed processes used to evaluate the competence of the certifying bodies. The reviewer observed procedures relating to the certification of organic operations according to OPR in order to determine how compliance with the referenced organic production and handling regulations would be carried out. The reviewer also interviewed personnel to determine their knowledge of organic accreditation, certification, production, handling and recordkeeping practices and their qualifications with respect to their duties and responsibilities.

4.4. The team visited four (4) organic operations to observe production, handling and labeling practices in order to determine the level of compliance accomplished by the certified operations; specifically, two (2) crop producers, one (1) dairy producer, and (1) handling operation. The reviewer interviewed responsible parties at each site, and participated in meetings with the production managers.

4.5. The team was accompanied by representatives of the COO throughout the review. At the certified operations (CO), representatives of the CO's certification body also accompanied the reviewer.

5. SUMMARY OF PREVIOUS REVIEWS

5.1. This was the NOP's third onsite review of the COR program for the purpose of determining implementation and ongoing compliance of the US/CAN Equivalence Arrangement. There were four (4) onsite review observations, from the NOP to COO, to consider for follow-up response from 2011. The COO provided responses to the observations, which the NOP reviewed and approved.

6. OBSERVATIONS

6.1. Report on Canada Organic Office (COO) Competent Authority and Control System

6.1.1 The Canada Organic Regime (COR), managed by the COO, is well organized and effective. The oversight over the Conformity Verification Bodies (CVB) is solid with good communication and regular audits conducted on schedule. The COO conducts regular face-to-face meetings with the CVBs (every 8 months) to ensure consistent application of the COR.

6.1.2 The complaint process followed at the COO was reviewed. Specifically, complaints received at the COO regarding certified operations are forwarded to the Certification Body (CB) responsible for the operation, through the CB's CVB. The COO maintains a spreadsheet of complaints received, actions taken by the COO including referral to CVBs/CBs, and outcomes of complaint investigations. For trade complaints received that are not related to certified operations, the COO does not have the authority to investigate or regulate in these areas. As such, the

COO refers these complaints to other applicable divisions of CFIA for follow-up. For example, labeling complaints for non-certified operations are referred to CFIA's Operations. Of the 20-30 complaints on the COO's spreadsheet back to 2011, investigation and follow-up by the COO itself has been minimal, considering the referral system in place. The COO does conduct its own complaint investigations when or if a complaint is received about a CVB, over which the COO has direct authority.

6.2. Report Observations from a Conformity Verification Body

6.2.1 The oversight of the Conformity Verification Body (CVB) observed over COR CBs is thorough and effective. The audits are regularly conducted and include the use of a technical expert; there is adequate separation of duties in reviewing and recommending accreditation decisions; and recordkeeping – primarily an electronic system – is closely controlled and well-organized. Documentation demonstrating experience, education, and training was on file for applicable staff.

6.2.2 The complaint process at the CVB was reviewed and some complaints received were sampled to verify investigation and follow-up to the COO. The CVB has a thorough system for documenting and tracking complaints, including investigation results and follow-up responses to applicable parties, including the COO. The spreadsheet contains links to investigation and responsive documents, is easy to follow, and very thorough.

6.3. Report Observations from Certification Bodies (CB)

6.3.1 Two CBs were evaluated, Certification Body 1, which is in the process of transferring oversight to another CVB, is located in Ottawa; also evaluated was

Certification Body 2, is located in Quebec. At both CBs, the certification files were complete and inspection reports were thorough and well documented. Experience, education and training was sampled and verified to be current and on file for review and inspection staff. Certification records demonstrated timely and thorough certification services provided by the CB. There are multiple management controls in place to ensure effective implementation of accreditation requirements.

6.3.2 Complaint investigation was reviewed at each CB. Processes are in place to investigate complaints received from outside parties as well as those from CVBs, some of which originate with the COO (per accreditation hierarchy, the COO works with the CVBs, which in turn work with the CBs; the COO does not contact CBs directly for complaint investigation requests). The CBs were able to show how complaints are tracked, investigated, and closed. Both CBs visited had low numbers of complaints received.

