



National Organic Program
1400 Independence Avenue, SW.
Room 2642-South, STOP 0268
Washington, DC 20250-0268

Accreditation Status Confirmation

June 25, 2024

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SPAIN

To Whom This May Concern:

Servicio de Certificación CAAE S.L.U. (CAAE) is a United States Department of Agriculture (USDA), National Organic Program (NOP) accredited certifying agent. Furthermore, CAAE is authorized to issue USDA NOP organic certification to Crops, Handling, and Wild Crops operations that comply with Title 7 Code of Federal Regulations (CFR) Part 205.

CAAE's accreditation certificate indicates a renewal date of February 13, 2024; however, its accreditation is in good standing and continues to be valid. USDA NOP granted CAAE an accreditation term extension until its accreditation renewal assessment is completed. USDA NOP expects the assessment process to conclude during 2024.

For questions concerning CAAE's status, please contact the NOP at (202) 720-3252 or NOP.Guidance@usda.gov.

Sincerely,

Melissa Lahullier
Assistant Director, Accreditation Division
National Organic Program



CERTIFICATE OF ACCREDITATION



United States Department of Agriculture

Agricultural Marketing Service

National Organic Program

SERVICIO DE CERTIFICACIÓN CAAE S.L.U.

Avenida Diego Amrinez Barrios 10,3 Mod.12, Sevilla, Andalucia, 41013, SPAIN

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, 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-20-24**

Effective Date: **06/24/2024**

Expiration Date: **02/13/2024**

Issue Date: **06/24/2024**

Jennifer Tucker, Ph.D.

Deputy Administrator

National Organic Program

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NATIONAL ORGANIC PROGRAM: AUDIT & CORRECTIVE ACTION REPORT

GENERAL INFORMATION

- **Certifier Name** CAAE Certification Service (CAAE)
- **Physical Address** Avenida Diego Amrinez Barrios 10,3Mod.12, Sevilla, Andalucia 41013, SPAIN
- **Audit Type** Mid-term Audit
- **Auditor(s) & Audit Dates** Alison Howard, Colleen O'Brien, Samuel Schaefer-Joel, 09/13/2021 to 09/17/2021
- **Audit Identifier** NOP-23-21

CERTIFIER OVERVIEW

A midterm audit was conducted for CAAE Certification Service's (CAAE) organic program. The National Organic Program (NOP) assessed the certifier's conformance to the USDA organic regulations during the period of July 5, 2019, through September 17, 2021.

CAAE Certification Service (CAAE) is a for-profit company with its main office in Sevilla, Spain. CAAE was accredited February 12, 2009, to the USDA National Organic Program (NOP).

The CAAE Organic Certification Program certifies 173 operations to the following certification scopes: Crops (77), Wild Crop (1) and Handling (124). CAAE provides certification services in Spain, Peru, and Portugal.

CAAE employs the following staff conducting NOP certification activities: a certification manager, a certification assistant manager, 8 technical review staff, and 12 inspectors.

NOP DETERMINATION:

NOP reviewed the audit results to determine whether CAAE'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 "**Cleared**" indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. 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

AIA-3466-20 – Cleared.

AIA-3467-20 – Cleared.

AIA-3468-20 – Accepted. (NOP-08-19.NC2) – 7 C.F.R. §205.510(b)(2) states, “Certifying agents must maintain records according to the following schedule: Records created by the certifying agent regarding applicants for certification and certified operations must be maintained for not less than 10 years beyond their creation.”

Comments: *The following records could not be located by CAAE personnel and reviewed by the auditor:*

1. *CAAE could not demonstrate to the auditor that notifications were submitted to the NOP pursuant to §205.501(a)(15)(i).*
2. *Records for certified products that appeared to contain capsules and other non-agricultural products not listed on §205.605 were not available for the auditor to determine compliance of those ingredients pursuant to §205.301(a)(b)(c).*

Corrective Action: The following corrective actions were submitted by CAAE:

1. An additional control measure has been established for notifications to NOP. When they are sent, the Head of Quality will be placed responsible for the NOP scheme that will verify the communications sent monthly. The updated communications table to NOP located in Section 21 of the CAAE NOP Procedures Manual (Rev 4, 11/19/19) verified this change.
2. The “NOP Documentation Paperwork” internal document has been modified to ensure all verifications of all input labels are going to be recorded and will be maintained for at least 10 years. The label review model has been modified on pages 13 to 16.

Verification of Corrective Action: The auditors’ review of records found CAAE has effectively implemented the corrective actions for point 1 of this noncompliance, but not point 2. The auditors reviewed CAAE staff records and verified CAAE submitted noncompliance and adverse action notifications to the NOP as required. However, when the auditors requested documentation of compliance for an input, CAAE did not provide the compliance documentation for the ingredients.

2023 Corrective Action: CAAE updated its “Procedures Manual National Organic Program (NOP)” section 16.3.2 in February 2023 with a material review policy that complies with ***NOP 3012 Material Review***, including maintaining compliance documentation for reviewed inputs. CAAE’s material review staff completed the Organic Integrity Learning Center course Input Material Review in November 2022, and in May 2023, CAAE conducted training of certification staff on the revisions to the Procedures Manual.

AIA-3474-20 - Accepted. (NOP-08-19.NC3) –7 C.F.R. § 205.501(a)(4) states, “A certifying agent under this subpart must: Use ... adequately trained personnel, including inspectors ... to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part.”

Comments: *During the audit, CAAE personnel did not consistently demonstrate an adequate understanding of the USDA organic regulations and NOP Policies. The following are examples as evidence:*

1. *In one residue analysis case reviewed by the auditor, the CAAE Reviewer correctly determined that the 5% of the EPA tolerance level was exceeded, but did not issue a noncompliance notification per §205.662(a)(1-3) with reference of §205.671 to the operator.*
2. *CAAE’s issued proposed suspension notifications indicate a 15-day period for the operator to either file an appeal or request mediation. A 15-day period was also identified in the proposed suspension and revocation notification templates. This does not meet*

requirements in accordance with §205.681(c).

3. *During one of the witness audits conducted and during the inspection exit interview, the inspector informed the operator of an identified issue, but did not reference the regulation. Further interviews of CAAE personnel and inspectors revealed that inspectors are instructed to identify issues without recording or citing the regulations. Certification reviewers will assign a regulatory reference or citation when and if an inspector's finding is classified as a noncompliance. This does not meet requirements in accordance with §205.403(d).*
4. *Inspectors are not identifying incomplete or inaccurate organic system plans during inspections as issues of concern. During the witness audit of an inspection of a certified Crops operation, the operation disclosed that manure was applied as fertilizer; however, the OSP indicated that the operation only used composted plant materials. This does not meet requirements in accordance with §205.403(c)(2).*
5. *The auditor's assessment of 10 reviewed operation records and interviewed CAAE certification personnel indicated that a single OSP is not maintained. The current record keeping system does not readily allow for a reviewer or auditor to understand what the current practices, approved materials, and monitoring system are employed by operations. In one operation file reviewed by the auditor, the Organic System Plan (OSP) indicated that the operation had no monitoring system (§205.102(a)(3)) in place; however, documents submitted with their initial application and the operator during an interview disclosed that a monitoring system existed. This does not meet requirements in accordance with §205.402(a)(1).*
6. *In the case of one witness audit, CAAE personnel stated that all certified site locations are not inspected annually. Sites and facilities that are determined not to have had any activities occur since the prior annual onsite inspection are not physically inspected. This does not meet requirements in accordance with §205.403(a)(1).*
7. *Several labels were identified by the auditor to be noncompliant. In one case, a "Made with Organic..." product label did not include the "Certified Organic By..." statement. Another label displayed ingredients as "100% Organic" rather than "Organic in the ingredient panel." These do not meet requirements in accordance with §205.303(b)(1-2) and §205.304(b)(1-2).*

Corrective Actions: The following corrective actions were submitted by CAAE:

1. Training was conducted for the NOP staff on November 22, 2019 indicating the incidents and corrections for the correct performance of the work. The "Treatment Flow Analytical Results" document has been updated to add communication to the operator to be compliant with the regulations.
2. CAAE has submitted updated Notice of Proposed Suspension and Notice of Proposed Revocation communication templates that allow for a 30-day period as required in §205.681(c). The certifier's NOP staff has been trained indicating the incidents and the corrections.
3. The procedure has been modified in the CAAE NOP Procedures Manual (Rev 4, 11/19/19), page 62 point 17.8.1, it has been established that inspectors determine report findings, citing the regulation in the inspection report. The NOP staff has been trained indicating the incidents and corrections on November 22, 2019.
4. This procedure has been modified in the CAAE NOP Procedures Manual (Rev 4, 11/19/19), section 17.2.4 which requires that the on-site inspection of an operation must verify that the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation. A "Work Order" document has been prepared for the inspector where all the information of the updated OSP is

collected every year. The NOP staff has been trained indicating the incidents and the corrections on November 22, 2019.

