USDA Agricultural Marketing Service

1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

Accreditation Status Confirmation

April 19, 2019

To Whom This May Concern:

Bio.Inspecta (BIOI) is a United States Department of Agriculture (USDA), National Organic Program (NOP) accredited certifying agent. Furthermore, BIOI is authorized to issue USDA NOP organic certification to agriculture producer and processor operations that comply with Title 7 Code of Federal Regulations (CFR) Part 205.

BIOI accreditation certificate indicates a renewal date of April 14, 2019; however, its accreditation is in good standing and continues to be valid. USDA NOP granted BIOI an accreditation term extension until its accreditation renewal assessment is completed. USDA NOP expects the assessment process to conclude during 2019.

For questions concerning BIOI's status, please contact the NOP at 202.720.3252.

Sincerely,

for cc

Cheri Courtney
Director, Accreditation & International Activities Division
National Organic Program

United States Department of Agriculture

Agricultural Marketing Service

National Organic Program

CERTIFICATE OF ACCREDITATION

Bio.inspecta AG

Ackerstrasse CH-5070, Frick, Switzerland

meets all the requirements prescribed in the USDA National Organic Program Regulations

7 CFR Part 205

as an Accredited Certifying Agent

for the scope of

Crops, Wild Crops, Livestock and Handling Operations

This certificate is receivable by all officers of all courts of the United States as prima facie evidence of the truth of the statements therein contained. This certificate does not excuse failure to comply with any of the regulatory laws enforced by the U.S. Department of Agriculture .

Status of this accreditation may be verified at **http://www.ams.usda.gov**

Certificate No: NP4252LCA
Effective Date: April 15, 2014
Expiration Date: April 14, 2019

Ruihong Guo

Ruihong Guo, Ph.D.
Acting Deputy Administrator
National Organic Program

USDA Agricultural Marketing Service

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

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a renewal assessment of Bio.inspecta AG. An onsite audit was conducted, and the audit report reviewed to determine Bio.inspecta AG's capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name:	Bio.inspecta AG (BioI)
Physical Address:	Ackerstrasse, CH-5070, Frick, Switzerland
Mailing Address:	Ackerstrasse, CH-5070, Frick, Switzerland
Contact & Title:	Julia Winter, Program Manager
E-mail Address:	julia.winter@bio-inspecta.ch
Phone Number:	+41 (0) 62 865 63 24
Reviewer (s) and Auditor(s):	Penny Zuck, NOP Reviewer; Lars Crail, Onsite Lead Auditor; Robert Yang, Audit Trainee.
Program:	USDA National Organic Program (NOP)
Review and Audit Date(s):	Corrective Action review: May 29, 2015 NOP Review date: November 30, 2014 Onsite assessment date: September 10-12, 2014
Audit Identifier:	NP4252LCA
Action Required:	Yes
Audit and Review Type:	Renewal Assessment
Audit Objective:	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of BioI's certification system.
Audit and Determination Criteria:	*7 CFR Part 205, National Organic Program as amended*
Audit and Review Scope:	Assessment of BioI's certification services in carrying out the audit criteria.

Bio.inspecta (BioI) currently has 75 clients certified to the USDA NOP that includes 6 crop, 1 wild crop, 17 livestock and 51 processing/handling operations; it has also certified 7 traders and 1 grower group. BioI is currently certifying operations to the USDA NOP in Switzerland, Albania, Tanzania, India, Lebanon, Indonesia, and Romania. The main office is located in Frick, Switzerland, with staff housed in a complex that includes an organic research and development division.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether BioI's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from Findings identified during the onsite audit.

Non-compliances from Prior Assessments

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance. Any noncompliance labeled as "**Accepted**," indicates that the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP6254EEA.NC1 – **Cleared**
NP9173ACA.NC2 – Cleared
NP9173ACA.NC7 – Cleared
NP1234NNA.NC1 – Cleared
NP1234NNA.NC2 – Cleared
NP1234NNA.NC3 – **Cleared**
NP1234NNA.NC4 – **Cleared**
NP1234NNA.NC6 – C**leared**
NP1234NNA.NC11 – **Cleared**

NP1234NNA.NC5 – **Accepted.** 7 CFR §205.501 (a)(8) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Provide sufficient information to persons seeking certification to enable them to comply with the applicable requirements of the Act and the regulations in this part." *BioI has not addressed the pasture practice standard under 7 CFR §205.240 and dry matter intake requirements under 7 CFR §205.237 with applicants or certified operations. BioI applies the Bio Suisse rules for requirements of pasture of 156 days with 25% dry matter from pasture. They feel this is a stricter standard and meets the NOP pasture standard*.

Corrective Actions: Beginning in January 2012, BioI will provide notice to clients on the pasture practice standard under 7 CFR § 205.240 and dry matter requirements under 7 CFR § 205.237. BioI has amended its quality system by modifying the livestock OSP form to request information relevant to the NOP pasture practice standard and pasture dry matter feeding requirements. During inspections, the inspector must also assess whether an operation is complying with the NOP requirement for 30% dry matter intake from pasture grazed during the grazing season, and determine if ruminants have had access to pasture for at least 120 days during the grazing season. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.

2014 Verification of Corrective Action: BioI does not currently certify any ruminant livestock operations or have any applicants seeking livestock certification. However, the current livestock OSP still does not address the requirements of the pasture plan standard under 7 CFR §205.240 and the inspection report does not include the verification of the

operation's grazing period. Also, inspectors have not yet been instructed on which requirements need to be verified during the onsite inspection with regard to dry matter intake and pasture access.

2015 Corrective Actions: BioI submitted the OSP and inspection checklist templates with the USDA-NOP organic pasture requirements included.

NP1234NNA.NC7 – **Accepted.** 7 CFR §205.501 (a)(18) states, "A private or governmental entity accredited as a certifying agent under this subpart must:…notify the inspector of its decision regarding certification of the production or handling operation site inspected by the inspector and of any requirements for the correction of minor non compliances." *BioI does not notify the inspector of the certification decision for all sites. The current practice is to only notify the inspector if there have been changes in the decisions from the inspection report.*

Corrective Actions: BioI has modified its procedures to indicate that an inspector will receive a copy of the certification decision when notification is provided to the operation. BioI has established letter and checklist templates for providing notifications on NOP certification decisions to clients and inspectors. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.

