United States Department of Agriculture

Agricultural Marketing Service
National Organic Program

CERTIFICATE OF ACCREDITATION

BIO.INSPECTA AG

Ackerstrasse 117, Frick, CH-5070, 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, Handling, Livestock, Wild Crops 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: USDA-51-25
Effective Date: 04/15/2024
Expiration Date: 04/15/2029
Issue Date: 04/11/2025

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National Organic Program
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NATIONAL ORGANIC PROGRAM: AUDIT & CORRECTIVE ACTION REPORT

GENERAL INFORMATION

- **Certifier Name** bio.inspecta AG, (BIOI)
- **Physical Address** Ackerstrasse 117, Frick, CH-5070, SWITZERLAND
- **Audit Type** Renewal Audit
- **Auditor(s) & Audit Dates** Joshua Lindau, Kendra Volk, 04/15/2024 to 04/20/2024
- **Audit Identifier** NOP-8-24

CERTIFIER OVERVIEW

The National Organic Program (NOP) conducted an onsite Renewal Audit of bio.inspecta AG's (BIOI) USDA organic certification program covering the period November 11, 2021, to April 19, 2024. The purpose of the audit was to verify BIOI's compliance with the Organic Foods Production Act of 1990 (OFPA), the USDA organic regulations (7 CFR Part 205), and the NOP Handbook. Audit activities included a review of certification activities, interviews with BIOI personnel, a records audit, two onsite witness audits and one onsite review audit. The review audit was conducted at a crops/handling operation in Turkey. The two witness audits consisted of two annual inspections of handling operations; both operations are in Switzerland.

BIOI is an incorporated company initially accredited on April 15, 2014. BIOI is accredited to the crops, wild crops, livestock, and handling scopes. BIOI's office is in Frick, Switzerland. BIOI certifies 164 operations and offers certification services in Albania, Azerbaijan, Belgium, Burkina Faso, Egypt, India, Indonesia, Iran, Kosovo, Kyrgyzstan, Lebanon, Moldova, Senegal, Switzerland, Tanzania, Turkey, Ukraine, and the United Arab Emirates. Certification activities are performed by 38 employees.

NOP DETERMINATION:

NOP reviewed the 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 audit.

Any noncompliance labeled as "**Accepted**" indicates acceptance of the corrective actions and verification of corrective action implementation will be conducted during the next onsite audit. Any noncompliance labeled as "**Cleared**" indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively.

Noncompliances from Prior Assessments

AIA-7710-21 - Cleared.
AIA-8501-21 - Cleared.
AIA-8504-21 - Cleared.
AIA-8505-21 - Cleared.
AIA-871-22 - Cleared.

AIA-7712-21 - Accepted. (NOP-28-19.NC5) 7 C.F.R. §205.501(a)(2) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart."

Comments: *BIOI's organic system plans do not demonstrate that BIOI fully complies with the requirements of 205.201(a)(1)-(6) in the following manner:*

- *BIOI's organic system plan forms do not demonstrate adequate descriptions of monitoring procedures and practices, which is a requirement of §205.201(a)(3). Additionally, inspection report forms do not include verification of an operation's monitoring plans and practices.*
- *For one certified operation that included seven sub-projects, there was no organic system plan for the entire operation. Instead, each project had a separate organic system plan and each operation received a separate inspection report.*
- *Maps for three Wild Crops sub-projects did not include sufficient detail per the requirements of **NOP 5022, Wild Crop Harvesting**, such as the location of collection points and buffer zones. The map did not show the orientation of all the regions.*
- *One handling operation organic system plan did not include a product composition profile for an organic dark mint chocolate product.*

Corrective Action: BIOI updated the following documents and procedures:

- BIOI updated the crop, handling/processing and livestock (apiculture) OSP templates to include 25_132EN OSP Processing: Chapters 3.5, 8 "Self- regulation and monitoring."
- BIOI updated the Ecert-Guidelines, from which the inspection reports are generated, to include the verification of an operation's monitoring plans and practices.
- BIOI updated the processing OSP template to include a section for "complex operations" that prompts operations to describe the monitoring of the "whole complex system / chain," including: Organizational chart, product flow chart, working instructions for each single unit including the main unit, and a monitoring plan for each single unit as well as the whole system. The operation noted by the auditor submitted an updated OSP using the new template.
- BIOI trained certification staff regarding the verification of detail in wild harvesting

maps March 2021. BIOI directed certification staff to check the level of detail during the evaluation of the operations OSP and to create a list for feedback to the inspector if necessary.

- BIOI has updated it process for reviewing the formulations for products. A reminder was sent to staff in March 2021. The issue observed was anomalous, and the auditor did not identify any additional products that did not have product profiles verified by certification staff.

Verification of Corrective Action: Bullet point one, two and four are cleared. Bullet point three is outstanding.

- The auditors reviewed certification files and verified that the BIOI OSPs and inspection reports contain adequate descriptions and verifications of an operation's monitoring procedures and practices. No issues were identified.
- The auditors reviewed one complex operation with sub-units and the OSP contained an adequate description of the entire operation with supporting documentation. No issues were identified.
- The auditors reviewed one wild crop operation's OSP and found maps that did not include sufficient detail as required by **NOP 5022, Wild Crop Harvesting**, specifically the location of collection points and buffer zones. The maps were not accurate and a portion of one of the designated collection areas included a village.
- The auditors reviewed one handling operation file and verified that all products had a corresponding approved product profile. No issues were identified.

2023 Corrective Action: BIOI conducted training for staff in March 2023 on the requirements of **NOP 5022** and on evaluating wild collection maps during OSP review. BIOI will monitor the effectiveness of the training in 2023-2024 by focusing on wild collection certification in reviews of certifications decisions completed in 2023.

2024 Verification of Corrective Action: The auditors reviewed wild crop certification files and found operation maps do not include sufficient detail as required by **NOP 5022, Wild Crop Harvesting.** BIOI also did not require the operations identified in the original noncompliance to provide updated maps with sufficient detail including the location of collection points and buffer zones.

2025 Corrective Action: BIOI re-verified the compliance of maps from each of its 17 wild crops operations and provided feedback to BIOI inspectors and certifiers (reviewers) on noncompliant maps identified during the review. For any maps identified as noncompliant, BIOI will request an updated map at the time of the next OSP review. BIOI updated its *Inspection Manual 24_2003EN* to include the requirements for maps for wild crops operations. BIOI plans to add a checkpoint to its inspector checklist prompting the inspector to verify that the operation's map is accurate and compliant. BIOI provided instruction to inspectors and certifiers (reviewers) for the 2024 season and plans to include map requirements for wild crops operations at its next annual inspector and certifier (reviewer) training.