5. The procedure for maintaining the OSP from year to year has been modified in the CAAE NOP Procedures Manual (Rev 4, 11/19/19), section 17.2.4 which requires that the on-site inspection of an operation must verify that the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation. A “Work Order” document has been prepared for the inspector where all the information of the updated OSP is collected every year. The NOP staff has been trained indicating the incidents and the corrections on November 22, 2019.
6. In the CAAE NOP Procedures Manual (Rev 4, 11/19/19), section 17.1.3. it has been clarified that CAAE 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.
7. The label review document, “NOP Documentation Paperwork” has been modified to ensure verifications of all labels will be recorded and separated in the appropriate category. The label review model has been modified on pages 13 to 16. The NOP staff has been trained indicating the incidents and corrections on November 22, 2019.

Verification of Corrective Action: The auditors found the following:

1. CAAE personnel still do not consistently demonstrate an adequate understanding of the USDA organic regulations and **NOP 2613 Instruction: Responding to Results from Pesticide Residue Testing**. The auditor's review of certification files found CAAE received a residue analysis that exceeded the EPA tolerance level but did not investigate or report the violation to local authorities as outlined in NOP 2613. CAAE has not effectively implemented this corrective action.
2. The auditor's review of adverse action files found CAAE issued notifications of proposed suspension with an operator response deadline of 15 days for both mediation and appeals. CAAE has not effectively implemented this corrective action.
3. The auditors reviewed inspection reports and noted inspectors are not following the updated NOP Procedures Manual (Rev 4, 11/19/19), page 56 point 17.8.1, which states, “inspector must indicate the regulation that is breached and leave it reflected in the inspection documents.” CAAE has not effectively implemented this corrective action.
4. CAAE inspectors are not consistently identifying incomplete or inaccurate organic system plans (OSPs) during inspections as issues of concern. The auditor's review of certification files found several instances where the inspector reported practices or procedures that did not align with the operation's OSP, but the inspector did not identify this as a possible noncompliance in their report. CAAE has not effectively implemented this corrective action.
5. The auditor reviewed certification files and interviewed CAAE staff and found that all components of operations' OSPs were not always readily available and auditable. The auditor's review of the “Work Order” found that it did not contain sufficient information for an inspector to verify an operation's practices and procedures. CAAE stated that all inspectors have access to the operation's complete file records through one of two software platforms, but the system but does not adequately communicate current practices, approved materials, and monitoring systems employed by operations. CAAE has not effectively implemented this corrective action.
6. The auditors reviewed certification files, interviewed staff, and determined CAAE is inspecting certified operations annually. No outstanding issues were found.

7. The auditor reviewed certification files and determined CAAE staff are using the updated label review document. However, the auditors found noncompliant labels in the certification files. In one case, a retail label did not identify all ingredients as organic in the ingredient statement, another label displayed a noncompliant organic seal, and a third did not display the statement, "Certified Organic by...." or similar phrase. This corrective action has not been effectively implemented.

2023 Corrective Action:

1. CAAE updated the "MP-NOP Procedures Manual National Organic Program Rev.11" section 16.14 on February 2, 2023. The updated procedure instructs CAAE staff to follow ***NOP 2613 Responding to Results from Pesticide Residue Testing*** when reviewing and responding to pesticide residue test results. In May 2023, CAAE conducted training for certification staff on the revisions to the Procedures Manual. CAAE provided the revised manual, and the training agenda, materials and attendance list to NOP.
2. CAAE updated its adverse action templates on February 2, 2023. The updated templates are compliant with §205.681(c) which allows operators 30 days to file an appeal with the NOP. In May 2023, CAAE conducted staff training on the updated templates.
3. CAAE updated page 8, section 8 of the Inspection Report template instructing the inspector to cite the NOP regulation not being followed. CAAE conducted inspector training on the revised template on October 18, 2021.
4. In January 2022, CAAE created an organic system plan (OSP) review form titled "MN-10-19 Informe de Revision Pt 848 PT NOP RTPO LPO JAS" for reviewers to document their verification that an OSP is complete. CAAE conducted inspector training in March 2022 which addressed documenting incomplete or inaccurate OSPs as issues of concern. CAAE also conducted certification staff and inspector training in July and November 2022 on the use of the OSP review form and evaluating the OSP for compliance. CAAE reported that inspectors are identifying incomplete or inaccurate OSPs as issues of concern, as evidenced through inspector field evaluation findings, inspection report surveillance, and noncompliances for incomplete OSPs issued to operations in 2022 and 2023.
5. CAAE created separate application and OSP templates. The templates and completed producer files are managed in a SharePoint system which is fully accessible by certification staff. CAAE inspectors use AgilePoint to access operation OSPs and inspection documents and submit their inspection reports. In May 2022, CAAE conducted training for certification staff and inspectors on the new templates and software systems.
6. This point was cleared during the audit, therefore corrective actions were not required.
7. CAAE conducted training for certification staff on the correct use of the label review document in May 2022. CAAE issued noncompliances to the operations with noncompliant labels and reviewed and approved revised compliant labels.

Noncompliances Identified during the Current Assessment

AIA-7729-21 - 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: *CAAE does not demonstrate the ability to fully comply with the requirements for accreditation. The auditors' review of certification files and interviews with staff found:*

1. *CAAE's noncompliance template does not include the date by which the applicant may rebut or correct the noncompliance, as required by §205.665(a)(3).*
2. *CAAE's Notice of Suspension template incorrectly states the NOP will determine the length of suspension. This is not in compliance with the adverse action process found in*

§205.662(c), which states the notice of proposed suspension shall state the impact of a suspension on future eligibility for certification.

3. *CAAE's organic certificate template does not include all elements of **NOP 2603 Organic Certificates**, which requires organic certificates to include the statement, "Certified to the USDA organic regulations, 7 CFR Part 205."*
4. *CAAE's organic certificates for operations that export organic products to Canada do not contain the following required attestation: "Certified in accordance with the terms of the U.S.-Canada Organic Equivalency Arrangement."*
5. *CAAE's crop production organic system plan forms do not demonstrate that CAAE fully verifies their operations' compliance with the requirements of §205.201(a), or the provisions of **NOP 5020 Guidance Natural Resources and Biodiversity Conservation**. There is no section for operators to describe biodiversity and maintaining or improving natural resources, including soil, water, wetlands, woodlands, and wildlife.*

Corrective Action:

1. CAAE updated its Notice of Noncompliance template "NOP-10-15 Resolution of the N.O.P. Certifying Commission Rev. 06 05/10/22" to include the date by which the applicant may rebut or correct the noncompliance. CAAE trained certification staff on the updated template on May 31, 2022.
2. CAAE updated the Notice of Suspension template "NOP-10-17 Rev.06 10/05/22" to remove the noncompliant statement and include the length of an operation's suspension. CAAE trained staff on the updated template on May 31, 2022.
3. CAAE updated the organic certificate template "F-NOP/06 Rev.06 25/10/21" to include the statement "Certified to the USDA organic regulations, 7 CFR Part 205." CAAE began using the updated template on September 23, 2022.
4. CAAE updated the organic certificate template "F/NOP-06/COR Rev.00 25/10/21" for operations exporting to Canada to include the statement "Certified in accordance with the terms of the U.S.-Canada Organic Equivalency Arrangement." CAAE began using the updated template September 23, 2022.
5. CAAE updated the "Crop OSP template MN-10-08 - Rev. 07 - 04/29/2022" to include section 4 Biodiversity Conservation and Section 9 Monitoring. The updated template was sent to producers at the beginning of 2023. CAAE trained certification staff on the revised OSP template on May 31, 2022

AIA-7730-21 - Accepted. 7 C.F.R. §205.670(g) states, "If test results indicate a specific agricultural product contains pesticide residues or environmental contaminants that exceed the Food and Drug Administration's or the Environmental Protection Agency's regulatory tolerances, the certifying agent must promptly report such data to the Federal health agency whose regulatory tolerance or action level has been exceeded. Test results that exceed federal regulatory tolerances must also be reported to the appropriate State health agency or foreign equivalent."