2014 Verification of Corrective Action: The auditor noted that BioI notifies the inspector of its certification decision only when the inspection review results in the operation receiving a Notice of Noncompliance.

2015 Corrective Action: BioI submitted the checklist template that is used when operations are notified of their certification decision. The checklist notes that a copy of the certification decision is sent to the inspector.

NP1234NNA.NC8 – **Accepted.** 7 CFR §205.504 (a)(1) states, "A private or governmental entity seeking accreditation as a certifying agent must submit the following documents and information to demonstrate its expertise in organic production or handling techniques… (1) A copy of the applicant's policies and procedures for training, evaluating, and supervising personnel." *BioI does not have a documented training program for staff who review applications for completeness and compliance. Furthermore, BioI has hired new staff to serve in this capacity since the 2009 NOP assessment. This is a concern as indicated by the findings outlined under noncompliances for 7 CFR §205.402 (a) (1) and (2). In addition the training program for new inspectors does not include the requirement that they participate in two acceptable shadow inspections before conducting inspections on their own.*

Corrective Actions: BioI revised its training programs for new inspectors and certifiers. The training program covers procedures for initially reviewing OSPs for completeness and compliance with the NOP regulations. BioI also modified its quality system procedures to indicate that new inspectors without experience must accompany experienced inspectors on inspections until sufficient experience is obtained. When the experience training is complete, the trained inspectors will be independently assigned to carry out inspections. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.

2014 Verification of Corrective Action: The review of training records indicated that BioI has implemented its corrective actions for training certifiers. However, BioI has not implemented a training program for new inspectors, which requires that new inspectors accompany experienced inspectors on inspections until sufficient experience is obtained.

2015 Corrective Action: BioI submitted the NOP Training Concept document which includes a section for inspectors requiring new inspectors to accompany experienced inspectors. The inspectors are assessed and shadow inspections are repeated until sufficient experience is obtained.

NP1234NNA.NC9 – **Accepted.** NOP §205.642 states, "Fees charged by a certifying agent must be reasonable, and a certifying agent shall charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator.… The certifying agent may require applicants for certification to pay at the time of application a nonrefundable fee which shall be applied to the applicant's fees-for-service account. The certifying agent may set the nonrefundable portion of certification fees; however, the nonrefundable portion of certification fees must be explained in the fee schedule submitted to the Administrator. The fee schedule must explain what fee amounts are nonrefundable and at what stage during the certification process fees become nonrefundable." *BioI forwarded a copy of the fee schedule for international clients to the Administrator. However, the price list for domestic clients was not submitted. It is not clear what portion of the fees is nonrefundable.*

Corrective Actions: BioI provided a 2012 fee schedule which describes NOP certification fees for both international and domestic clients. The disclaimer, "all fees are nonrefundable," is noted on the fee schedule.

2014 Verification of Corrective Action: The review of BioI's fee schedules indicated that though its nonrefundable policies are stated on the Domestic Processing, Domestic Agriculture, and International fee schedules, it is not stated on the fee schedule for Turkey.

2015 Corrective Action: BioI submitted the revised fee schedule for Turkey and it includes a non-refundable statement in reference to NOP fees.

NP1234NNA.NC10 – **Accepted.** NOP §205.662 (a) states, "When an inspection, review, or investigation of a certified operation by a certifying agent… reveals any noncompliance with the Act or regulations in this part, a written notice of noncompliance shall be sent to the certified operation." *BioI sent a notice of suspension to a certified operation without first issuing a Notice of Noncompliance, and a Notice of Proposed Suspension. The inspection report noted several noncompliances; however, the operation was not given the opportunity to correct or rebut the noncompliances. Additionally, BioI allowed the operation to reapply for certification as a new applicant directly through BioI without the operation first requesting to be reinstated through the Secretary of Agriculture as required by 7 CFR §205.662(f).*

Corrective Actions: BioI modified its procedures to implement noncompliance procedures for certified operations described in 7 CFR §205.662 when noncompliances are identified during certification activities. Adverse actions will be issued to operations when noncompliances cannot be resolved. On October 10, 2011, BioI issued a combined Notice of Noncompliance and Denial of Certification to the operation cited in the noncompliance description. BioI's November 2011 submission of corrective actions did not address requirements for reinstating suspended operations. The NOP reviewer requested additional information on BioI's procedures for reinstating suspended operations. BioI's response indicated that, in 2012, it will implement NOP reinstatement procedures described in the NOP Program Handbook when suspended operations request NOP reinstatement.

Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.

2014 Verification of Corrective Action: BioI follows the instructions of NOP 2605 Reinstating Suspended Organic Operations when suspended operations apply for certification. However, BioI issued a certified operation a termination of certification notice without following the noncompliance and adverse actions process as required by the USDA organic regulations.

2015 Corrective Action: The procedure was revised in the Inspection and Certification checklist (document 25_154EN) to show proper process of adverse actions according to the regulations. Revised document 25_154EN was submitted to the NOP. BioI provided training to the staff and submitted the power point presentation that was used, which included these revised procedures.

Non-compliances Identified during the Current Assessment

Any noncompliance labeled as "**Accepted**," indicates that the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP4252LCA.NC1 – Accepted. 7 CFR §205.660(d) states that "Each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued pursuant to §205.662, §205.663, and §205.665 and each response to such notification must be sent to the recipient's place of business via a delivery service which provides dated return receipts."

Comments: *Notifications of noncompliance resolution are not issued by BioI via a delivery service which provides dated return receipts.*

2015 Corrective Action: BioI submitted an updated Inspection and Certification checklist with the procedure to send all notification of noncompliance resolutions via registered letter.

NP4252LCA.NC2 – Accepted. 7 CFR §205.642 states, "The certifying agent shall provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification."