6.3.3 At Certification Body 2, the CVB representative was present for the review at the CB as well as the two certified operations visited. The CVB provided some translation at the certified operations and was there as a resource for any accreditation questions that may arise.

6.3.4 Six observations were observed at the CBs (please see 8.1-6 below).

6.4. Report Observations from Certified Operations

6.4.1 Two organic crop producers, one dairy producer, and one handler were selected for observation.

6.4.2 The first operation, a small grain producer, provided an overview of organic activities in place, including a thorough tour of the organic certification paperwork including extensive recordkeeping, the production system in place, and a short tour of a field and storage bins. Some certification documentation was reviewed for incoming seed suppliers, planting, harvest, storage, and sales of organic products.

6.4.3 The second operation, also a small grain producer, provided an overview of organic activities in place, including a thorough discussion of organic management practices, a tour of two of five fields that were recently planted, and some recordkeeping documents for the previous year's certification.

6.4.4 The third operation, a medium-sized dairy operation, provided an overview of the production system and certification processes. Some paperwork, specifically showing production and sales, was reviewed. The office at the dairy is above the barn, which also serves as the milking facility. Animals were observed in tie-stalls with clean, fresh wood chip and sawdust bedding. Equipment is brought to the cow for milking and, as such, the animals live and milk in the same area.

6.4.5 The fourth and last operation, a handler of repackaged pasta products and sauces, provided an overview of the handling system, including the previous year's inspection report and results, as well as a complete audit trail for two randomly selected production runs. Receiving documents were reviewed for ingredients received for the production run(s). Selected repackaged pasta products are listed on the operation's certificate as 'certified to the terms of the US-Canada Organic Equivalency Arrangement' and have labeling intended for the US market,

specifically with the display of the USDA organic seal. Two observations were identified at the processor, one regarding labeling in accordance with NOP requirements, and another regarding incoming certificate for USCOEA ingredients.

6.4.6 As noted above, two observations were observed at the fourth operation (please see 8.7 and 8.8 below).

7. INTRODUCTION TO OBSERVATIONS

7.1. The assessment activities took place in two (2) of Canada's ten (10) provinces, Ontario and Quebec. The assessment included visits to crop, livestock and handling operations; a wild crop operation was not included.

7.2. The NOP reviewed a livestock operation in the province of Quebec, specifically a dairy farm, and was able to review a production system compliant with OPR requirements. The farm visited did not ship milk to the United States; as such, the reviewer did not have an opportunity to review compliance with the critical variance under the USCOEA for products exported from Canada.

8. OBSERVATIONS

8.1. Observation 1. Certification Body 1: During discussion with the certification body (CB) and in review of communication between the CB and a certified operation (CO), it was found that the CB does not accept attestations from NOP operators that are compliant with the NOP Policy Memo, PM 10-3, in order to demonstrate compliance with the USCOEA, specifically if the attestation is provided by a party other than the operation's certifier (i.e. by the producer). The CB only accepts USCOEA compliance documents from a certifier. In review of a particular situation with the CB's client, the

CB prohibited the client from using sugar from Peru that was certified by an NOP-accredited certifier in Guatemala because the attestation was not provided by the certifier directly. It was noted that the sugar operation and certifier in Guatemala are unilingual Spanish-speaking operations, making obtaining an attestation difficult for the CB and its operator.

CFIA/COO Response: Certification Body 1 has clarified what is required as an attestation of COR equivalency for NOP-certified products with its clients, verification officers and staff. Form ORG_36 has been updated to reflect the requirements for attestations of equivalency to COR. ORG_36_Canada-US equivalence has been amended to require an attestation only from a supplier, and not the supplier's certification body. An "Equivalency Fact Sheet" has been prepared for distribution to the CB's clients, applicants and verification officers. Equivalency requirements shall be reviewed with verification officers (at training sessions planned for October 31 and November 4, 2013) and with staff (meeting planned for September 30, 2013).