Comments: *CAAE does not fully carry out the procedures of **NOP 2613 Instruction Responding to Results from Pesticide Residue Testing**, and **NOP 2610 Instruction Sampling Procedure Residue Testing**, section 4.5. The auditor's review of pesticide residue analysis reports and staff interviews found the following:*

1. *CAAE's inspectors prepare three samples; one that is sent directly to the laboratory for analysis, one that is left with the operator, and one that is retained by CAAE. If the first sample sent to the laboratory returns a positive result, CAAE allows for the other two samples to be sent, and if either of those samples return a non-detect, CAAE does not investigate the first positive sample. This practice does not meet NOP policies on sampling procedures or how to respond to results from pesticide residue testing.*

2. CAAE does not always inform operations that their product may be sold as organic when residues are not detected.

Corrective Action:

1. CAAE revised the “Inspection Report Organic Production F/RTPO -PT - NOP -12 Rev.07 Date: 10/18/21” document to state that for NOP sampling events, only one sample will be analyzed, and the results of that single sample will be the only valid results. On September 30, 2021, CAAE trained its pesticide residue test review staff on the updated sampling protocol.
2. CAAE updated the “Certification Decision Letter NOP-10-10 Rev.06 10/05/22” to indicate an operator’s products may be sold as organic when the residue sample test results were negative. CAAE implemented the updated template and conducted training for certification staff on May 31, 2022.

AIA-7732-21 - Accepted. 7 C.F.R. §205.403(a)(2)(ii) states, “The Administrator or State organic program’s governing State official may require that additional inspections be performed by the certifying agent for the purpose of determining compliance with the Act and the regulations in this part.

Comments: *The auditor’s review of unannounced inspection reports found that CAAE inspectors are providing more than four hours notice before unannounced inspections. This practice does not meet the requirements of **NOP 2609 Instruction Unannounced Inspections**, which only allows more than four hours advance notice in extenuating circumstances.*

Corrective Action: CAAE updated the “Procedures Manual National Organic Program (NOP)” section 16.9 to include compliant language consistent with **NOP 2609 Unannounced Inspections**. CAAE also updated its inspection report templates, “Inspection Report Organic Production F/RTPO-PT-NOP-12 Rev.07 Date: 10/18/21” and “Inspection Report EU/NOP NOP-20-06 Rev.15 Date:18/10/2021” with a checkpoint on page one to indicate whether the inspector had given the operation no notice or no more than four hours advance notice. On May 31, 2022, CAAE conducted training for certification staff and inspectors on the revised Procedures Manual.

AIA-7733-21 - Accepted. 7 C.F.R. §205.406(c) states, “If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in §205.404, that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with §205.662.”

Comments: *CAAE does not consistently issue its certified operations a notification of noncompliance even though the review of certification files and inspection reports finds that the operation does not comply with the USDA organic regulations. The auditor’s review of records found that CAAE allows operations to submit corrective actions to address issues of concern identified at inspection prior to the final certification decision. CAAE’s inspectors submit the operator’s corrective actions with the inspection report. As a result, staff do not consistently issue Notices of Noncompliance when such a notice should be issued to the operation.*

Corrective Action: CAAE conducted training for certification staff and inspectors on May 31, 2022, on when it is required to issue noncompliances from inspection report findings and that inspectors are not to accept corrective actions from the operation.

AIA-7734-21 - Accepted. 7 C.F.R. §205.501(a)(5) states “A private or governmental entity accredited as a certifying agent under this subpart must: Ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to

successfully perform the duties assigned.”

Comments: CAAE does not consistently ensure that its employees and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to perform the duties assigned. The auditor’s review of information submitted by CAAE found that inspectors, reviewers, and those making certification decisions are not consistently implementing USDA organic regulations and NOP policies. The following are examples:

1. A notification of noncompliance sent to a certified operation referenced a violation of §205.671, although the residue testing did not detect prohibited substances at levels that are greater than 5 percent of the Environmental Protection Agency's tolerance for the specific residue detected.
2. CAAE certification staff are not complying with the requirements of §205.662, the noncompliance and adverse action process. In one instance, CAAE issued a notification of noncompliance with corrective actions included in the notice and no opportunity for the operation to rebut the noncompliance; in another case, CAAE issued a Notice of Surrender when an operation did not submit an updated organic system plan and pay the annual fees required for certification; in one case, CAAE issued a notification of proposed suspension without first issuing a notification of noncompliance. In another case, the auditors reviewed a certification file in which CAAE issued an operation a Notice of Suspension without first issuing a notification of noncompliance and notification of proposed suspension.

Corrective Action: CAAE conducted certification staff training on May 12, 2022, and September 9, 2023 that covered pesticide residue test results interpretation and the noncompliance and adverse action process. CAAE also submitted examples of correct noncompliances issued to operations since the training.

AIA-7735-21 - Accepted. 7 C.F.R. §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: CAAE is not carrying out the provisions of the Act and regulations described in §205.402-406. CAAE does not consistently identify incomplete, nor inaccurate organic system plans during the initial review, the on-site inspection, and the final certification decision stages. The auditors’ review of certification files found incomplete or inaccurate Organic System Plans (OSPs) and supporting documents, including the following examples:

1. A HACCP plan relied upon to describe the operation’s compliance with §205.271-272 did not adequately address the provisions of these standards.
2. The product flow diagram for an operation included the use of two processing aids, but the OSP did not describe compliant use of these inputs as required by §205.201(a)(2).
3. An operation’s OSP did not include a map of an organic farm parcel that demonstrates how the parcel meets the requirements of §205.202(c), which requires maps to have distinct, defined boundaries and buffer zones.
4. One operation’s OSP did not include an updated input list.
5. CAAE did not verify an operation’s compliance with §205.206(a)-(d) prior to the operation using pest or disease control substances included on the National List, as required by §205.206(e).

Corrective Action: CAAE created an organic system plan (OSP) review document “MN-10-19 Informe de Revision Pt 848 PT NOP RTPO LPO JAS.” In July and November 2022, CAAE conducted training for certification staff on the new form and the following NOP requirements:

correct organic system plan components to demonstrate compliance with §205.271-272; the OSP input list verification at review and inspection; compliant map components, and compliance with §205.206(a-d) prior to approval of pest control inputs.

AIA-7736-21 - 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: *CAAE’s material review policies and procedures do not demonstrate that CAAE has the ability to verify compliance with the requirements of §205.201(a)(2) as clarified in NOP 3012 Interim Instruction Material Review. The auditor’s review of CAAE’s material review policy and procedures found these documents do not include sufficient written instructions outlining the expectations regarding the depth and frequency of the review, and providing clear direction for the evaluation of ingredients, sub-ingredients, processing aids, and manufacturing methodologies at all stages associated with the production of formulated products.*

Corrective Action: CAAE updated the “Procedures Manual National Organic Program (NOP)” section 16.3.2 with language that material input review will be compliant with **NOP 3012 Material Review**. CAAE’s material review staff completed the Organic Integrity Learning Center course Input Material Review in November 2022, and in May 2023, CAAE conducted training of certification staff on the revisions to the Procedures Manual.