Comments: *In general, BioI provides new applicants and operations for continuing certification its published fee schedule that allows them to estimate their certification costs. International operations and operations that request an estimate of certification expenses are provided one. However, BioI is not providing all new applicants and all continuing operations a cost estimate of initial or continuing certification.*

2015 Corrective Action: BioI will provide all applicants and all continuing operations a cost estimate. The templates for the estimates were submitted. One is for new applicants and one is for continuing operations. BioI also submitted the procedure for NOP Inspection and Certification. Chapter 2 of the procedure was updated to clarify that BioI staff would use the new templates for both new applicants and continuing operations. The term "Offer" was added to the documents 22_001, 23_001 and 25_1001, referring to the estimate of certification costs. Additionally, the procedure was added to the document NOP concept 25_422EN. The certification staff and inspectors were trained on the new procedure.

NP4252LCA.NC3 – Accepted. 7 CFR §205.501(a)(1) states that certifiers must "Have sufficient expertise in organic production or handling techniques to fully comply with and implement the terms and conditions of the organic certification program established under the Act and the regulations in this part."

- 7 CFR §205.662(a) states, "When an inspection, review, or investigation of a certified operation by a certifying agent or a State organic program's governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation."
- 7 CFR §205.662(c) states, "When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance.
- 7 CFR §205.662(e)(1) states, "If the certified operation fails to correct the noncompliance, to resolve the issue through rebuttal or mediation, or to file an appeal of the proposed suspension or revocation of certification, the certifying agent…shall send the certified operation a written notification of suspension or revocation."

Comments: *BioI issued a certified operation a Notice of Certification Termination without following the noncompliance and adverse actions processes as required by the USDA organic regulations.*

2015 Corrective Action: The procedure was updated in the Inspection and Certification checklist to show proper process of adverse actions according to the regulations. BioI plans to check the compliance of the procedure as part of the internal audit. BioI provided training to the staff and submitted the power point presentation that was used, which included this procedure.

NP4252LCA.NC4 – Accepted. 7 CFR §205.501(a)(1) states that certifiers must "Have sufficient expertise in organic production or handling techniques to fully comply with and implement the terms and conditions of the organic certification program established under the Act and the regulations in this part."

- 7 CFR §205.662(a)(1) states that, "When an inspection, review, or investigation of a certified operation by a certifying agent or a State organic program's governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation. Such notification shall provide: A description of each noncompliance."

Comments: *Several noncompliances were reviewed for content and applicability during the audit. Noncompliances did not correctly match the regulatory citation to the evidence or the inspector's description. Several noncompliances cited a general regulatory reference without specifically identifying the applicable subsection of the regulation. Inspectors are not required to reference the organic regulation when identifying issues of concern in their reports or during the exit interview. During one of the witness audits, the inspector identified an issue of concern relating to record keeping (7 CFR §201.103(b)(4)), but indicated to the auditor that it was a label violation (7 CFR §205.300-311). When the auditor questioned the inspector for more specifics about the reference, the inspector showed the auditor BioI handouts from a recent training as supporting evidence of the noncompliance.*

2015 Corrective Action: BioI provided training to the inspectors and submitted the power point presentation that was used, which included this topic.

NP4252LCA.NC5 – Accepted. 7 CFR §205.501(a)(21) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms or conditions determined by the Administrator to be necessary." Furthermore, NOP Policy Memo (PM) 11-10 (dated 01/21/11) states, "Grower group certification… accredited certifying agents should use the National Organic Standards Board (NOSB) recommendations of October 2002 and November 2008 as the current policies."
Comments: *There are several grower group certified operations located in Turkey and on the January 2, 2014 list submitted to the NOP. A review of those operations revealed that they do not meet the definition of a grower group because there is no Internal Control System (ICS) and the groups are not responsible for their own certification. Instead these operations are a group of independent farmers that are contracted by a trader or exporter to provide product; the trader or exporter is the named party on the organic certificate.*
2015 Corrective Action: BioI submitted a plan that will be implemented over the next two years as follows and will require the operations in Turkey to either 1) obtain individual certification or 2) develop an Internal Control System to be certified as a grower group:

- Phase 1 (2015) – inform clients regarding options (1 & 2 above) and costs, BioI and clients consider and decide suitable option for each client situation, BioI prepares training sessions for ICS, and BioI trains staff regarding ICS in Turkey.
- Phase 2 (2016) – Implementation and complete inspections and certification of those clients who choose option 1) to obtain individual certification.
- Phase 2 (2016) – BioI trains farmer groups regarding requirements for ICS in Turkey, farmer groups develop and start introduction of ICS, BioI conducts pre-audits at pilot farmer groups, and BioI approved inspectors for ICS in Turkey.
- Phase 3 (2017) – Implementation and complete inspections and certifications of option 2) ICS farmer groups.

BioI is required to submit progress reports to the NOP on a regular basis during each Phase of the plan.

NP4252LCA.NC6– Accepted. 7 CFR §205.501(a)(21) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms or conditions determined by the Administrator to be necessary." Furthermore, NOP 4009 "Who Needs to be Certified?" in the program handbook states, "When organically producing or handling agricultural products, a certified operation may not: Allow an uncertified operation to produce or handle agricultural products, under contract or other arrangement, on the uncertified operation's land or premises (i.e., at units, facilities, or sites not explicitly subject to inspection or compliance action by the NOP or a certifying agent*)."*
Comments: *In addition to the groups of producers listed as certified by BioI, there appear to be several contracted processing facilities involved in the handling (drying, sorting, storing, and packing) of crops supplied by these groups that are being labeled as organic.*
2015 Corrective Action: BioI provided training to the inspectors and staff and submitted the power point presentations that were used, which included this topic. A letter was sent out to all applicable clients via email February 24, 2015 informing them of the requirement that all

operations must obtain their own organic certification and cannot be subcontracted within the certification of another operation and referring to NOP 4009. A copy of the letter was submitted to NOP. BioI is currently conducting inspections and processing certifications of these operations. They expect certifications to be carried out until December 2015.

NP4252LCA.NC7 – **Accepted.** 7 CFR §205.403(e)(2) states, "A copy of the onsite inspection report and any test results will be sent to the inspected operation by the certifying agent."

Comments: *Pesticide residue results obtained by BioI are not consistently issued to the operations.*

2015 Corrective Action: BioI submitted the revised Sample Collection and Analysis of Residues procedure to include sending the results of analysis to the client. BioI provided training to the inspectors and staff and submitted the power point presentations that were used, which included this topic.

NP4252LCA.NC8 – **Accepted.** 7 CFR § 205.403 (c)(1) states, "The onsite inspection of an operation must verify: the operation's compliance or capability to comply with the Act and the regulations in this part."