Noncompliances Identified during the Current Assessment and Corrective Actions

AIA-1904-24 – Accepted. 7 CFR § 205.501(a)(3) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§ 205.402 through 205.406 and § 205.670;"

Comments: *BIOI does not carry out the provisions of the Act and regulations. The auditors reviewed certification files and found BIOI incorrectly determined a material input to be compliant. Specifically, BIOI incorrectly allowed nonorganic ethanol to be used as a processing aid for an organic product.*

Corrective Action: BIOI notified the operation of the incorrect material input determination and determined that the operation was using organic ethanol, however there was an error in the operation's supplier information. BIOI created and updated several documents in its quality management system, including declaration forms and its *NOP Inspection and Certification Manual 25_111EN*, and trained inspectors and certifiers (reviewers) on the procedure during its 2024 annual training. Additionally, the Product Manager of Input plans to randomly check the input evaluations done by BIOI's material review certifiers (reviewers).

AIA-1906-24 - Accepted. 7 CFR § 205.403(d)(4) states "The on-site inspection of an operation must verify: Mass-balances, in that quantities of organic product and ingredients produced or purchased account for organic product and ingredients used, stored, sold, or transported (that is, inputs account for outputs);"

Comments: *BIOI does not consistently conduct mass-balances during on-site inspections. During a witness audit, the auditors observed the inspector did not conduct a mass-balance and instead conducted three traceability exercises.*
Corrective Action: The Product Manager for NOP and national team located at the head office in Switzerland will review mass balance and traceability exercises. The team will ensure traceability exercises are captured on form *Template for Qualitative Traceability* and mass balances are reported in an Intact Platform neutral deviation as per the *Flow of Goods Instruction*.

AIA-1908-24 - Accepted. 7 CFR § 205.501(a)(3) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§ 205.402 through 205.406 and § 205.670;"

Comments: *BIOI does not carry out the provisions of the Act and regulations. BIOI does not fully verify the accuracy and compliance of an operation's organic system plan (OSP). The auditors reviewed certification files and found the following issues that were not addressed by reviewers or identified as an issue of concern by inspectors.*

1. *A handling operation's OSP listed nine suppliers of organic products that were not NOP certified organic.*
2. *A producer group's OSP contained noncompliant responses to questions and conflicting information. For example, the operation answered 'no' to whether its recordkeeping complied with the regulations and 'no' to pest and disease control despite the operation having materials on its input list used for these purposes.*
3. *A handling operation's OSP did not indicate contamination and commingling prevention measures for an operation using the same equipment for NOP organic and non-NOP organic production.*

Corrective Action: BIOI conducted training for its certifiers (reviewers) on how to more accurately verify information in OSPs. BIOI plans to conduct additional training on the topic at its 2025 annual inspector and certifier (reviewer) trainings.

AIA-2567-24 - Accepted. 7 CFR § 205.501(a)(3) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§ 205.402 through 205.406 and § 205.670;"

Comments: *BIOI does not carry out the provisions of the Act and regulations. The auditors reviewed certification files and found BIOI's inspectors do not consistently follow BIOI's procedures for conducting and recording traceability activities. During a witness audit, the auditors observed that the BIOI inspector did not document the traceability exercises on the required BIOI form. Additionally, the inspector only recorded the name of the documents*

reviewed and did not include the actual data contained in the documents, which is required by BIOI's policy.

Corrective Action: BIOI relocated its Product Manager for NOP to its head office in Switzerland to ensure effective communication and information exchange between BIOI's national (Swiss) team and the Product Manager for NOP. The NOP staff at the head office in Switzerland check mass balance and traceability exercises conducted during on-site audits and document their work in an Intact Platform neutral deviation. In addition, BIOI updated the inspection manual to explain mass balance and traceability information may be captured in either form *24_2665 Traceability Assessment Record* or in the Intact Platform inspector checklist depending on the location of the inspection.

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NATIONAL ORGANIC PROGRAM: AUDIT & CORRECTIVE ACTION REPORT

GENERAL INFORMATION

- **Certifier Name** bio.inspecta AG, (BIOI)
- **Physical Address** Ackerstrasse 117, Frick, CH-5070, SWITZERLAND
- **Audit Type** Material Review Assessment
- **Auditor(s) & Audit Dates** Samuel Schaefer-Joel, 11/13/2023 to 11/17/2023
- **Audit Identifier** NOP-334-23

CERTIFIER OVERVIEW

The National Organic Program (NOP) conducted a remote audit of bio.inspecta AG's (BIOI) material review activities. The purpose of the audit was to verify BIOI's compliance with the Organic Foods Production Act of 1990 (OFPA), the USDA organic regulations (7 CFR Part 205), and the NOP Handbook. Audit activities included the assessment of BIOI's material input review policies and procedures, and a review of compliance documentation for inputs used by BIOI's certified clients.
BIOI is public limited company initially accredited on April 15, 2014 for the scopes of crops, wildcrops, livestock, and handling. BIOI's office is in Frick, Switzerland. BIOI certifies 162 operations in 16 countries.

NOP DETERMINATION:

NOP reviewed the 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 audit.

Any noncompliance labeled as "**Accepted**" indicates acceptance of the corrective actions and verification of corrective action implementation will be conducted during the next audit.

Noncompliances from Prior Assessments

None

Noncompliances Identified during the Current Assessment and Corrective Actions

AIA-6668-23 - Accepted. 7 C.F.R. §205.501(a)(2) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart."

Comments: *BIOI does not demonstrate the ability to fully comply with the requirements for accreditation. The auditor reviewed BIOI's material review policy and procedures and found they do not provide clear direction for the evaluation of manufacturing processes of inputs and input ingredients as required in* ***NOP 3012 Interim Instruction Material Review****. Additionally, BIOI does not any have written material review procedures for evaluating inputs used in processing.*

Corrective Action: BIOI submitted updated material review policy and procedures that provide direction for the evaluation of manufacturing processes and input ingredients. The updates also include procedures for evaluating inputs used in processing. BIOI submitted training logs and training agendas showing that review staff and inspectors were trained on the updated procedures. BIOI also submitted screenshots from their INTACT database showing new checklist items have been added to ensure inputs are verified at both OSP review and inspection for both crop and processing scopes.