AIA-7738-21 - Accepted. 7 C.F.R. §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: *CAAE is not carrying out the provisions of the Act and regulations. The auditors’ review of certification files and input documentation found CAAE does not always verify sufficient information to determine the compliance of input material. The following are examples:*

1. *CAAE did not request or review documentation to verify the compliance of processing aids used in direct contact with an organic product.*
2. *CAAE did not request or review documentation of cleaners and sanitizer products used in organic handling.*

Corrective Action: CAAE updated the “Procedures Manual National Organic Program (NOP)” section 16.3.2 with language that material input review will be compliant with **NOP 3012 Material Review**. CAAE updated organic system plan (OSP) templates for all scopes by adding an input documentation section for operations to complete. CAAE also updated the OSP Review document “MN-10-19 Informe de Revision Pt 848 PT NOP RTPO LPO JAS” to include a material input review tab. CAAE trained staff on the updated templates and OSP review form in July and November of 2022, and CAAE material review staff took the OILC Input Material Review training in November 2022. CAAE conducted training of certification staff on the revisions to the Procedures Manual in May 2023.

AIA-1432-22 – 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: *CAAE did not issue a notification of noncompliance to its certified operation, even though the operation was found to be noncompliant. The auditor’s review of certification files found that CAAE did not issue a notification of noncompliance to producers for failure to pay annual certification fees and submit an updated organic system plan as required by*

§205.406(a).

Corrective Action: CAAE issued notices of noncompliance to the operations in question. CAAE updated the “Procedures Manual National Organic Program (NOP)” section 16.12.1 and 16.12.2 to include the compliant process of issuing a noncompliance when an operation does not submit an updated organic system plan (OSP) and renewal fees by the required deadline. CAAE conducted staff training September 28 and October 1, 2021, on the noncompliance process.

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

An onsite renewal assessment of CAAE Certification Service (CAAE)'s organic program was conducted June 24 – July 4, 2019. The National Organic Program (NOP) reviewed the auditor's report to assess CAAE's compliance to the USDA organic regulations. This report provides the results of NOP's assessment.

GENERAL INFORMATION

Applicant Name	CAAE Certification Service (CAAE)
Physical Address	Avenida Diego Martinez Barrios no 10, 3rd floor, Modulo 12 Sevilla 41013, Spain
Mailing Address	Same as above
Contact & Title	Ricardo Porto Martin, Head of Quality
E-mail Address	rporto@caae.es
Phone Number	34 955 018 968
Reviewer & Auditor	Jon Frady, NOP Reviewer; Lars Crail, On-site Auditor
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP corrective action review: February 5 – April 21, 2020 NOP assessment review: October 7, 2019 Onsite audit: June 24 – July 4, 2019
Audit Identifier	NOP-08-19
Action Required	Yes
Audit & Review Type	Renewal Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of CAAE's certification
Audit & Determination Criteria	7 CFR Part 205, National Organic Program as amended
Audit & Review Scope	CAAE's certification services in carrying out the audit criteria during the period: February 2017 through July 2019

CAAE is a for-profit company with its main certification office in Sevilla, Spain. CAAE has no satellite offices conducting NOP certification activities. The auditor visited CAAE's Lima, Peru office which provides client outreach consisting of marketing and communication, certification inspections, and administers the invoicing of CAAE services. CAAE is planning on growing the number of NOP clients in Latin America, mainly in Mexico and Ecuador.

CAAE is accredited for Crops, Wild Crops, and Handling/Processing scopes. At the time of the onsite renewal audit, CAAE certifies 88 operations in Spain and Peru: Crops (45), Wild Crops (0), and Handler/Processor/Exporters (57). CAAE certifies 12 grower groups located in Peru.

Two witness audits were conducted as part of the onsite audit. These were: (1) observation of a Crops and Handler (Processing) operation additional inspection in Peru on June 25-26, 2019; and, (2) a witness audit of an annual inspection of a Handler (Processing) operation in Spain on July 2, 2019. The scheduled grower group witness audit was canceled the day before the inspection by the operator. The NOP plans to conduct a grower group witness audit at a later date.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether CAAE corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to CAAE.

Noncompliances from Prior Assessments and Corrective Actions

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 “**Accepted**” indicates acceptance of the corrective actions and verification of corrective action implementation will be conducted during the next onsite audit.

NP6172ZZA.NC1 – Cleared.

NP6172ZZA.NC2 – Cleared.

NP6172ZZA.NC3 – Cleared.

NP6172ZZA.NC4 – Cleared.

NP6172ZZA.NC5 – Accepted. 7 C.F.R. § 205.642 states, “...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.”

Comments: *A review of the fee schedule and billing records found the grower group operations in Turkey are charged differently than the fee schedule on file with the Administrator. Grower groups certified in Turkey are charged fees based on an agreement between the certifier and a Turkish inspection body providing inspection services on their behalf instead of in accordance to the fee schedule on file with the Administrator.*

2016 Corrective Action: CAAE submitted a revised fee schedule that includes the inspection costs for operations certified in Turkey (CAAE Fees Rev. 14). CAAE submitted its procedures manual. The procedure requires that CAAE notify the NOP when changes are made to the fee schedule.

2019 Verification of Correction Action: The corrective action was not implemented adequately. Changes to the fee schedules (Spain and Peru) are filed with the NOP as part of the Annual Report (February); however, this is after the updated fee schedules are published and implemented. The most recent changes to and implementation of those published fees occurred 4/25/19 for Spanish operations and 6/9/19 for Peruvian operations. The modified fee schedules are scheduled to be submitted with the February 2020 Annual Report. Missing from the current

NOP Procedure Manual (Rev. 3, 6/20/17) are procedures for notifying the NOP of certification fee schedule changes.

2019 Corrective Action: CAAE submitted an updated communication table that requires any changes to the fees schedule be submitted to NOP before being put into use. They also provided the updated CAAE NOP Procedures Manual (Rev 4, 11/19/19) which requires any fee schedules to be approved before use of those fees with their clients.

Noncompliances Identified during the Current Assessment and Corrective Actions

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.

NOP-08-19.NC1 – Accepted. 7 C.F.R. § 205.660(d) states, “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: *CAAE is not using a delivery system that provides dated return receipts. CAAE is using a Microsoft Outlook feature that notifies the sender when email has been delivered and opened.*

2019 Corrective Action: CAAE is modifying their procedure setting that all the communications “ 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” would be made by a delivery system with dated acknowledgement of receipt, by post mail or by courier with dated acknowledgement of receipt.

NOP-08-19.NC2 – Accepted. 7 C.F.R. §205.510(b)(2) states, “Certifying agents must maintain records according to the following schedule: Records created by the certifying agent regarding applicants for certification and certified operations must be maintained for not less than 10 years beyond their creation.”

Comments: *The following records could not be located by CAAE personnel and reviewed by the auditor:*

- a. *CAAE could not demonstrate to the auditor that notifications were submitted to the NOP pursuant to §205.501(a)(15)(i)*

2019 Corrective Action: An additional control measure has been established for notifications to NOP. When they are sent, the Head of Quality will be placed responsible for the NOP scheme that will verify the communications sent monthly. The updated communications table to NOP located in Section 21 of the CAAE NOP Procedures Manual (Rev 4, 11/19/19) verified this change.

- b. *Records for certified products that appeared to contain capsules and other non-agricultural products not listed on §205.605 were not available for the auditor to determine compliance of those ingredients pursuant to §205.301(a)(b)(c)*

2019 Corrective Action: The “NOP Documentation Paperwork” internal document has been modified to ensure all verifications of all input labels are going to be recorded and will be maintained for at least 10 years. The label review model has been modified on pages 13 to 16.

NOP-08-19.NC3 – Accepted. 7 C.F.R. § 205.501(a)(4) states, “A certifying agent under this subpart must: Use ... adequately trained personnel, including inspectors ... to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part.”