Comments: *During the witness inspection of a handler operation, the inspector did not verify transportation clean-out documentation even though it was clear that the operation was responsible for procuring transportation of the organic wheat from the crop operations to the storage facility.*

2015 Corrective Action: BioI submitted a revised checklist with the added note for inspectors to check that cleaning documentation is available. BioI provided training to the inspectors and submitted the power point presentation that was used, which included this topic

NP4252LCA.NC9 – **Accepted.** 7 CFR § 205.403 (e)(2) states, "A copy of the onsite inspection report … will be sent to the inspected operation by the certifying agent."

Comments: *During the witness inspection of a handler operation, it was confirmed that the operator was not provided with a copy of its inspection report in 2013.*

2015 Corrective Action: BioI submitted the revised Inspection and Certification checklist that requires a copy of the inspection report to be sent to all national and international operations.

NP4252LCA.NC10 – **Accepted.** 7 CFR § 205.404 (b) states, "The certifying agent must issue a certificate of organic operation…." NOP 2603 Organic Certificates indicates that "Organic certificates should … include the following:

- Categories of organic operation (crops, wild crops, livestock, and handling/processing)
- Anniversary date (when the certified operation must submit its annual update)

Comments: *The categories on organic certificates issued by BioI are production, preparation, storage, and trade, which do not comply with the categories required by the USDA NOP. The anniversary date is not listed on organic certificates.*

2015 Corrective Action: BioI submitted certificates to show the categories of operation, according to the NOP regulations, and the anniversary date have been added.

1400 Independence Avenue, S.W.
Room 2648-South, STOP 0268
Washington, D.C. 20250

AUDIT INFORMATION

Applicant Name:	Bio.inspecta AG
Est. Number:	N/A
Physical Address:	Ackerstrasse, CH-5070 – Frick, Switzerland
Mailing Address:	Ackerstrasse, CH-5070 – Frick, Switzerland
Contact & Title:	Julia Winter, Head of NOP Certification
E-mail Address:	julia.winter@bio-inspecta.ch
Phone Number:	+41 (0) 62 865 63 24
NOP Reviewer	Robert Pooler, NOP Accreditation Manager
Program:	USDA National Organic Program (NOP)
Audit Date(s):	January 20 – February 15, 2012
Audit Identifier:	NP1234NNA
Action Required:	No
Audit Type:	Mid-Term Assessment / Corrective Action Review
Audit Objective:	To verify continuing compliance to the audit criteria.
Audit Criteria:	*7 CFR Part 205 National Organic Program (NOP) Final Rule,* dated December 21, 2000; as amended February 14, 2012.
Audit Scope:	The company's quality manual including personnel, processes, procedures, facilities, and related records.
Location(s) Audited:	Desk audit

Bio.inspecta AG's (Bio.inspecta) Mid-Term Assessment was conducted on August 22 – 25, 2011.

On September 26, 2011, the NOP issued a Notice of Non-compliance to Bio-inspecta for eleven non-compliances (NP1234NNA.NC1 – 11) identified during the Mid-Term assessment, and for three outstanding noncompliances (NP6254EEA.NC1, NP9173ACA.NC2 & 7) identified during previous NOP accreditation assessments conducted in 2006 and 2009.

On October 25, 2011, Bio.inspecta submitted proposed corrective actions for non-compliances NP1234NNA.NC1 – 11, and for the three outstanding noncompliances, NP6252EEA.NC1 and

NP9173ACA.NC2 & 7. On January 25 – 26, 2012, the NOP reviewer requested additional information on NP1234NNA.NC3, 10 &11 and NP9173ACA.NC2. In response to this request, Bio.inspecta submitted additional information on its certification program, along with associated program forms on January 30, 2012. To address the noncomplainces, Bio.inspecta submitted the following proposed corrective actions:

- A summary of proposed corrective actions for noncompliances NP1234NNA.NC1 – 11 identified during the 2011 Mid-Term assessment, and proposed corrective actions for the three outstanding noncompliances, NP6254EEA.NC1 and NP9173ACA.NC2 & 7, identified during previous NOP accreditation assessments.
- Amended handling organic system plan form and annual update form for handling operations.
- Amended livestock organic system plan form which requests descriptions of pasture practices for implementation of NOP regulation requirements.
- Bio.inspecta Noncompliance notification templates.
- Revised Bio.inspecta NOP training program.
- Bio.inspecta 2012 fee schedule for NOP certification.
- Bio.inspecta combined notice of Noncompliance and denial of certification.
- Results of residue tests conducted in 2011.
- Bio.inspecta form on NOP inspection and certification decision.
- 2011 Bio.inspecta conflict of interest disclosure reports.
- Bio.inspecta instructions on sample collection, procedure for analysis of residues, and sampling record template.

FINDINGS

Documents and records reviewed determined that Bio.inspecta AG has adequately addressed the eleven non-compliances identified during the Mid-Term Assessment and the three outstanding noncompliances from previous NOP accreditation assessments.

NP6254EEA.NC1 – Accepted and Adequately Addressed - NOP §205.501 11 (v) - General Requirements for Accreditation states, "Prevent conflicts of interest by: requiring all persons who review applications for certification, perform on-site inspection, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent to complete an annual conflict of interest disclosure report." *The Board of Directors and two employees did not have current (annual) conflict of interest statements on file since their "Contract Agreement" uses different terminology, and does not contain the conflict of interest clause that all other personnel contracts contain.* **Corrective Action:** No corrective action submitted. **Corrective Action (August 27, 2007):** Bio.inspecta AG stated in the corrective actions that they submitted Conflict of Interest Disclosure Reports; however,

there were no conflict of interest disclosure reports attached to the corrective actions. **Corrective Action (December 5, 2007):** Conflict of Interest Disclosure Reports were submitted for all 12 principles and inspectors of the society. This adequately addresses the finding. **Verification of Corrective Action (June 2009):** Conflict of Interest Disclosure Reports were reviewed for the previous and current personnel involved in inspections, document review and certification of operations and most were found to be in compliance. However, the Bio.inspecta Division Managers, one Division Quality Manager, and one Inspector had not completed the conflict of interest disclosure report. **Corrective Action:** Conflict of interest disclosure reports for the Division Managers, Quality Manager, and inspector was submitted and reviewed. **2011 Mid-Term Assessment Finding:** There were no conflict of interest disclosure reports on file for one of the five members on the Administrative board of directors and one of the five members on the Executive board of directors. Also, there were no current conflict of interest disclosure reports on file for three of the subcontracted inspectors. Based upon this finding, the noncompliance, accepted as adequately addressed in 2009, was reverted to outstanding.