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NATIONAL ORGANIC PROGRAM: AUDIT & CORRECTIVE ACTION REPORT

GENERAL INFORMATION

Certifier Name	bio.inspecta AG, (BIOI)
Physical Address	Ackerstrasse 117, Frick, CH-5070, SWITZERLAND
Audit Type	Compliance Audit
Auditor(s) & Audit Dates	Lars Crail, Alicia Hudson, Jonathan Surrency, Joshua Lindau, 10/16/2023 to 11/08/2023
Audit Identifier	NOP-435-23

CERTIFIER OVERVIEW

The National Organic Program (NOP) conducted surveillance activities in India October 16 – November 8, 2023, to verify bio.inspecta AG's (BIOI) compliance with the Organic Foods Production Act of 1990 (OFPA), the USDA organic regulations (7 CFR Part 205), and the NOP Handbook, with a focus on organic export supply chains. Audit activities included a review of certification files, onsite audit activities at certified operations, and product sampling and analysis for pesticide residues.

BIOI is a public limited company initially accredited on April 15, 2004. BIOI's primary office is in Frick, Switzerland. BIOI is accredited to the crops, wild crops, livestock, and handling categories and currently certifies 32 operations including producer groups in India.

NOP DETERMINATION:

NOP reviewed the 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 audit.

Any noncompliance labeled as "**Accepted**" indicates acceptance of the corrective actions and verification of corrective action implementation will be conducted during the next onsite audit.

Noncompliances from Prior Assessments

None

Noncompliances Identified during the Current Assessment

AIA-1082-24 - Accepted. 7 C.F.R. §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: *BIOI does not fully verify an operation's compliance with the USDA organic regulations. Through the review of a BIOI inspection report and a review audit of a handling operation, the auditors found that BIOI inspectors did not identify violations of the USDA organic regulations as issues of concern. Examples of violations that the inspectors should have identified as issues of concern include record-keeping deficiencies, use of a storage facility not described in the operation's organic system plan (OSP), and discrepancies between records regarding inventory counts observed during a mass balance activity.*
Corrective Action: BIOI updated its *Inspections and certification Manuel 25_111EN* to clarify the OSP review process. BIOI conducted annual inspector training in February and March 2024 and certifier (reviewer) training in March 2024, which included training on the importance of the OSP being complete. Additionally, BIOI is no longer working with some inspectors in India that it previously used to conduct inspections.

AIA-1083-24 - Accepted. 7 C.F.R. §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."
Comments: *BIOI does not review applications to ensure completeness. The auditors reviewed certification files and found that the organic system plans (OSP) of applicants for certification were incomplete because the applicant did not answer various questions and BIOI did not require the applicants to provide the missing information. Examples of missing information that BIOI did not require the applicants to provide include:*

1. *A description of the applicant's monitoring practices and procedures for verifying that the OSP is effectively implemented,*
2. *A description of production processes,*
3. *A description of off-site warehouses used,*
4. *An explanation of the applicant's lot numbering system,*
5. *A description of how the applicant prevents contamination of organic product with quaternary ammonia sanitizer, and*
6. *Supplier information for the ethanol used in organic oil extraction.*

Corrective Action: BIOI updated its *Inspections and certification Manuel 25_111EN* to clarify the OSP review process. BIOI conducted annual inspector training in February and March 2024

and certifier (reviewer) training in March 2024, which included training on the importance of the OSP being complete and training on the importance of links between documents. BIOI hired a new 'Product Manager for Input' who will be responsible for managing all operation inputs and processing aids. BIOI created new documents for managing inputs: *Natural-Flavor-Declaration 24_709EN*, *NOP-Feed-Additive-Declaration 24_710EN*, and *NOP-Processing-Ingredient-Declaration 24_711EN*. BIOI's new Product Manager for Input provided training to BIOI's inspectors and certifiers (reviewers) on March 1, 2024, prior to the 2024 inspection season. Additionally, BIOI now manages approved and rejected processing aids in a Sharepoint list to improve ease of use.

AIA-1084-24 - Accepted. 7 C.F.R. §205.403(e)(2) states, "A copy of the on-site inspection report and any test results will be sent to the inspected operation by the certifying agent."
Comments: *BIOI does not consistently send operations a copy of their inspection report. The auditor reviewed certification files and found that the inspector incorrectly provides the inspected operation with a copy of its inspection report.*
Corrective Action: BIOI updated its *Inspection Manual 24_003EN* to state the certifying agent will send a copy of the inspection report and any test results to the client. BIOI conducted annual inspector training in February and March 2024, which included training on reporting requirements for inspectors. Additionally, BIOI is no longer working with some inspectors in India that it previously used to conduct inspections.

USDA Agricultural Marketing Service

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NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

An onsite renewal assessment of bio.inspecta AG's (BIOI) organic program was conducted November 12-14, 2019. The National Organic Program (NOP) reviewed the auditor's report to assess BIOI's compliance to the USDA organic regulations. This report provides the results of the assessment by NOP and review of corrective actions.

GENERAL INFORMATION

Applicant Name	bio.inspecta AG (BIOI)
Physical Address	Ackerstrasse, Frick, CH-5070, Switzerland
Mailing Address	Same as above
Contact & Title	Ulrike Zdralek, Certifier and Deputy of Product Manager for NOP
E-mail Address	ulrike.zdralek@bio-inspecta.ch
Phone Number	41 62 865 63 24
Reviewers & Auditors	Jon Frady, Alexis Randolph, NOP Reviewers; Lars Crail, Joshua Lindau, On-site Auditors
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	Corrective Action Review: July 22, 2021-September 1, 2021 NOP assessment review: May 28, 2020 Onsite audit: November 12-14, 2019
Audit Identifier	NOP-28-19
Action Required	None
Audit & 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
Audit & Determination Criteria	*7 CFR Part 205, National Organic Program as amended*
Audit & Review Scope	BIOI's demonstrated conformance and program implementation during the period: June 2016 through October 2019

BIOI was initially accredited as a USDA National Organic Program certifying agent on April 15, 2004 to the scopes of Crops, Wild Crops, Livestock, and Handling. BIOI's office is in Frick, Ackerstrasse, Switzerland.

BIOI's list of NOP certified operations at the time of the assessment consisted of 68 operations: Crops (24), Wild Crops (9), Livestock (1), and Handler/Processor (62). BIOI certifies nine grower groups outside of Switzerland. Certification services are provided in the following countries: Afghanistan, Albania, Iran, Kazakhstan, Lebanon, Switzerland, Tanzania, Turkey and the United Arab Emirates.