Comments: *During the audit, CAAE personnel did not consistently demonstrate an adequate understanding of the USDA organic regulations and NOP Policies. The following are examples as evidence:*

- a. *In one residue analysis case reviewed by the auditor, the CAAE Reviewer correctly determined that the 5% of the EPA tolerance level was exceeded, but did not issue a noncompliance notification per §205.662(a)(1-3) with reference of §205.671 to the operator.*

2019 Corrective Action: Training was conducted for the NOP staff on November 22, 2019 indicating the incidents and corrections for the correct performance of the work. The “Treatment Flow Analytical Results” document has been updated to add communication to the operator to be compliant with the regulations.

- b. *CAAE’s issued proposed suspension notifications indicate a 15-day period for the operator to either file an appeal or request mediation. A 15-day period was also identified in the proposed suspension and revocation notification templates. This does not meet requirements in accordance with §205.681(c).*

2019 Corrective Action: CAAE has submitted updated Notice of Proposed Suspension and Notice of Proposed Revocation communication templates that allow for a 30-day period as required in §205.681(c). 15-day period for the operator to either file an appeal or request mediation. The certifier’s NOP staff has been trained indicating the incidents and the corrections.

- c. *During one of the witness audits conducted and during the inspection exit interview, the inspector informed the operator of an identified issue, but did not reference the regulation. Further interviews of CAAE personnel and inspectors revealed that inspectors are instructed to identify issues without recording or citing the regulations. Certification reviewers will assign a regulatory reference or citation when and if an inspector’s finding is classified as a noncompliance. This does not meet requirements in accordance with §205.403(d).*

2019 Corrective Action: The procedure has been modified in the CAAE NOP Procedures Manual (Rev 4, 11/19/19), page 62 point 17.8.1, it has been established that inspectors determine report findings, citing the regulation in the inspection report. The

NOP staff has been trained indicating the incidents and corrections on November 22, 2019.

- d. *Inspectors are not identifying incomplete or inaccurate organic system plans during inspections as issues of concern. During the witness audit of an inspection of a certified Crops operation, the operation disclosed that manure was applied as fertilizer; however, the OSP indicated that the operation only used composted plant materials. This does not meet requirements in accordance with §205.403(c)(2).*

2019 Corrective Action: This procedure has been modified in the CAAE NOP Procedures Manual (Rev 4, 11/19/19), section 17.2.4 which requires that the on-site inspection of an operation must verify that the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation. A “Work Order” document has been prepared for the inspector where all the information of the updated OSP is collected every year. The NOP staff has been trained indicating the incidents and the corrections on November 22, 2019.

- e. *The auditor’s assessment of 10 reviewed operation records and interviewed CAAE certification personnel indicated that a single OSP is not maintained. The current record keeping system does not readily allow for a reviewer or auditor to understand what the current practices, approved materials, and monitoring system are employed by operations. In one operation file reviewed by the auditor, the Organic System Plan (OSP) indicated that the operation had no monitoring system (§205.102(a)(3)) in place; however, documents submitted with their initial application and the operator during an interview disclosed that a monitoring system existed. This does not meet requirements in accordance with §205.402(a)(1).*

2019 Corrective Action: The procedure for maintaining the OSP from year to year has been modified in the CAAE NOP Procedures Manual (Rev 4, 11/19/19), section 17.2.4 which requires that the on-site inspection of an operation must verify that the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation. A “Work Order” document has been prepared for the inspector where all the information of the updated OSP is collected every year. The NOP staff has been trained indicating the incidents and the corrections on November 22, 2019.

- f. *In the case of one witness audit, CAAE personnel stated that all certified site locations are not inspected annually. Sites and facilities that are determined not to have had any activities occur since the prior annual onsite inspection are not physically inspected. This does not meet requirements in accordance with §205.403(a)(1).*

2019 Corrective Action: In the CAAE NOP Procedures Manual (Rev 4, 11/19/19), section 17.1.3. it has been clarified that CAAE 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.

- g. *Several labels were identified by the auditor to be noncompliant. In one case, a “Made with Organic...” product label did not include the “Certified Organic By...” statement. Another label displayed ingredients as “100% Organic” rather than “Organic in the ingredient panel.” These do not meet requirements in accordance with §205.303(b)(1-2) and §205.304(b)(1-2).*

2019 Corrective Action: The label review document, “NOP Documentation Paperwork” has been modified to ensure verifications of all labels will be recorded and separated in the appropriate category. The label review model has been modified on pages 13 to 16. The NOP staff has been trained indicating the incidents and corrections on November 22, 2019.

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a mid-term assessment of CAAE Certification Service (CAAE). An onsite audit was conducted, and the audit report reviewed to determine CAAE's capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	CAAE Certification Service (CAAE)
Physical Address	Avenida Emilio Lemos n° 2, Edificio Torre Este, Modulo 603 41020 Sevilla, Andalucía, Spain
Mailing Address	Avenida Emilio Lemos n° 2, Edificio Torre Este, Modulo 603 41020 Sevilla, Andalucía, Spain
Contact & Title	Ricardo J. Porto Martín, Head of Quality
E-mail Address	rporto@caae.es
Phone Number	+34 902 521 555
Reviewer(s) & Auditor(s)	Graham Davis, NOP Reviewer; Corey Gilbert, On-site Auditor.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	Corrective actions review: February 9, 2017 NOP assessment review: November 15, 2016 Onsite audit: June 20-24, 2016
Audit Identifier	NP6172ZZA
Action Required	None
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of CAAE's certification system.
Audit & Determination Criteria	7 CFR Part 205, National Organic Program as amended
Audit & Review Scope	CAAE's certification services in carrying out the audit criteria during the period: May 8, 2014 through June 20, 2016

The NOP conducted an onsite mid-term assessment of CAAE Certification Service (CAAE) on June 20-24, 2016.

CAAE is a non-profit business which was accredited on February 13, 2009, and maintains the accreditation scopes of crops, wild crops, and handling. CAAE certifies operations in Spain and grower group operations in Turkey. CAAE is accredited to ISO 17065 for scope of organic farming and Global GAP.

CAAE maintains five offices in Spain. Certification activities are only conducted out of the main office in Sevilla. The regional offices in Castilla-La Mancha, Almeria, Granada, and Cordoba are utilized by inspectors to access the certification network system or to conduct office work; however, no certification decisions are made in these office.

CAAE staff includes the technical manager, certification manager, quality manager, crops and wild crops manager, handling manager, 13 technical staff (reviewers), 7 staff inspectors, 4 contract inspectors, and several administrative assistants.

As part of the mid-term onsite audit, one witness audit was conducted on a crop operation (cucumbers) in Motril, Granada, Spain and one review audit was conducted on a handling operation (winery) in Las Pedroñeras, Cuenca, Spain. CAAE has three certified grower group operations which are all located in Turkey. Due to US government travel restrictions, it was not possible to conduct a witness or review audit in Turkey in 2016; therefore, only a file review was conducted.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether CAAE'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.

NP0270MMA.NC3 – Cleared.

NP0270MMA.NC6 – Cleared.

NP4125OOA.NC1 – Cleared.

NP4125OOA.NC2 – Cleared.

NP4125OOA.NC3 – Cleared.

NP4125OOA.NC4 – Cleared.

NP4125OOA.NC5 – Cleared.

NP4125OOA.NC6 – Cleared.

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.

NP6172ZZA.NC1 – Accepted. 7 C.F.R. § 205.662 (e)(1) states, “If the operation fails to correct the noncompliance, to resolve the issue through rebuttal or mediation, or to file an appeal of the proposed suspension ..., the certifying agent ... shall send the certified operation a written notification of suspension....”

Comments: *CAAE accepted corrective actions from an operation it had issued a Notice of Proposed Suspension and sent a Notice of Proposed Suspension Resolution to the operation upon accepting the corrective actions.*

2016 Corrective Action: CAAE submitted a revised Notice of Proposed Suspension Template. The notice no longer instructs the operation to submit corrective actions to the noncompliance upon receiving a notice of proposed suspension. CAAE held a training on January 12, 2017, for its staff to review the noncompliances and the use of the revised document.