Corrective Actions: The corrective actions adequately address the noncompliance. Bio.inspecta submitted the missing conflict of interest disclosure reports as part of its corrective actions. Bio.inspecta modified its quality system procedures to indicate that conflict of interest reports will be compiled annually at the end of February. Verification of these corrective actions will be determined at the next on-site NOP accreditation assessment.

NP9173ACA.NC2 – Accepted and Adequately Addressed - NOP §205.501 (a)(6) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services." *One member of the Certification Committee had no current performance evaluation. Also, the contract inspectors did not have current performance evaluations.* **Corrective Action:** Bio.inspecta submitted a statement indicating that all inspectors and certifying staff will have a performance evaluation at least once a year. **2011 Mid-Term Assessment Finding:** One staff and one subcontracted inspector's most recent performance evaluation was dated in 2009, and two subcontracted inspectors did not have a performance evaluation in their file at all. Based upon this finding, the noncompliance, accepted as adequately addressed in 2009, was reverted to outstanding.

Corrective Actions: The corrective actions have adequately addressed the noncompliance. Bio.inspecta's corrective actions submitted in November 2011 were the same corrective action as submitted in 2009. The 2011 Mid-Term Assessment determined that this corrective action was not effectively implemented. The NOP reviewer requested additional information on when

Bio.inspecta staff have had or will have performance evaluations. Bio.inspecta's January 2012 response indicated that inspector / contractor inspector reports are assessed by certification staff and these assessments are part of the performance evaluation given at Bio.inspecta's annual staff training in February and March 2012. Certification staff will also receive their performance evaluations at the annual training. Verification of these corrective actions will be determined at the next on-site NOP accreditation assessment.

NP9173ACA.NC7 – Accepted and Adequately Addressed - NOP §205.662(a)(3) & (b) states, "When an inspection, review, or investigation of a certified operation by a certifying agent… reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation. Such notification shall provide: (3) the date by which the certified operation must rebut or correct each noncompliance and submit supporting documentation… (b) When a certified operation demonstrates that each noncompliance has been resolved, the certifying agent… shall send the certified operation a written notification of noncompliance resolution." *Bio.inspecta had a client that had a noncompliance identified during the onsite inspection but the client submitted corrective actions before the report was sent out. Bio.inspecta did not send a written notification of noncompliance resolution.* **Corrective Action:** Bio.inspecta has modified and added a new check point on form 24_154 to ensure that a noncompliance resolution is sent to the client. Bio.inspecta stated they did inform the referenced client that the corrective actions submitted were adequate. **2011 Mid-Term Assessment Finding:** While Bio.inspecta has been issuing notices of noncompliance in the required manner, notices of resolution have not been sent to certified operations when corrective action is accepted as adequate. Based upon this finding, the noncompliance, accepted as adequately addressed in 2009, was reverted to outstanding.

Corrective Actions: The corrective actions adequately address the noncompliance. Bio.inspecta submitted a Notice of Noncompliance Resolution template as part of its corrective actions for this noncompliance. Bio.inspecta has modified its quality system procedures to indicate that noncompliance resolution letters will be sent to operations when noncompliances are resolved. Verification of these corrective actions will be determined at the next on-site NOP accreditation assessment.

NP1234NNA.NC1 – Accepted and Adequately Addressed. NOP §205.402 (a)(1) states, "Upon acceptance of an application for certification, a certifying agent must: Review the application to ensure completeness pursuant to §205.401." *Certification files reviewed verified that applications that include the organic system plan (OSP) are not complete before the inspection is assigned.*
The OSP for the handler witness audit did not contain:

- *Cleaning procedures for all equipment; in particular the equipment used for oil distillation. The witness audit verified that sometimes alcohol is used to clean the equipment but this information was not included in the OSP. The OSP indicated that only water and vinegar were used for cleaning;*

- *A list or general information on all equipment utilized;*
- *Procedures for how raw materials are verified as being NOP organic upon receipt;*
- *Procedures for monitoring and the frequency of the monitoring activities of receiving, production, and shipping practices to ensure the organic system plan is effectively implemented;*
- *Current labels utilized by the operation; and*
- *The process for how the product is treated with CO2.*

The OSP for the livestock witness audit did not contain or identify:

- *Homeopathic materials used on the livestock operation.*

Corrective Actions: The corrective actions adequately address the noncompliance. Bio.inspecta's handling OSP forms have been amended to include requests for information on equipment utilized and cleaning procedures used during processing. The amended handling OSP also requires the operation provide:

- A complete list of products, ingredients, additives, processing aids, and suppliers.
- A description of monitoring and internal quality control practices, including practices used for monitoring receipt of and use of ingredients.
- Labels used on organic products.

Bio.inspecta's inspection form for organic livestock production has been amended to include an assessment of medications, including homeopathic materials, which may be used during livestock health care practices. Certifiers will review this information for NOP compliance before scheduling inspections. If the OSP is not compliant or is incomplete, the inspection will not be scheduled. To prevent this noncompliance from reoccurring, Bio.inspecta modified its quality system by amending the OSP forms to require more detailed descriptions and amended its OSP review procedures to assess OSP's for NOP compliance before inspections are scheduled. Verification of these corrective actions will be determined at the next on-site NOP accreditation assessment.