BIOI's staff consists of 32 individuals: Certification Manager (1), Certification Officers (13), Inspectors (17), and Administrative/support staff (1).

As part of the on-site accreditation audit activities, one witness audit of an annual announced inspection of a processor/handler was conducted in Switzerland.

NOP DETERMINATION

The 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.

Noncompliances 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 acceptance of the corrective actions and verification of corrective action implementation will be conducted during the next accreditation audit.

NP1234NNA.NC10 – **Cleared.**
NP4252LCA.NC3 – **Cleared.**
NP4252LCA.NC8 – **Cleared.**
NP7173MVA.NC2 – Cleared.
NP7173MVA.NC3 – Cleared.
NP7173MVA.NC4 – **Cleared.**
NP7201LCA.NC1 – **Cleared.**
NP7201LCA.NC2 – **Cleared.**

AIA-7626-21 (NP4252LCA.NC1) – **Accepted.** 7 C.F.R. §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.

2016 Verification of Corrective Actions: File reviews verified BIOI does not properly issue notifications to the recipient's place of business via a delivery service which provides dated return receipts. Interviews verified BIOI communicates its certification decisions (notice of noncompliance, notice of resolution, etc.) through foreign inspection partners, who then communicate the decision/notice to the operator in that country. BIOI could not provide

verification that their inspection partners issue notices using a delivery service which provides dated return receipts.

2016 Corrective Actions: BIOI has revised it "Administrative Workflow International Services" procedure to require all notifications be sent via registered letter. Notifications delivered by inspection partners must be sent to the inspection partner via registered letter and delivered to the operation via registered letter. Delivery receipts are returned to BIOI to be maintained in BIOI records. The process was formalized with all participating staff on November 8, 2016. This process served as the training for staff. Inspection partners were emailed the updated procedure within days of completing the changes.

2019 Verification of Corrective Actions: The auditor's review of several issued notifications revealed that a system of return receipts is not used. Notifications are sent via registered mail, but no return receipt is obtained.

2021 Corrective Actions: BIOI updated its process for sending of notifications to require a return receipt via a registered email service. BIOI trained certification staff regarding the use of registered email on April 20, 2021. BIOI began using registered email with a return receipt at the beginning of the 2021 certification cycle. BIOI will conduct at least one evaluation annually of each certification staff member's sent notices to confirm the proper use of registered email.

AIA-7627-21 (NP7173MVA.NC1) – **Accepted.** 7 C.F.R. §205.403(a)(1) states, "A certifying agent must conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested. An on-site inspection shall be conducted annually thereafter for each certified operation that produces or handles organic products for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue."

Comments: *BIOI does not inspect all fields or production units of their certified operations each year. The BIOI Inspection Manual (24_003EN) section 3.2 states that for risk countries and large operators (>5000 hectares) the inspector must inspect at least one third of all fields. Two thirds of an operation's fields may not be inspected annually.*

Corrective Action: BIOI updated their inspection policy to require that all plots/fields are physically inspected each year. BIOI submitted a revised inspection manual 24_003EN that included the new requirements. BIOI will train inspectors and staff on the new inspection policy in February and March of 2018 for the 2018 inspection season.

2019 Verification of Corrective Actions: A review of one Wild Crops operation file revealed that BIOI conducted two inspections of the operation in 2018 for a total of 8.5 hours covering 12 regions that consisted of approximately 5,750 hectares. There was no record in the inspection reports of how these regions were visited and verified.

2021 Corrective Actions: BIOI updated its inspection manual July 1, 2020 to require that all areas of a wild crop operation must be visited during the annual inspection. BIOI updated its inspection report to note the date the inspector visits each location. BIOI annual training for certification staff and inspectors in 2020 and 2021 noted all wild collection areas must be visited every year as part of the annual inspection. BIOI certification staff will review inspection reports to verify all sites of an operation have been inspected. BIOI incorporated verification that inspectors are visiting all sites of an operation as part of the BIOI's performance assessment.

AIA-7707-21 (NP7201LCA.NC3) – Accepted. 7 C.F.R. §205.501(a)(4) states, "A private or governmental entity accredited as a certifying agent under this subpart must:… Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part; …."

Comments: *The auditors observed the following situations that indicated BIOI Turkey staff did not have sufficient knowledge and understanding of the USDA organic regulations and NOP policies:*

- *Two of three retail labels reviewed by the auditor were noncompliant, and the certifier identified the labels as compliant.*
- *One Certifier had difficulty identifying the restrictions for using citric acid in processed products (i.e. produced by microbial fermentation of carbohydrate substances).*

Corrective Action: BIOI conducted training for all certifiers in Turkey on the labeling requirements and the inputs for processed products. BIOI created a checklist for label approval and includes a reminder of the BIOI guidelines as a resource for labelling. BIOI plans to train all certifiers again on this issue in early 2018.

2019 Verification of Corrective Actions: The auditor reviewed BIOI's label review policy and procedures with BIOI personnel. Personnel cited the USDA organic regulations and referred to the BIOI checklist used for the label review. New labels created after the submission of the organic system plan are not required to be reviewed and approved by BIOI personnel prior to use. Instead new labels are reviewed at the time of inspection. The auditor identified a certified operation label that was noncompliant and had been approved since 2011. This issue had not been identified by BIOI personnel.

2021 Corrective Actions: BIOI updated its label approval process and trained staff regarding the label approval at the annual BIOI certifier training in 2020 and 2021. BIOI requested its operations resubmit all labels for the 2021 certification cycle to re-check any previously approved labels. BIOI updated its Processing Organic System Plan (OSP) in December 2019 to direct operations to submit new labels to BIOI for approval prior to use. Label review and approval is now included in BIOI's internal audit process and a sample of labels will be checked during internal audits. If a noncompliant label is found, the certification staff responsible for reviewing and approving the noncompliant label will be retrained on the label approval process.

Noncompliances Identified during the Current Assessment

AIA-7708-21 (NOP-28-19.NC1) – Accepted. 7 C.F.R. §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 and implement measures to correct any noncompliances with the Act and the regulations in this part that are identified in the evaluation;"

Comments: *BIOI's Turkey and Albania regional offices conduct key certification activities; however, an adequate annual review of those activities is not conducted. The auditor's review of the 2019 monitoring activities of BIOI's Turkey office consisted of a review of one operation's*

records and its evaluation by the certification staff. The review process is not sufficient enough to determine if the regional office is properly implementing the USDA organic regulations and NOP policies.