8.2. Observation 2. Certification Body 1: During the office visit at the CB the certification process was discussed, along with the inspector selection process. The CB indicated that inspectors are allowed to inspect at the same operation for only 3 years in a row, after which a new inspector would be selected. At the first certified operation visited, however, it was found that the same inspector has visited the operation for the previous four years of organic certification and was also selected for the current – and fifth – year in 2013, which is not in line with the CB's own policies for inspector selection.

CFIA/COO Response: Certification Body 1 is in a process of developing an internal process which will identify the verification officer (VO) who has done the previous three

inspections for any of its clients. This will enable the CB's Compliance Evaluators to assign VOs in accordance with section 2.2 of ORG-SWI 10.1.1. This report will be issued in February 2014 when assignments are established. Target completion date is October 31, 2013.

8.3. Observation 3. Certification Body 1: During a visit to the second certified operation, it was found some seed used to plant crops had seed tags showing certification by an NOP-certifier, and also displayed the USDA organic seal. There was no certificate on file for the seed, and no attestation for the incoming product. It was found that this was not caught by the inspector at the previous year's inspection (to which the purchase of this seed applied).

CFIA/COO Response: Although verification officers have been trained on requirements under equivalency arrangements, and Certification Body 1 staff has been trained to review files for equivalency requirements when requested by a client, the CB's farm system plan (ORG_FAR_04 and ORG_FAR_03) and seed listing (ORG_FAR_06) do not explicitly mention equivalency or the requirement for an attestation. This requirement will be included in the verification officers training planned for October 31 and November 4, 2013. The CB's farm forms (ORG_FAR_04; ORG_FAR_03; and ORG_FAR_06) will be updated to reflect the requirement for a certificate and attestation for NOP-certified seed. The issue of equivalency and attestations for seed will be included in the "Equivalency Fact Sheet" to be prepared by the CB for distribution to its clients. Target completion date is November 4, 2013.

8.4. Observation 4. Certification Body 1: During review of certificates for clients certified to the USCOEA, it was found that the CB does not include the specified and required statement on the organic certificate, per COO's Directive 09-01 amended June 18, 2010.

CFIA/COO Response: The CB's certificates (for farms, livestock and processors) have been amended to use the correct statement "certified to the terms of the US-Canada organic equivalency arrangement" according to Directive 09-01 as of September 27, 2013. The three certificates (farm, livestock and processor) have been changed in the CB's database to use the correct statement. A copy of the new certificate is attached.

8.5. Observation 5. Certification Body 2: In reviewing a file for a certified operation, it was found that the CB's inspector cited an issue on the operator's inspection report specific to the USCOEA that was not also identified on the inspection exit interview. Per the CB, this is out of compliance with their policies – all issues on the inspection report must be reflected on the exit interview. This discrepancy was not caught by the CB's review staff or certification decision-maker.

CFIA/COO Response: Specific instructions were given to all verification officers and certification officers with regards to issues found during inspection. All issues related to the standard being inspected must be indicated on the exit interview and report. A reminder regarding non-compliances that need to be listed in the 2 documents: exit interview and inspection report has been sent out. Training for both certification officers and verification officers is planned for December 2013. A copy of the applicable sections of the training is attached.

8.6. Observation 6. Certification Body 2: The specific USCOEA issue referenced in Observation 5 above was that the inspector required in the inspection report that a

certificate be on file for incoming NOP-certified ingredients, which is not in line with NOP PM 10-3. This memo specifies that the attestation may be issued an organic certificate, a transaction certificate, bill of lading or any other affirmative attestation. As noted in Observation 5, there was no mention of the issue in the exit interview; further, the inspection report did not have any additional details on the topic – such as whether an attestation statement in another form was available.

CFIA/COO Response: The CFIA accredited CBs are not expected to be in line with the NOP Policy Memos. The CBs should follow the CFIA requirements and directives. The COO suggests that this observation is revised to reflect this comment.

The Certification Body 2 certification officers and verification officers were reminded of this issue during the training sessions that took place on June 14, 2013, and June 20, 2013.