NP6172ZZA.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: (2) demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart.” 7 C.F.R. §205.504(b)(2) 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; its ability to fully comply with and implement the organic certification program established in §§205.100 and 205.101, §§205.201 through 205.203, §§205.300 through 205.303, §§205.400 through 205.406, and §§205.661 and 205.662; and its ability to comply with the requirements for accreditation set forth in §205.501: (b) *Administrative policies and procedures.* (2) A copy of the procedures to be used for reviewing and investigating certified operation compliance with the Act and the regulations in this part and the reporting of violations of the Act and the regulations in this part to the Administrator.”

Comments: *CAAE does not have template documents for a Notice of Proposed Revocation or Notice of Revocation, and their NOP procedures do not adequately address the requirements for revocation. CAAE certification staff did not have a clear understanding of the requirements for proposed revocation and revocation. CAAE has not issued any proposed revocation or revocation notifications.*

2016 Corrective Action: CAAE submitted a Notice of Proposed Revocation and a Notice of Revocation Template. The notice no longer instructs the operation to submit corrective actions to the noncompliance upon receiving a notice of proposed revocation. CAAE held a training on January 12, 2017, for its staff to review the noncompliances and the use of the revised documents.

NP6172ZZA.NC3 – 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 2027 Instruction Personnel Performance Evaluations, 3.2.b. Field Evaluation (Inspectors only) states, “Inspectors should be evaluated during an onsite inspection by a supervisor or peer (another inspector) at least annually.”

Comments: *CAAE did not conduct annual field evaluations (specific to the USDA organic regulations) of all inspectors in 2014 (1 of 10) and 2015 (2 of 11). Annual field evaluations specific to the EU organic regulations are typically conducted for all inspectors. CAAE has*

scheduled to conduct field evaluations specific to the USDA organic regulations for 10 of 11 inspectors in the third quarter of 2016. CAAE did not have an onsite field evaluation scheduled in 2016 for the one inspector in Turkey because one had been conducted in 2015. Annual performance evaluations (document review) are conducted for all inspectors.

2016 Corrective Action: CAAE revised and submitted their personnel evaluation policy that outlines a risk based points system to determine field evaluations of their inspectors. In 2016, CAAE conducted a field evaluation for 1 of 11 inspectors because that inspector accumulated enough points to warrant a field evaluation. In 2017, field evaluations will be made to all the other inspectors since they have accumulated a point total that requires a field evaluation every two years. CAAE conducted a training session on January 12, 2017, to notify their staff of changes to this procedure.

NP6172ZZA.NC4 – Accepted. 7 C.F.R. § 205.501(a)(8) states, “A private or governmental entity accredited as a certifying agent under this subpart must: (8) 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;” 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 2609 Instruction Unannounced Inspections, 4.1.13 states, “A certifying agent should clearly disclose the protocols for unannounced inspections to certified operations.”

Comments: *Certified operations are not provided the protocols (policies/procedures) for unannounced inspections. Certified operations are informed they are subject to unannounced inspections, but detailed information is not provided.*

2016 Corrective Action: CAAE submitted a revised inspection policy that includes a section for unannounced inspections. The procedure instructs the inspector to inform the operation that they are representing CAAE, the reason the operation was chosen for an unannounced inspection, and that they may need to take samples. CAAE created and submitted a letter template that explains the criteria for unannounced inspections. The letter was sent to all of their clients in January of 2017. CAAE conducted a training session on January 12, 2017 to notify their staff of changes to this procedure.

NP6172ZZA.NC5 – Accepted. 7 C.F.R. § 205.642 states, “...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.”

Comments: *A review of the fee schedule and billing records found the grower group operations in Turkey are charged differently than the fee schedule on file with the Administrator. Grower groups certified in Turkey are charged fees based on an agreement between the certifier and a Turkish inspection body providing inspection services on their behalf instead of in accordance to the fee schedule on file with the Administrator.*

2016 Corrective Action: CAAE submitted a revised fee schedule that includes the inspection costs for operations certified in Turkey (CAAE Fees Rev. 14). CAAE submitted its procedures manual. The procedure requires that CAAE notify the NOP when changes are made to the fee schedule.

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a renewal assessment of CAAE Certification Service (CAAE). An onsite audit was conducted and the audit report reviewed to determine CAAE's capability to continue operating as a USDA accredited certifying agent. This report provides the results of the renewal assessment and review of CAAE's corrective actions.

GENERAL INFORMATION

Applicant Name	CAAE Certification Service (Servicio de Certificación CAAE S.L.U.)
Physical Address	Avenida Emilio Lemos nº 2. Edificio Torre Este, Modulo 603, 41020 Seville Andalucía, Spain
Mailing Address	Avenida Emilio Lemos nº 2. Edificio Torre Este, Modulo 603, 41020 Seville Andalucía, Spain
Contact & Title	Juan Manuel Sánchez Adame, Head of Quality
E-mail Address	jmsanchez@caae.es
Phone Number	34 902 521 555
Auditor(s) & Reviewer(s)	Robert Yang, NOP Reviewer; Darrell Wilson, On-site Auditor.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	Review of Corrective Actions: October 22, 2014 Onsite Audit Dates: May 5-8, 2014
Audit Identifier	NP4125OOA
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 CAAE's certification system.
Audit and Determination Criteria	7 CFR Part 205, National Organic Program as amended
Audit & Review Scope	Review of corrective actions submitted on August 15, 2014 for noncompliances resulting from the renewal assessment.

The CAAE Certification Service (CAAE) is part of the CAAE Association, which is a non-profit private organization. CAAE consists of the main office in Sevilla, Spain and four regional offices located in Castilla-La Mancha, Almeria, Granada, and Cordoba, Spain. All certification activities are carried out from the main office.

CAAE is currently accredited as a certifying agent to the USDA National Organic Program

(NOP) for the scopes of crops, wild crops, and handling. CAAE was initially accredited by the NOP on February 13, 2009. CAAE currently has 23 clients certified to the USDA organic regulations; 12 for crops and 11 for handling of which 10 are processors and 1 is a trader. CAAE certifies operations to the NOP in Spain. CAAE does not currently certify grower groups. CAAE also maintains accreditations for other organic certification programs, including Bio Suisse, JAS, and the EU (EC 834/2007 and 889/2008).

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether CAAE'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.

NP0270MMA.NC1 – Cleared
NP0270MMA.NC2 – Cleared
NP0270MMA.NC4 – Cleared
NP0270MMA.NC5 – Cleared
NP0270MMA.NC7 – Cleared
NP0270MMA.NC8 – Cleared
NP0270MMA.NC9 – Cleared
NP0270MMA.NC10 – Cleared
NP0270MMA.NC11 – Cleared

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.

NP0270MMA.NC3 – Accepted. 7 CFR §205.404(b)(2) and (3) states, "The certifying agent must issue a certificate of organic operation which specifies the: (2) Effective date of certification; and (3) Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation." *CAAE is placing "First Certification Issuance Date" as the initial certification date of CAAE if first time applicants have never*

applied to another ACA. However, if the applicant was certified by another ACA then they are using the date the applicant was certified by the other ACA and not the date certified by CAAE. Additionally, the two certificates issued to wild crop operations did not identify the scope of certification as a wild crop.

Corrective Action (April 2011): CAAE adjusted the E-CERT system to include a new category, “wild harvest.” The format of the certificates has been modified to include “wild crop” as a category of certification. Also, the Procedures Manual (1.1) has been modified to include “NOP Wild Harvest” as an applicable certification category. To correct the issue at the certified operation level, CAAE revised the applicable certificates to display “wild crops” as appropriate and forwarded the revised certificates along with a letter explaining the change to the operators. For all areas of response, CAAE provided objective evidence.

Verification of Corrective Action (May 2014): The 6 certificates reviewed did not contain the scope of certification (currently crops and handling). Therefore, certificates are still not in compliance with the USDA organic regulations.