2021 Corrective Actions: BIOI conducts file reviews of all certification staff and inspectors work using the evaluation checklist. The head of certification selects more complex operations for review and has the certification checked by another certifier on the basis of document 12_021 "Certification evaluation checklist" or by the Ecert certification evaluation checklist. The BIOI Program Manager or the Head of Certification attends the certification committees for each office. Issues identified with file reviews, while attending certification committees or other meetings, are communicated back to the certifiers directly. Further internal audits for the offices are performed to ensure that the processes are kept as described in the BIOI Quality Management documents. BIOI has 17 (four in Albania, ten in Turkey and three in Switzerland) files on the schedule for review in 2021 for its 113 NOP operations.

AIA-7709-21 (NOP-28-19.NC2) – Accepted. 7 C.F.R. §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."

Comments: *BIOI's inspectors are incorrectly issuing noncompliances to operations. As a result, operations are submitting responses (i.e. corrective actions). BIOI accepts those responses and issues the operation a notification of noncompliance resolution without ever having issued the operation a notification of noncompliance.*

2021 Corrective Actions: At the annual BIOI inspector training in 2020 and 2021, BIOI trained the inspection staff they are not to issue noncompliances during NOP operation inspections. BIOI trained staff that they are to issue noncompliances even if the operation submits corrective actions prior to issuance. BIOI added "Correct issuing of Noncompliances" to the evaluation of certification staff during BIOI's internal audit process.

AIA-7710-21 (NOP-28-19.NC3) – Accepted. 7 C.F.R. §205.662(c) states, "Proposed suspension or revocation. 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."

Comments: *The auditors identified the following issues with notices of proposed suspension issued by BIOI:*

- *One reviewed Notice of Proposed Suspension incorrectly indicated that the operation could not sell product during the proposed suspension period. Additionally, the impact of suspension was not stated.*
- *One reviewed Notice of Proposed Suspension was issued for one year after the deadline stated on the notification of noncompliance.*

2021 Corrective Actions: BIOI updated the templates for the proposed adverse action notices to explain the rights of the operation and impact of the proposed suspension or revocation. BIOI updated its certification manual outlining timelines for the adverse action process. BIOI

certification staff were trained how to use the templates during the annual trainings in 2020 and 2021. BIOI training emphasized the importance of maintaining the timeline of the adverse action process. BIOI has added verification of the adverse action timeline to the evaluation checklist QM-12-BINT Evaluierung Zertifizierung used to review all NOP files.

AIA-7711-21 (NOP-28-19.NC4) – Accepted. 7 C.F.R. §205.663 states, "Any dispute with respect to denial of certification or proposed suspension or revocation of certification under this part may be mediated at the request of the applicant for certification or certified operation and with acceptance by the certifying agent. Mediation shall be requested in writing to the applicable certifying agent... If mediation is unsuccessful, the applicant for certification or certified operation shall have 30 days from termination of mediation to appeal the certifying agent's decision pursuant to § 205.681…"

Comments: *Mediation was requested and granted by BIOI, but there was no record of the request for mediation.*

2021 Corrective Actions: BIOI updated its quality manual and conducted training for issuing notices of noncompliance and the adverse action process at the 2020 and 2021 annual training for certifiers. BIOI's quality manual now indicates that mediation requests must be in writing. BIOI training hosted in March 2021 communicated to staff that mediation requests must be submitted in writing.

AIA-7712-21 (NOP-28-19.NC5) – Accepted. 7 C.F.R. §205.501(a)(2) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart."

Comments: *BIOI's organic system plans do not demonstrate that BIOI fully complies with the requirements of 205.201(a)(1)-(6) in the following manner:*

- *BIOI's organic system plan forms do not demonstrate adequate descriptions of monitoring procedures and practices, which is a requirement of §205.201(a)(3). Additionally, inspection report forms do not include verification of an operation's monitoring plans and practices.*
- *For one certified operation that included seven sub-projects, there was no organic system plan for the entire operation. Instead, each project had a separate organic system plan and each operation received a separate inspection report.*
- *Maps for three Wild Crops sub-projects did not include sufficient detail per the requirements of NOP 5022, Wild Crop Harvesting, such as the location of collection points and buffer zones. The map did not show the orientation of all the regions.*
- *One handling operation organic system plan did not include a product composition profile for an organic dark mint chocolate product.*

2021 Corrective Actions: BIOI updated the following documents and procedures:

- BIOI updated the crop, handling/processing and livestock (apiculture) OSP templates to include 25_132EN OSP Processing: Chapters 3.5, 8 "Self- regulation and monitoring."
- BIOI updated the Ecert-Guidelines, from which the inspection reports are generated, to include the verification of an operation's monitoring plans and practices.

- BIOI updated the processing OSP template to include a section for "complex operations" that prompts operations to describe the monitoring of the "whole complex system / chain," including: Organizational chart, product flow chart, working instructions for each single unit including the main unit, and a monitoring plan for each single unit as well as the whole system. The operation noted by the auditor submitted an updated OSP using the new template.
- BIOI trained certification staff regarding the verification of detail in wild harvesting maps March 2021. BIOI directed certification staff to check the level of detail during the evaluation of the operations OSP and to create a list for feedback to the inspector if necessary.
- BIOI has updated it process for reviewing the formulations for products. A reminder was sent to staff in March 2021. The issue observed was anomalous, and the auditor did not identify any additional products that did not have product profiles verified by certification staff.

AIA-7713-21 (NOP-28-19.NC6) – Accepted. 7 C.F.R. § 205.501(a)(11)(v) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Prevent conflicts of interest by: Requiring 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 all parties responsibly connected to the certifying agent to complete an annual conflict of interest disclosure report"

Comments: *The auditor's interviews with BIOI staff found that a conflict of interest (COI) is not signed for every year for every staff member involved in the certification process. The auditor's personnel file review confirmed that five employees did not have a signed COI for every year of employment with BIOI.*

2021 Corrective Actions: Starting in 2020, BIOI instructed the Quality Manager of the local offices and the head of training to collect conflict of interest for each inspector and certifier every year and send it to HR department for approval and data entry into Ecert. BIOI updated its "Procedure for Conflict of Interest" section of the certification manual to reflect the updated policy.

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NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

An onsite audit of Bio.inspecta AG's satellite office in Turkey was conducted on July 20-21, 2017. The National Organic Program (NOP) reviewed the auditor's report to assess Bio.inspecta AG's compliance to the USDA organic regulations. Bio.inspecta AG submitted corrective actions and this report provides the results of NOP's assessment.