8.7. Observation 7. Certified Operation: The processor repackages pasta products into packaging for the US market that are listed on the certificate as "certified to the terms of the US-Canada Organic Equivalency Arrangement," though product is not always sold to the US. Packages display the USDA organic seal and an ingredient statement compliant with the NOP labeling requirements; however, the "certified organic by…" required statement was not properly displayed. Additionally, the CB's logo was displayed more prominently (on the same panel in a larger size) than the USDA organic logo. COO Directive 10-5 for "Labeling of organic products under the Canada Organic Regime," under section 3.0 and "Labeling Requirements related to import/export arrangements" states, "Organic products shall meet the labeling requirements of the importing country; that is, the country where it is marketed and sold." The Directive is

noted at the top as "Intended for: CFIA designated CVBs, CFIA accredited CBs, and all operations under the COR." It was found that neither issue was caught by the inspector or the certifier.

CFIA/COO Response: The client has been informed that his labels used for sales in the USA are non-compliant and needed to be corrected. The client sent all labels bearing the USDA logo for verification on September 24, 2013. The CB's label approval manager has reviewed all labels and informed the client on all necessary changes on September 30, 2013. The Certification Body 2 label verification approval document has been amended in July 2013 to include the specific requirements for the countries with which Canada has an equivalency arrangement. A reminder was sent to the verification officers and certification officers in regards to the equivalency arrangement on October 2, 2013. A copy of the CB's label approval form is attached.

8.8. Observation 8. Certified Operation: At the processor, audit trail documents were reviewed for two randomly selected production runs of product qualifying for the USCOEA certification. It was found that a certificate for organic cheese and butter, which is used in an Alfredo sauce labeled with the USDA Organic seal that is certified under the USCOEA, did not contain the required certification statement for USCOEA products/ingredients, per COO Directive 09-01 amended June 18, 2010. Under this Directive, "Products imported or exported under the terms of this arrangement must be accompanied by documents which would have the following attestation added to the product by the Certification body verified the product: certified to the terms of the US-Canada Organic equivalence arrangement." The certificate from the CB for the supplier of cheese and butter stated only, "Equivalency Arrangement Etats-Unis-Canada." As

these are dairy products, which have a restrictive critical variance under the terms of the USCOEA, being used in a product labeled with the USDA organic seal and certified for sale to the US under the USCOEA, incoming ingredient documents must properly demonstrate compliance, per COO's own Directive. It was found that the inspector did not catch this issue at the processor's most recent inspection conducted prior to the peer review.

CFIA/COO Response: A reminder was sent to the Certification Body 2 staff in regards to the equivalency arrangement on September 20, 2013. A copy of the CB's Internal Note is attached.

9. CLOSING MEETING

9.1. The reviewer conducted a closing meeting with COO officials in Quebec City, Quebec, Canada on June 14, 2013. At the meeting, the U.S. reviewer provided a complete summary and discussion of all observations in this report.

9.2. Also in attendance at the closing meeting, as with all parts of the peer review, was Cheri Courtney, Director of NOP's Accreditation and International Activities Division, and Bernd Winkler, Observer from the EU's Food and Veterinary Office.

10. CONCLUSIONS AND RECOMMENDATIONS

10.1. All personnel involved in the review – from the staff at the COO, the CVB, the CBs, and the COs – were helpful, responsive, and accommodating to the reviewer's requests, both prior to and during the peer review.

10.2. Staff at the COO was incredibly helpful in assisting the NOP peer reviewer with the peer review scheduling, ensuring all components were finalized before the U.S. team arrived.

10.3. It was generally observed that the accreditation and certification system implemented through Canada's Organic Regime is thorough and sufficiently oversees organic activities at COO, CVB and CB levels.

10.4. The NOP and the CFIA Peer Review reports will be posted for public access on each program's website.

END OF REPORT

United States Department of Agriculture

Agricultural Marketing Service

STOP 0268 – Room 2646-S
1400 Independence Ave. SW
Washington, DC 20250

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

REVIEW TEAM: Mark A. Bradley, National Organic Program

Darrell Wilson, Livestock and Seed Program

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

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

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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 RECOMMENTATIONS

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

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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.