Corrective Action: CAAE reissued the 6 organic certificates with the certification scopes properly identified and revised the certificate template in its E-CERT system to include the crops and handling certification scopes.

NP0270MMA.NC6 – Accepted. 7 CFR §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.” *A review of personnel files verified that 9 of 33 CAAE personnel working with the NOP program did not have current conflict of interest statements.*

Corrective Action (April 2011): CAAE obtained current Conflict of Interest statements from all staff and submitted as objective evidence with the response. The Procedures Manual “has been modified to include the obligation to update the disclosure of conflict of interest statements by January 31st of each year.”

Verification of Corrective Action (May 2014): There were no current conflict of interest statements for personnel involved with NOP certification. The Head of Quality indicated that they have restructured the conflict of interest document and did not get them sent out early enough to receive them back before the previously signed documents expired.

Corrective Action: CAAE obtained completed Conflict of Interest forms from all certification personnel. Procedures have been amended to state that even if the Conflict of Interest form is scheduled for revision the current version will be used in order to receive completed Conflict of Interest statements from staff by January 31st.

NP4125OOA.NC1 – Accepted. 7 CFR §205.404 (b)(4) states, “The certifying agent must issue a certificate of organic operation which specifies the name, address, and telephone number of the certifying agent.” *Certificates in the files reviewed did not contain the address of the certifying*

agent.

Corrective Action: CAAE revised the certificate template in its E-CERT system to include the address of CAAE's head office and reissued organic certificates to all its certified operations using the revised template.

NP412500A.NC2 – Accepted. 7 CFR § 205.405 (d) states, "A notice of denial of certification must state the reason(s) for denial and the applicant's right to: (2) Request mediation pursuant to §205.663 or, if applicable, pursuant to a State organic program; or (3) File an appeal of the denial of certification pursuant to §205.681 or, if applicable, pursuant to a State organic program." *CAAE's Notices of Denial do not include the applicant's right to request mediation pursuant to §205.663 or file an appeal pursuant to §205.681.*

Corrective Action: CAAE revised its Notice of Denial to include the applicant's right to request mediation or appeal the denial of certification.

NP412500A.NC3 – Accepted. 7 CFR §205.406 (a)(1) states, "To continue certification, a certified operation must annually pay the certification fees and submit the following information, as applicable, to the certifying agent: (1) An updated organic production or handling system plan which includes: (i) A summary statement, supported by documentation, detailing any deviations from, changes to, modifications to, or other amendments made to the previous year's organic system plan during the previous year; and (ii) Any additions or deletions to the previous year's organic system plan, intended to be undertaken in the coming year, detailed pursuant to §205.200." *Letters that CAAE sends out notifying the operation that their annual update is coming up indicates that, if there are no changes, they do not need to make any reply to CAAE. If no reply is received, the inspector is directed to contact the operation and schedule an inspection.*

Corrective Action: CAAE amended its Procedures Manual (section 16.7 Annual renewals) to include a procedure for certified operators to be sent an Annex NOP Renovation/Modification form on which the operator will report changes to their Organic Management Plan. Staff training on the new procedure and form was conducted on July 23, 2014.

NP412500A.NC4 – Accepted. 7 CFR § 205.662 (c)(2) states, "The notification of proposed suspension or revocation of certification shall state: The proposed effective date of such suspension or revocation." *The notifications of proposed suspension address the date by which the certified operation must respond to the proposed suspension. However, if the operation does not reply within the stated time frame, or the response is deemed insufficient or inappropriate in addressing the non-compliances, then the certified operation's certification may be suspended. The notices do not contain a defined date when the proposed suspension will become effective.*

Corrective Action: CAAE revised its Resolution of the N.O.P. Certifying Commission document to include a date when the proposed suspension or revocation becomes effective. Staff training on the revised document was conducted on July 23, 2014.

NP412500A.NC5 – 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.” NOP 2609, Section 4.1.6 states, “An unannounced inspection should not include prior notification of the inspector’s arrival. However, there may be special cases where extenuating circumstances make it impossible to conduct an unannounced inspection on the operation without prior notification (e.g. biosecurity issues). In such cases, the certifying agent may notify the operation up to four (4) hours prior to the inspector arriving on-site to ensure the appropriate representatives are present.” *CAAE’s current policy is to provide 24 hours prior notification to the operations (this mostly affects crop operations) for an unannounced inspection. The reasoning for this two-fold; first there are a number of operations where the responsible person does not live at the site of the operation and, in some cases, must travel longer than four hours to reach the site of the operation. Second, most of the crop operations that CAAE certifies are fenced and have locked access to the operation. Personnel and workers who are regularly on site at these operations in most cases do not have the knowledge or authority to assist inspectors with what they need for the unannounced inspections. However, this should not be standard policy for all operations.*

Corrective Action: CAAE revised its Procedures Manual (section 16.8 Control Visit) to state that unannounced visits should not be previously communicated to the operator and that operations may be notified up to four hours in advance only when extenuating circumstances make it impossible to conduct an unannounced inspection without notification. Staff training on the new procedure was conducted at the head office on July 23, 2014.

NP412500A.NC6 – Accepted. 7 CFR §205.670 (c) states, “A certifying agent must conduct periodic residue testing of agricultural products to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).” Samples may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples. Such tests must be conducted by the certifying agent at the certifying agent's own expense.” *CAAE conducted two (2) samplings for NOP during the calendar year 2013. The tests for these samples were paid for by the certified operation.*

Corrective Action: CAAE issued refunds to its certified operators who were charged for sample testing. Additionally, CAAE revised its Resolution of the N.O.P. Certifying Commission document and Procedures Manual (section 17.6 Sampling) to state that the cost of the sampling will be paid by CAAE and not the operator. Staff training on the revised procedure and document was conducted on July 23, 2014.

Applicant Name:	Servicio de Certificacion CAAE S.L.U. (CAAE Certification Service)
Est. Number:	NA
Physical Address:	Avenida Emilio Lemos n° 2. Edificio Torre Este, Modulo 603, 41020 Sevilla-Andalucía, Spain
Mailing Address:	Same
Contact & Title:	Ricardo J. Porto Martin, Quality Control
E-mail Address:	rporto@caae.es
Phone Number:	34 955 024 150
Auditor(s):	Meg Kuhn, RAM – East Region
Program:	USDA National Organic Program (NOP)
Audit Date(s):	April 15 – 19, 2011
Audit Identifier:	NP0270MMA
Action Required:	No
Audit Type:	Corrective Action Audit
Audit Objective:	To verify review and approve corrective actions addressing the non-compliances identified during the Initial On-site Audit.
Audit Criteria:	7 CFR Part 205, National Organic Program; Final Rule, dated December 21, 2000; revised February 17, 2010.
Audit Scope:	CAAE's response letter and supporting attachments, received April 15, 2011, to the Initial On-site Audit non-compliance report
Location(s) Audited:	Desk

AUDIT INFORMATION

During the Initial On-site Audit, eleven (11) non-compliances were identified. CAAE was notified of these findings in a notice from the NOP on March 15, 2011. CAAE forwarded a response, with supporting objective evidence, to all non-compliance findings on April 15, 2011. CAAE's submitted response, along with supporting objective evidence, adequately addresses all non-compliance findings sighted.