NP1234NNA.NC2 – Accepted and Adequately Addressed. NOP §205.402 (a)(2) states, "Upon acceptance of an application for certification, a certifying agent must: Determine by a review of the application materials whether an applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part." *The files reviewed and interviews conducted verified that inspectors are making approval decisions for labels, materials, and inputs during inspections. Additionally, there is no procedure or process for the ACA to review and approve labels prior to inspection to enable inspectors to verify the use of approved labels. Three of three labels reviewed for one handler (Sabo) had the "Certified by" statement above the information identifying the distributor as opposed to below it. The review of livestock files verified that Bio.inspecta approved the use of Endex (levamasole) and the antibiotic Engemycin (tetracycline) in cattle. Neither substance is on the National List of approved substances.*

Corrective Actions: The corrective actions adequately address the noncompliance. Bio.inspecta amended its procedures on reviewing organic system plans, or amendments to plans, to specify that production practices, materials, labels, and other plan information are reviewed for compliance by a staff certifier prior to scheduling an inspection. The amended procedures also indicate that OSP's or amended OSP's will be verified during the inspection. The inspector will only verify the OSP and will not be making certification decisions. If the OSP is not complete or is not compliant with the NOP regulations, the certifier will not schedule the inspection. When reviewing labels, the certifiers will not approve labels unless the term "certified by" appears below the information identifying the distributor. Also, certifiers will review livestock medications for NOP compliance and will only approve materials that comply with the NOP regulations. Verification of these corrective actions will be determined at the next on-site NOP accreditation assessment.

NP1234NNA.NC3 – Accepted and Adequately Addressed. NOP §205.406 (b) states, "Following the receipt of the information specified in paragraph (a) of this section, the certifying agent shall within a reasonable time arrange and conduct an on-site inspection of the certified operation pursuant to §205.403." *Bio.inspecta has not required operators to submit updates to the organic system plan if there are no changes to the plan. Updates to the organic system plan are collected at the time of inspection.*

Corrective Actions: The corrective actions adequately address the noncompliance. Bio.inspecta changed its certification review checklist to specify that certifiers will review annual OSP updates for compliance before scheduling inspections. The change in the checklist has been incorporated into the quality manual procedures. In March 2012, Bio.inspecta will train staff involved with NOP certification on the amended procedures. Verification of these corrective actions will be determined at the next on-site NOP accreditation assessment.

NP1234NNA.NC4 – Accepted and Adequately Addressed. NOP §205.501 (a)(7) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Have an annual program review of its certification activities conducted by the certifying agent's staff, an outside auditor, or a consultant who has expertise to conduct such reviews…" *Bio.inspecta conducts annual program reviews; however, the reviews are general in nature and do not include NOP specifically in the scope. The program review was specific to the quality management system as it pertained to the requirements of Bio.inspecta's ISO accreditation in general and not specific to the NOP Final Rule requirements.*

Corrective Actions: The corrective actions adequately address the noncompliance. Bio.inspecta will include NOP regulation requirements within the scope of its next annual review in March 2012. Verification of these corrective actions will be determined at the next on-site NOP accreditation assessment.

NP1234NNA.NC5 – **Accepted and Adequately Addressed.** NOP §205.501 (a)(8) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Provide sufficient information to persons seeking certification to enable them to comply with the applicable requirements of the Act and the regulations in this part." *Bio.inspecta has not addressed the Pasture practice standard under §205.240 and dry matter intake requirements under §205.237 with applicants or certified operations. Bio.inspecta applies the Bio Suisse rules for requirements of pasture of 156 days with 25% dry matter from pasture. They feel this is a stricter standard and meets the NOP pasture standard.*

Corrective Actions: The corrective actions adequately address the noncompliance. Beginning in January 2012, Bio.inspecta will provide notice to clients on the pasture practice standard under § 205.240 and dry matter requirements under § 205.237. Bio.inspecta has amended its quality system by modifying the organic livestock OSP form to request information on the NOP pasture practice standard and pasture dry matter feeding requirements. During inspections, the inspector must also assess whether an operation is complying with the NOP requirement for 30% dry matter intake from pasture grazed during the grazing season, and determine if ruminants have had access to pasture for at least 120 days during the grazing season. Verification of these corrective actions will be determined at the next on-site NOP accreditation assessment.

NP1234NNA.NC6 – **Accepted and Adequately Addressed.** NOP §205.501 (a)(11)(iv) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Prevent conflicts of interest by: Not giving advice or providing consultancy services, to certification applicants or certified operations, for overcoming identified barriers to certification." *The review of letters of noncompliance sent to operators indicated that Bio.inspecta is outlining corrective actions for the operator to implement to resolve noncompliances.*

Corrective Actions: The corrective actions adequately address the noncompliance. In 2012, inspectors will no longer assess noncompliances. Certifiers will issue Notices of Noncompliance to certified operations or new applicants. The operation receiving the notice will be required to propose and implement corrective actions to resolve noncompliances. Bio.inspecta has modified its quality system procedures to implement these changes when noncompliances are identified during NOP certification activities. Verification of these corrective actions will be determined at the next on-site NOP accreditation assessment.

NP1234NNA.NC7 – **Accepted and Adequately Addressed.** NOP §205.501 (a)(18) states, "A private or governmental entity accredited as a certifying agent under this subpart must: …notify the inspector of its decision regarding certification of the production or handling operation site inspected by the inspector and of any requirements for the correction of minor non compliances." *Bio.inspecta does not notify the inspector of the certification decision for all sites. The practice has been to only make notification to the inspector if there have been changes in the decisions from the inspection report.*

Corrective Actions: The corrective actions adequately address the noncompliance. Bio.inspecta has modified its procedures to indicate that an inspector will receive a copy of the certification decision when notification is provided to the operation. Bio.inspecta has established letter and checklist templates for providing notifications on NOP certification decisions to clients and the inspector. Verification of these corrective actions will be determined at the next on-site NOP accreditation assessment.

NP1234NNA.NC8 – **Accepted and Adequately Addressed.** NOP §205.504 (a)(1) states, "A private or governmental entity seeking accreditation as a certifying agent must submit the following documents and information to demonstrate its expertise in organic production or handling techniques… (1) A copy of the applicant's policies and procedures for training, evaluating, and supervising personnel." *Bio.inspecta does not have a documented training program for their certifiers which conduct the initial review of applications for completeness and compliance. This is a concern as indicated by the findings outlined under non-compliances for §205.402 (a) (1) and (2) and interviews conducted which verified that Bio.inspecta has hired new certifiers since the previous NOP assessment conducted in 2009. In addition the training program for new inspectors does not include the requirement that they forego two acceptable shadow inspections before conducting inspections on their own as indicated by Bio.inspecta during interviews.*

Corrective Actions: The corrective actions adequately address the noncompliance. Bio.inspecta revised its training programs for new inspectors and certifiers. The training program covers procedures for initially reviewing OSP's for completeness and compliance with the NOP regulations. Bio.inspecta also modified its quality system procedures to indicate that new inspectors without experience must accompany experienced inspectors on inspections until sufficient experience is obtained. When the experience training is complete, the trained inspectors will be independently assigned to carry out inspections. Verification of these corrective actions will be determined at the next on-site NOP accreditation assessment.