GENERAL INFORMATION

Applicant Name	Bio.inspecta Kontrol ve Sertifikasyon Ltd.
Physical Address	Mansuroğlu Mah. 284/1 sok. No:11 D:11-12 Bayraklı / İzmir / Turkey
Mailing Address	Mansuroğlu Mah. 284/1 sok. No:11 D:11-12 Bayraklı / İzmir / Turkey
Contact & Title	(Ms.) Emel F.T.Erkan, Head of Turkish Branch and Certifier
E-mail Address	emel.erkan@bio-inspecta.com
Phone Number	+90 232 347 4868 (Turkey)
Reviewer(s) & Auditor(s)	Penny Zuck, NOP Reviewer; Lars Crail and Mark Bradley, Onsite Auditors.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	Corrective action review: January 4, 2018 NOP assessment review: August 31, 2017 Onsite audit: July 20-21, 2017
Audit Identifier	NP7201LCA
Action Required	None
Audit & Review Type	Satellite Office Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of BIOI's certification system.
Audit & Determination Criteria	*7 CFR Part 205, National Organic Program as amended*
Audit & Review Scope	BIOI's certification services in carrying out the audit criteria.

The National Organic Program (NOP) conducted an onsite audit of Bio.inspecta AG's (BIOI) satellite office (BIO Turkey) in Izmir, Turkey. BIOI Turkey conducts all key activities with oversight from BIOI's main office in Switzerland.

The auditors reviewed the office's accreditation and certification activities through file review and personnel interviews. No witness or review audits were conducted by NOP during the satellite office audit.

BIOI opened a branch office in Turkey in 2010. In 2015, BIOI Turkey was authorized by BIOI to conduct all NOP key activities. BIOI Turkey manages certification activities in the following countries: Turkey, Kazakhstan, and Lebanon. BIOI Turkey manages 64 certified operation with the following scopes: Crops (23), Wild Crops (13), and Handlers (32). BIOI Turkey certifies 27 grower groups.

Nine individuals work at or from the BIOI Turkey office. There is one Head of Turkish Branch/Certifier, one Administrative Staff, one additional Certifier (i.e. reviewer/decision maker), and six staff inspectors. BIOI Turkey also offers certification services for the European Union organic regulations, Turkey organic regulations; BioSuisse, Demeter, UTZ, Krav, and Naturland.

NOP DETERMINATION:

NOP reviewed corrective actions submitted as a result of noncompliances issued from Findings identified during the onsite audit.

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.

NP7201LCA.NC1 – **Accepted**. 7 C.F.R. §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 and conditions determined by the Administrator to be necessary." NOP 5031 Certification Requirements for Handling Unpackaged Organic Products, Section 4.3, states, "An operation that handles unpackaged organic products (other than transporting), and is not an exempt or excluded handling operation, must be certified."

Comments: *BIOI Turkey is not requiring handlers of unpackaged organic grain products operating in the supply chain to be certified. Cargo loading companies are transferring unpackaged grain from truck or train bulk containers to shipping vessel cargo hulls.*

Corrective Action: BIOI notified operations, inspectors, and certifiers of the requirement for handlers of unpackaged organic grain products to be certified and of the additional directive from the NOP on testing of grain shipments. BIOI has revised the organic handling plan to request information regarding handling of unpackaged organic products. BIOI will conduct training for inspectors and certifiers on this issue in early 2018. This will be a focus during the 2018 audit season and a question will be included in the NOP audit checklist.

NP7201LCA.NC2 – **Accepted.** 7 C.F.R. §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 and conditions determined by the Administrator to be necessary." NOP 2601, The Organic Certification Process, Section 3.4, states that inspectors are to verify compliance through records and reconciliation of the volume of products produced and/or handled.

Comments*:* *BIOI Turkey inspectors do not consistently record traceability and quantitative (i.e. mass-balance) activities on inspection reports. Inspection reports describe traceability and quantitative activities (such as specific lot, quantity, time frame, etc.) only when the operation is identified as risky. Otherwise, inspectors record only the outcome of these activities and not the specific records reviewed and inventories observed.*

Corrective Action: BIOI developed traceability/flow of goods forms to be completed by the inspector. BIOI Turkey and Switzerland offices have already implemented the forms. BIOI notified inspectors these forms must be used during each inspections for all operations. BIOI plans to expand the questions for flow of goods and traceability on the 2018 NOP audit checklists to require the inspectors to document which records are checked during the audit.

NP7201LCA.NC3 – Accepted. 7 C.F.R. §205.501(a)(4) states, "A private or governmental entity accredited as a certifying agent under this subpart must:… Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part; …."

Comments: *The auditors observed the following situations that indicated BIOI Turkey staff did not have sufficient knowledge and understanding of the USDA organic regulations and NOP policies:*

- *Two of three retail labels reviewed by the auditor were noncompliant, and the certifier identified the labels as compliant.*
- *One Certifier had difficulty identifying the restrictions for using citric acid in processed products (i.e. produced by microbial fermentation of carbohydrate substances).*

Corrective Action: BIOI conducted training for all certifiers in Turkey on the labeling requirements and the inputs for processed products. BIOI created a checklist for label approval and includes a reminder of the BIOI guidelines as a resource for labelling. BIOI plans to train all certifiers again on this issue in early 2018.

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NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a mid-term assessment of the Bio.Inspecta AG (BioI). An onsite audit was conducted, and the audit report reviewed to determine BioI's capability to continue operating as a USDA accredited certifying agent. This report provides the results of the mid-term assessment and review of BioI's corrective actions.

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, NOP Program Manager
E-mail Address	julia.winter@bio-inspecta.ch
Phone Number	+41 (0) 62 865 63 24
Reviewer **Auditors**	Jason Lopez, NOP Reviewer Miguel A. Caceres and Renée Gebault King, On-site Auditors.
Program	USDA National Organic Program (NOP)
Review Dates **Audit Dates**	NOP assessment review: November 29-30, 2016 Onsite audit: June 13-17-2016
Audit Identifier	NP6165MMA
Action Required	No
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of BioI's certification system.
Audit & Determination Criteria	*7 CFR Part 205, National Organic Program as amended*
Audit & Review Scope	BioI's certification services in carrying out the audit criteria during the period: September 2014 through May 2016

Bio.inspecta AG is a private for-profit corporation, which was initially accredited as a USDA National Organic Program (NOP) certifying agent on April 15, 2004 for the scopes of crops, wild crops, livestock and handling. The main office is in Frick, Switzerland (Bio.inspecta AG) and a satellite office is located in Izmir, Turkey (Bio.inspecta Ltd). Bio.inspecta's current list of NOP certified operations includes 80 operations and 18 grower groups, consisting of 27 crop, 11 wild crops, 0 livestock and 67 processing/handling operations. Bio.inspecta certifies operations in Switzerland, Albania, Bulgaria, Germany, Hungary, Iran, Kazakhstan, Romania, Russian Federation, , Tanzania, Turkey, Ukraine, and United Arab Emirates.

A witness audit of a handling operation Switzerland was conducted during the mid-term

assessment. The importer makes accommodations for transport of product from the supplier's location/facility to the port of debarkation for transport directly to clients. A witness audit was also conducted at an organic wild crop and handling operation located in Romania. The inspector observed the wild harvest of mushrooms.

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 acceptance of the corrective actions and verification of corrective action implementation will be conducted during the next onsite audit.

NP1234NNA.NC5 – Cleared
NP1234NNA.NC7 – Cleared
NP1234NNA.NC8 – Cleared
NP1234NNA.NC9 – Cleared
NP4252LCA.NC2 – Cleared
NP4252LCA.NC4 – Cleared
NP4252LCA.NC5 – Cleared
NP4252LCA.NC6 – Cleared
NP4252LCA.NC7 – Cleared
NP4252LCA.NC9 – Cleared
NP4252LCA.NC10 – Cleared

NP1234NNA.NC10 – Accepted - 7 C.F.R. §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."

Comments: *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 C.F.R. §205.662(f).*

2011 Corrective Actions: BioI modified its procedures to implement noncompliance procedures for certified operations described in 7 C.F.R. §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.

2016 Verification of Corrective Actions: The review revealed that BioI was still not properly following the adverse action process. In one of the three files reviewed BioI sent a certified operation a Notice of Noncompliance and a Notice of Suspension without first issuing a Notice of Proposed Suspension. In another file reviewed BioI sent a Notice of Noncompliance Resolution without first issuing a Notice of Noncompliance.

2016 Corrective Actions: On October 6, 2016, BioI informed personnel of the proper adverse action process via email. The email contained flow charts properly illustrating the adverse action process and directed personnel to review and confirm their comprehension of the material. The email also stated all draft notices must be submitted to BioI's NOP product manager for review. In January 2017, the BioI personnel were trained and tested on the adverse action process. BioI will randomly check compliance with this new process during the next internal review.

NP4252LCA.NC1 – **Accepted -** 7 C.F.R. §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.

2016 Verification of Corrective Actions: File reviews verified BioI does not properly issue notifications to the recipient's place of business via a delivery service which provides dated return receipts. Interviews verified BioI communicates its certification decisions (notice of noncompliance, notice of resolution, etc.) through foreign inspection partners, who then communicate the decision/notice to the operator in that country. BioI could not provide

verification that their inspection partners issue notices using a delivery service which provides dated return receipts.
2016 Corrective Actions: BioI has revised it "Administrative Workflow International Services" procedure to require all notifications be sent via registered letter. Notifications delivered by inspection partners must be sent to the inspection partner via registered letter and delivered to the operation via registered letter. Delivery receipts are returned to BioI to be maintained in BioI records. The process was formalized with all participating staff on November 8, 2016. This process served as the training for staff. Inspection partners were emailed the updated procedure within days of completing the changes.

NP4252LCA.NC3 – **Accepted -** 7 C.F.R. §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 C.F.R. §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 C.F.R. §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 C.F.R. §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.
2016 Verification of Corrective Actions: The review of files revealed that BioI is not properly following the progression of the adverse action process. The review of records verified the training had been conducted and the procedure was updated.
2016 Corrective Actions: On October 6, 2016, BioI informed personnel of the proper adverse action process via email. The email contained flow charts properly illustrating the adverse action process and directed personnel to review and confirm their comprehension of the material. The email also stated all draft notices must be submitted to BioI's NOP product manager for review. In January 2017, the BioI personnel will be trained and tested on the adverse action process. BioI will randomly check compliance with this new process during the next internal review.

NP4252LCA.NC8 – **Accepted** - 7 C.F.R. § 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.

2016 Verification of Corrective Actions: The file review of a wild crop operation revealed that the inspection report did not contain information to verify product transport after packaging.

2016 Corrective Actions: BioI is currently revising audit checklist and Organic System Plan for wild crop to include issues of transportation. These revision are scheduled to be implemented during the 2017 certification season. BioI personnel were trained on these revision at the training to be held in January 2017. BioI will randomly check compliance with this new process during the next internal review.

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.

NP6165MMA.NC1 – **Accepted** - 7 C.F.R. §205.402(a)(1) and (2) states, "Upon acceptance of an application for certification, a certifying agent must: Review the application to ensure completeness pursuant to §205.401; Determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements…"

Comments: *A review of six certification files verified that the organic systems plans (OSP) were not complete or did not contain sufficient information to determine compliance or the capability to comply. The OSP's reviewed did not include descriptions of practices and procedures or monitoring practices and procedures to be performed and the frequency with which they would be performed. The OSP's did not describe the management practices and physical barriers established to prevent commingling of organic products with nonorganic products or prohibited substances. In addition, the OSP's do not have sufficient information on product transportation for incoming product (as applicable) or outgoing products*.

2016 Corrective Actions: BioI is currently revising Organic System Plan templates include descriptions and information for each area described above and will submit the revision to the NOP for approval. These revision are scheduled to be implemented during the 2017 certification season. BioI personnel were trained on these revision in January 2017. BioI will randomly check compliance with this new process during the next internal review.

NP6165MMA.NC2 – **Accepted -**7 C.F.R. §205.501(a)(2) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart."

Comments: *Interviews with staff revealed BioI does not have a formal materials review procedure and/or a checklist. BioI reviews each material on an individual or "case-by-case" basis. The staff explained that BioI is developing a checklist for material reviews; a draft of which was shown to the auditor.*
2016 Corrective Action: BioI has developed an input approval and review process that has been added to the "NOP Procedure Inspection and Certification" process. BioI added this workflow to the Ecert system in January 2017 and trained inspection and certification staff. Additional training will be provided at the certifier training in March 2017.

NP6165MMA.NC3 – **Accepted -** 7 C.F.R. §205.501(a)(4) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part."