NP1234NNA.NC9 – **Accepted and Adequately Addressed.** NOP §205.642 states, "Fees charged by a certifying agent must be reasonable, and a certifying agent shall charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator.… The certifying agent may require applicants for certification to pay at the time of application a nonrefundable fee which shall be applied to the applicant's fees-for-service account. The certifying agent may set the nonrefundable portion of certification fees; however, the nonrefundable portion of certification fees must be explained in the fee schedule submitted to the Administrator. The fee schedule must explain what fee amounts are nonrefundable and at what stage during the certification process fees become nonrefundable." *Bio.inspecta forwarded a copy of the fee schedule for international clients to the Administrator. However, the price list for domestic clients was not submitted. It is not clear what portion of the fees is nonrefundable.*

Livestock and Seed Program
Audit, Review, and Compliance Branch
Quality System Audit Report

AUDIT INFORMATION

Applicant Name:	bio.inspecta AG
Est. Number:	N/A
Physical Address:	Ackerstrasse, CH-5070 – Frick, Switzerland
Mailing Address:	Ackerstrasse, CH-5070 – Frick, Switzerland
Contact & Title:	Raffaella Mini, Head of NOP Certification
E-mail Address:	raffaella.mini@bio-inspecta.ch
Phone Number:	+41(0)62 865 63 24
Auditor(s):	David J. Hildreth
Program:	USDA National Organic Program (NOP)
Audit Date(s):	December 9, 2009 and March 23, 2010
Audit Identifier:	NP9173ACA
Action Required:	Yes
Audit Type:	Corrective Action Audit
Audit Objective:	To verify that corrective actions adequately address the non-compliances identified during the surveillance-accreditation renewal audit.
Audit Criteria:	*7 CFR Part 205 National Organic Program (NOP) Final Rule*, dated December 21, 2000; updated May 14, 2009.
Audit Scope:	Submitted corrective actions
Location(s) Audited:	Desk
NOP Reviewer:	Meg Kuhn, Regional Accreditation Manager
NOP Review:	October

Bio.inspecta submitted corrective actions to the National Organic Program for the non-compliances identified during the surveillance-accreditation renewal audit conducted June 22-26, 2009. The corrective actions were forwarded to the auditor on September 18, 2009. Additional information was received from bio.inspecta on November 20, 2009. Further corrective actions from bio.inspecta were requested by the auditor on December 8, 2009 and February 8, 2010. On October 6, 2010, the NOP requested additional correction responses from bio.inspecta regarding NP9173ACA.NC6. A response was received October 20, 2010.

FINDINGS

The corrective actions submitted by bio.inspecta adequately addressed ten of the eleven non-compliances identified during the previous audit. One non-compliance has been cleared and one non-compliance remains outstanding (not adequately addressed).

NP6254EEA.NC6 - Minor – Cleared - NOP § 205.670(b) Inspection and testing of agricultural products states, "Such tests must be conducted by the applicable State organic program's governing State official or the certifying agent at the official's or certifying agent's own expense." *Bio.inspecta procedures allow the company to charge the client if the results of testing are positive. This is not in accordance with the Rule.* **Corrective Action:** No corrective action submitted. **Corrective Action (Submitted August 27, 2007):** bio.inspecta AG will no longer charge the client for testing. The Internal NOP Procedures: Inspection, Evaluation and Certification (25_125e/Version 1.2, Clause 11.4.2) was revised and now states, "…Analysis Results – If bio.inspecta believes that organic product has been in touch with a prohibited substance bio.inspecta will order and pay some analysis." This change in the procedure now meets the NOP requirement. **Verification of Corrective Action***:* The fee schedule that was submitted as the corrective action was revised since its submission and the current fee schedule submitted to the administrator in 2009 allows the company again to charge the client if the results of testing are positive. **Corrective Action (Submitted September 18, 2009):** Bio.inspecta amended clause 11.4.2 of the new document 25_111/Version 1.0 to reflect the requirements of the NOP. **Onsite Verification:** Verified change to clause 11.4.2 during onsite audit and bio.inspecta has not charged clients for testing.

NP6254EEA.NC1 – Minor – Adequately Addressed - NOP § 205.501 11 (v) - General Requirements for Accreditation states, "Prevent conflicts of interest by: requiring all persons who review applications for certification, perform on-site inspection, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent to complete an annual conflict of interest disclosure report." *The Board of Directors and two employees did not have current (annual) conflict of interest statements on file since their "Contract Agreement" uses different terminology, and does not contain the conflict of interest clause that all other personnel contracts contain.* **Corrective Action:** No corrective action submitted. **Corrective Action (Submitted August 27, 2007):** Bio.inspecta AG stated in the corrective actions that they submitted Conflict of Interest Disclosure Reports; however, there were no conflict of interest disclosure reports attached to the corrective actions. **Corrective Action (December 5, 2007):** Conflict of Interest Disclosure Reports were submitted for all 12 principles and inspectors of the society. This adequately addresses the finding. **Verification of Corrective Action Onsite:** Conflict of Interest Disclosure Reports were reviewed for the previous and current personnel involved in inspections, document review and certification of operations and most were found to be in compliance. However, the bio.inspecta Division Managers, one Division Quality Manager, and one Inspector had not completed the conflict of interest disclosure report. **Corrective Action:** Conflict of interest disclosure reports for the Division Managers, Quality Manager, and inspector was submitted and reviewed.