Comments: *In two files reviewed, the certification decision was rendered a full year after the client applied for renewal. Interviews with the BioI staff revealed there was insufficient staff in 2015 to manage all the certification files.*
2016 Corrective Action: BioI has revised its administrative process to require inspectors to submit inspection documents within 14 days of completing the onsite inspection. The division head will be responsible for managing the timely completion of certifications. The division head will receive a weekly report of incomplete certifications to manage. BioI hired an additional certifier on October 1, 2016 to increase the timely completion of the certification process. This practice has be fully implemented in Switzerland and implementation continues in Turkey. All staff were trained in this new process in September 2016 with additional training planned in March 2017.

NP6165MMA.NC4 – **Accepted -** 7 C.F.R. §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…" and NOP 2027 Instruction Personnel Performance Evaluations states, "Field Evaluation (Inspectors only). Inspectors should be evaluated during an onsite inspection by a supervisor or peer (another inspector) at least annually."

Comments: *BioI does not conduct annual field evaluations of all inspectors. This was verified via interviews and the document review. The BioI NOP Training Concept states that one inspector per year will be accompanied by the BioI Program Manager or his/her deputy or an experienced NOP inspector as opposed to each inspector having an annual field evaluation.*
2016 Corrective Action: BioI has revised its inspector training concept to include a required yearly field evaluation. The field evaluation assignments will be determined by the BioI NOP program manager. The evaluation will be recorded and retained and considered as part of the annual staff appraisal review. Inspectors and certifiers will be trained on this process during the March 2017 certifier training.

NP6165MMA.NC5 – **Accepted -** 7 C.F.R. §205.501(a)(10) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Maintain strict confidentiality with respect to its clients under the applicable organic certification program and not disclose to third parties (with the exception of the Secretary or the applicable State organic program's

governing State official or their authorized representatives) any business-related information concerning any client obtained while implementing the regulations in this part, except as provided for in §205.504(b)(5)"

Comments: *A review of two of the six agreements BioI has with its Partner Control Bodies verified that one agreement did not adequately cover the contracted inspectors maintaining confidentiality. The agreement covered only the confidentiality requirements that BioI had to maintain regarding the agreement.*

2016 Corrective Action: BioI has revised the "Contract Partner Control Body" contract and the contract now requires the partner control body guarantee all of its staff adhere to the state rules of confidentiality. BioI additionally has a contract template for external inspection bodies that sufficiently address the confidentiality of information. New contracts will be signed in 2017 to correct the deficiency identified in the noncompliance.

NP6165MMA.NC6 – **Accepted -** 7 C.F.R. §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 and conditions determined by the Administrator to be necessary." NOP 2603 Instruction Organic Certificates states, "Organic certificates should be issued in English and include the following: 4. Issue date (when the certifying agent issued the organic certificate);… 7. Specific certified organic products covered by the organic certificate…; 8. Labeling category for each product certified under the handling/processing certification category…; and 10. The statement, "Once certified, a production or handling operation's organic certification continues in effect until surrendered, suspended or revoked."

Comments: *Organic certificates reviewed were found to be inconsistent with NOP 2603 in the following ways:*

- *The certificates stated they were valid until the issue of the new certificate and BioI reserved the right to revoke certification.*
- *Certificates did not list specific certified organic products or the labeling category for each product certified. All certified organic products and labeling categories are included on a separate product list. Recipients of an organic certificate must follow the link on the certificate to "Easy-Cert.com" to obtain the product list or obtain a hard copy from the certified operation or BioI.*
- *The "Issue" date is not clearly identified but appears to be the date above the signature.*

2016 Corrective Action: BioI has updated the Ecert system with a corrected organic certificate template. Product lists are updated in the Ecert and INTEGRITY databases once BioI confirmed products and product categories are compliant.

NP6165MMA.NC7 – **Accepted -** 7 C.F.R. §205.662(a) states, "When an inspection, review, or investigation of a certified operation by a certifying agent… reveals any noncompliance…a written notification of noncompliance shall be sent to the certified operation. Such notification shall provide…"

Comments: *The BioI certification procedures incorrectly state the operator may respond to a notice of noncompliance by rebutting the noncompliance, requesting mediation, or filing an appeal. Mediation and appeal are not options for resolving a notification of noncompliance.*

2016 Corrective Action: BioI has amended the notice of noncompliance template to include the options of rebuttal and the submission of corrective action as resolutions to identified noncompliances. BioI staff were informed of this change at the March 2016 certifier training.

NP6165MMA.NC8 – **Accepted** - 7 C.F.R. §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 and conditions determined by the Administrator to be necessary." NOP 4002 Instruction Enforcement of the USDA Organic Regulations: Penalty Matrix section 4.1 Minor Issues states, "The … penalty matrix addresses minor issues. These types of violations require correction, but do not preclude certification and do not necessitate a Notice of Noncompliance (NONC)."
Comments: *BioI notification templates do not correctly use language defined in NOP 4002. Auditors found a certification decision letter granting certification and a notice of noncompliance that incorrectly defined "Minor Issues" as "Recommendations." Notifications must correctly identify "Minor Issues" as such. Additionally, BioI incorrectly identified the application of a prohibited material as a "minor issue," which should be identified as a noncompliance.*
2016 Corrective Actions: BioI's January 2017 training included a session to review the content of NOP 4002 "*Instruction Enforcement of the USDA Organic regulations: Penalty Matrix."* The training attendees will be tested on their comprehension and understanding of the material.

NP6165MMA.NC9 – **Accepted -** 7 C.F.R. §205.681(a) states, "(a) *Certification appeals.* An applicant for certification may appeal a certifying agent's notice of denial of certification, and a certified operation may appeal a certifying agent's notification of proposed suspension or revocation of certification to the Administrator, *Except,* That, when the applicant or certified operation is subject to an approved State organic program the appeal must be made to the State organic program which will carry out the appeal pursuant to the State organic program's appeal procedures approved by the Secretary.
Comments: *BioI's Turkish subsidiary office issued a certification letter granting certification to an operation. This letter incorrectly offers the operation the option to appeal.*
2016 Corrective Action: BioI has revised its process to correctly identify a notice of noncompliance resolution will be sent when noncompliances have been resolved. BioI processes have been amended and clearly identifies the correct letter template to generate from the Ecert system in all situations. The process was implemented on February 19, 2016 and staff were trained on this process at the certifier training in March 2016.

USDA Agricultural Marketing Service

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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)
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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.

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AUDIT INFORMATION

Applicant Name:	Bio.inspecta AG
Est. Number:	N/A
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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.