NP6254EEA.NC3 - Minor – Adequately Addressed - NOP § 205.404(b) 2 requires that the certifying agent must issue a certificate of organic operation which specifies the: effective date of certification. *The current bio.inspecta certificate does not contain the effective date of certification, but does contain the*

most current information regarding certification and products certified. This is a departure from the style of certificate originally submitted to the Secretary at accreditation. **Corrective Action**: No corrective action submitted. **Corrective Action (Submitted August 27, 2007):** bio.inspecta AG stated in the corrective action that the first date of certification appears on the revised NOP certificate; however, a revised certificate was not submitted for review. **Corrective Action (December 5, 2007):** A copy of the most current version of the National Organic Program Certificate was submitted. This update adequately addresses the finding. **Verification of Corrective Action:** The certificate currently used by bio.inspecta only has the year of the "First Certification". The certificate issued by bio.inspecta does not include the complete effective date. **Corrective Action:** Bio.inspecta revised the NOP certificate and it now has a complete effective date.

NP9173ACA.NC1 – Adequately Addressed - NOP §205.404 (b)(3) states, "The certification agent must issue a certificate of organic operation which specifies the: (3) Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation." *The certificates issued by bio.inspecta do not include the categories of organic operation on the certificate.* **Corrective Action:** Bio.inspecta revised the NOP certificated and submitted an example certificate that included the categories of organic operation.

NP9173ACA.NC2 – Adequately Addressed - NOP § 205.501 (a)(6) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services." *One member of the Certification Committee had no current performance evaluation. Also, the contract inspectors did not have current performance evaluations.* **Corrective Action:** Bio.inspecta submitted a statement indicating that all inspectors and certifying staff will have a performance evaluation at least once a year.

NP9173ACA.NC3 – Adequately Addressed - NOP § 205.401(c) states, "The names of any organic certifying agent to which application has previously been made; the years of application, the outcome of the application(s) submission, including, when available, a copy of any notification of noncompliance or denial of certification issued to the applicant for certification; and a description of the actions taken by the applicant to correct the noncompliance noted in the notification of noncompliance, including evidence of such correction." *The current application does not include questions to address this requirement of the NOP rule.* **Corrective Action:** Bio.inspecta has revised the application to include an area and question if the applicant has applied to other certifying agents for certification.

NP9173ACA.NC4 – Adequately Addressed - NOP §205.642 states, "…The certifying agent shall provide each applicant with an estimate of the total cost of certification and estimate of the annual cost of updating the certification." *The current bio.inspecta procedures do not provide clients with fee estimates with the application.* **Corrective Action:** Bio.inspecta revised the fee schedule and will provide each applicant an estimate prior to the onsite evaluation.

NP9173ACA.NC5 – Adequately Addressed - NOP §205.510(a) states, "An accredited certifying agent must submit annually to the Administrator, on or before the anniversary date of the issuance of the notification of accreditation, the following report and fees: (1)-(5)." *Bio.inspecta has not submitted the 2009 Annual Update to the Administrator*. **Corrective Action:** Bio.inspecta has spoken with NOP and they stated that bio.inspecta must submit the 2009 annual update prior to April 15, 2010.

NP9173ACA.NC7 – Adequately Addressed - NOP §205.662(a)(3) & (b) states, "When an inspection, review, or investigation of a certified operation by a certifying agent… reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation. Such notification shall provide: (3) the date by which the certified operation must rebut or correct each noncompliance and submit supporting documentation… (b) When a certified operation demonstrates that each noncompliance has been resolved, the certifying agent… shall send the certified operation a written notification of noncompliance resolution." *Bio.inspecta had a client that had a noncompliance identified during the onsite inspection but the client submitted corrective actions before the report was sent out. Bio.inspecta did not send a written notification of noncompliance resolution.* **Corrective Action:** Bio.inspecta has modified and added a new check point on form 24_154 to ensure that a noncompliance resolution is sent to the client. Bio.inspecta stated they did inform the referenced client that the corrective actions submitted were adequate.

NP9173ACA.NC8 – **Adequately Addressed -** NOP §205.303(b)(1) states, "For products labeled "organic," identify each organic ingredient in the ingredient statement with the word, "organic," or with an asterisk or other reference mark which is defined below the ingredient statement to indicate the ingredient is organically produced." *One of the labels reviewed did not identify each organic ingredient in the ingredient statement with the word "organic" or with an asterisk or other reference mark.* **Corrective Action:** Bio.inspecta modified the form 25_169 stating that the labels have to identify each organic ingredient in the ingredient statement with the word organic or with an asterisk or other reference mark.

NP9173ACA.NC6 - Adequately Addressed - NOP § 205.237 (a) states, "The producer of an organic livestock operation must provide livestock with a total feed ration composed of agricultural products, including pasture and forage, that are organically produced and, if applicable, organically handled." *During the on-site witness inspection, it was noted that the dairy operation was using an unapproved feed processor to convert home raised corn silage into corn pellets. The inspector stated that this was approved because the farmer supervised the processing of his own forages.* **Corrective Action:** Bio.inspecta stated the feed processor did not have to be certified to the NOP standards due to the company not having an income of more than $5000.00. Further clarification from the NOP stated, "If an operation is processing products for a certified operation, it must be certified as a handler or included in the OSP for the farmer who owns the silage. Either way, the ACA must approve and review the operation." Additional corrective action was requested from bio.inspecta via email on December 8, 2009 and February 8, 2010; however, no response has been received.

NOP Reviewer: A response to this item was requested on October 6, 2010. The response was received October 20, 2010.

NOP Review: The audit where the NC was cited occurred in June 2009, prior to the Access to Pasture rule change in the Federal Register. The change in the Federal Register occurred on February 17, 2010. The change included the requirement that all feed be certified organic; the previous release of the Rule stated, "the producer of an organic livestock operation must provide livestock with a total feed ration composed of agricultural products… that are organically produced and, if applicable, organically handled…." The "further clarification from the NOP" referenced in the "Corrective Action" response from the ARC Auditor above was sent to the ARC Auditor on January 14, 2010 – prior to the release of the new "certified" requirement for all organic feed. The practice of allowing feed from an exempt producer prior to February 17, 2010 was widely accepted in the organic industry; once the Feb 17, 2010 Federal Register was released, this practice became non-compliant. Bio.inspecta confirmed its understanding of the new rules for feed per §205.237(a); confirmed that it no longer allows feed from exempt producers as acceptable feed for their NOP certified organic livestock operations; and demonstrated that its procedures have been appropriately updated to reflect this rule change. Therefore, the NC is considered adequately addressed.