FINDINGS

NP0270MMA.NC1 –Adequately Addressed: NOP §205.201(a)(5) states, “An organic production or handling system plan must include: (5) A description of the management practices and physical barriers established to prevent commingling of organic and nonorganic products on a split operation and to prevent contact of organic production and handling operations and products with prohibited substances.” *Observations made during the witness inspection of the wild crop verified that the maps that the inspector used did not indicate all of the areas where the wild crops were collected. Topographic maps were used of the areas controlled by the city where the collection of the wild crops occurs. The maps contained the area of the city along with wild areas, and plots that were owned by individuals. There was no identification of the buffer zones along the city area or plots that were owned by individuals; or the use of the plots by individuals to make any determination of possible contamination risks. It was observed during*

*the witness inspection that some of the plots in the area had been cultivated but there had been no verification of the crops planted. It was noted during a review of operator files, that maps were included but there were few if any notations on the maps on the use of land surrounding the organic operations. Inspectors made notations in the inspection report that the buffers were viewed and that there was little risk of contamination. The buffer zones and collection areas were not well defined and identified in the organic system plan or maps. **Corrective Action:** CAAE provided maps of plots for the specific producers in question from the witness / case file audits that demonstrate the buffer zone borders in use. CAAE also updated 18.3.2.f of the Procedures Manual (copy of update attached) to “include express instructions regarding the importance of checking for buffer zones.” The CAAE Review Report has also been modified “to detail the information that needs to be shown on the maps;” a copy of this Review Report was attached for review.*

NP0270MMA.NC2 – Adequately Addressed: NOP §205.303(b)(2) states, “Agricultural products in packages described in §205.301(a) and (b) must: (2) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, “Certified organic by * * *,” or similar phrase, identify the name of the certifying agent that certified the handler...” *Eighteen (18) of 25 approved organic labels reviewed had the statement “Certified NOP by S.C. CAAE.” **Corrective Action:** CAAE provided an update to the Procedures Manual (18.3.2.f, doc attached) to “include instructions to check that all labels contain the term ‘certified organic by CAAE,’ or in the case of those which might lead to confusion, ‘certified organic NOP by CAAE.’” CAAE, in addition to the Procedures Manual update, forwarded 3 examples of the new label review process captured in the Manual; the label review process includes a review report that must be completed and approved for each label, and includes the requirement to verify the correct “COB...” statement.*

NP0270MMA.NC3 – Adequately Addressed: NOP §205.404(b)(2) and (3) states, “The certifying agent must issue a certificate of organic operation which specifies the: (2) Effective date of certification; and (3) Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation.” *CAAE is placing “First Certification Issuance Date” as the initial certification date of CAAE if first time applicants have never applied to another ACA. However, if the applicant was certified by another ACA then they are using the date the applicant was certified by the other ACA and not the date certified by CAAE. Additionally, the two certificates issued to wild crop operations did not identify the scope of certification as a wild crop. **Corrective Action:** CAAE adjusted the E-CERT system to include a new category, “wild harvest.” The format of the certificates has been modified to include “wild crop” as a category of certification. Also, the Procedures Manual (1.1, doc attached) has been modified to include “NOP Wild Harvest” as an applicable certification category. To correct the issue at the certified operation level, CAAE revised the applicable certificates to display “wild crops” as appropriate and forwarded the revised certificates along with a letter explaining the change to the operators. For all areas of response, CAAE provided objective evidence.*

NP0270MMA.NC4 – Adequately Addressed: NOP §205.405(a) states, “When the certifying agent has reason to believe, based on a review of the information specified in §205.402 or §205.404, that an applicant for certification is not able to comply or is not in compliance with the

requirements of this part, the certifying agent must provide a written notification of noncompliance to the applicant.” Also, 205.406(c) states, “If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in §205.404, that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with §205.662.” *CAAE is not properly documenting notifications of non-compliances which are submitted to clients. Notifications of non-compliances are provided by the inspectors during the exit interview. Inspectors can then accept corrective actions and also make a determination on when the non-compliances have to be addressed. In two of three files reviewed for the requirement, non-compliances identified by the inspectors were not identified as non-compliances by the certification technician or certification committee and were not included on the certification decision document which is where CAAE identifies non-compliances to clients. In one file the non-compliance was included on the decision document as a “reminder” to the client.* **Corrective Action:** CAAE created and implemented (completed: April 11, 2011) notices of non-compliance that clearly indicate the non-compliance issue cited. The Procedures Manual (16.6 and 16.9, docs attached) has been updated to “provide detailed instructions regarding the different types of Resolution that the Certifying Commission may make, including the Resolution to send a Notice of Non-compliance.” Further, the format of the Resolution of the Certifying Commission has been “modified to clearly differentiate between what is considered a ‘non-compliance’ and what is simply a ‘comment or reminder’.” Inspectors have also been instructed to discontinue citing non-compliances at the time of audit and that they are not able to communicate issues of non-compliance at audit. Objective evidence was provided for all response points.

NP0270MMA.NC5 – Adequately Addressed: NOP §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.” *A review of the files verified that on at least one occasion CAAE did not conduct a full review of the material inputs. Instead CAAE accepted an affidavit from the supplier of a fungicide that the inert ingredients were in compliance with the NOP standards and listed on EPA List 4 or EPA List 3. On another occasion a crop operation sprayed their olive trees with a copper oxychloride product for fungus control in October 2009. The olives were harvested December through the beginning of February and the olive oil produced from the olives was subsequently processed as NOP eligible product. There was not enough information available at the time of the USDA audit to determine if product was actually marketed as NOP certified product. The copper oxychloride product contained mono-ethylene glycol as an inert.* **Corrective Action:** at the operator level, inspections were conducted (Aug and Oct 2010) and found that the input in question (ZZ Cuprocol) was no longer in use. The CAAE “Policy Memorandum 11-4,” which provides a list of materials approved for the NOP, has been revised to list this material (ZZ Cuprocol) as “prohibited.” The evaluation report was modified to include the types of tests that should be conducted for materials in use, and the Procedures Manual (16.3.2.c, doc attached) was revised to include requirements for material review and approval. Objective evidence was submitted for all response points.

NP0270MMA.NC6 – Adequately Addressed: NOP §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.” *A review of personnel files verified that 9 of 33 CAAE personnel working with the NOP program did not have current conflict of interest statements.* **Corrective Action:** CAAE obtained current Conflict of Interest statements from all staff and submitted as objective evidence with the response. The Procedures Manual “has been modified to include the obligation to update the disclosure of conflict of interest statements by January 31st of each year” (doc of update attached to response).

NP0270MMA.NC7 – Adequately Addressed: NOP §205.501(a)(11)(vi) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Prevent conflicts of interest by: Ensuring that the decision to certify an operation is made by a person different from those who conducted the review of documents and on-site inspection.” *Initial file reviews and final reviews prior to the file being sent to the two member certification committee was conducted by the same certification technician in five of seven files reviewed. In all cases the final review by the certification technician was the same day as the day the certification committee signed the certification decision documents prepared by the certification technician. The reviews conducted by the certification committee are cursory reviews based on the findings of the certification technician.* **Corrective Action:** CAAE’s certification system is set up such that the application reviewer and inspection report reviewer may or could be the same personnel. The final decision is made by the Certifying Commission. The NOP accepts this structure, as the person(s) making the final decision is different from those that conducted a review of documents (application review) and / or the on-site inspection.

NP0270MMA.NC8 – Adequately Addressed: NOP §205.501(a)(15)(i) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Submit to the Administrator a copy of: (i) Any notice of denial of certification issued pursuant to §205.405, notification of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, and notification of suspension or revocation sent pursuant to §205.662 simultaneously with its issuance.” *The list of non-compliances identified by CAAE included 61 notifications of non-compliance. None of which had been submitted to NOP.* **Corrective Action:** CAAE has revised the certification system to ensure all notices of non-compliance are submitted to AMS, including minor non-compliance issues. The Procedures Manual has been modified to include a detailed section on Notices to AMS and which notices would apply; further, the format for the Resolution of the Certifying Commission was revised to include instructions regarding delivery of notices to the AMS Administrator. CAAE sent confirmation (objective evidence) showing that all applicable notices have been sent to AMS for the 2011 certification year thus far.

NP0270MMA.NC9 – Adequately Addressed: NOP §205.501(a)(18) states “A private or governmental entity accredited as a certifying agent under this subpart must: Provide the inspector, prior to each on-site inspection, with previous on-site inspection reports and notify the inspector of its decision regarding certification of the production or handling operation site inspected by the inspector and any requirements for the correction of minor non-compliances.”

CAAE just recently started notifying inspectors of its decision regarding certification of operations. Inspectors are notified on a monthly basis. This change was due to a non-compliance identified during an internal audit. However, CAAE does not inform the inspectors of the requirement for correction of any minor non-compliances identified by CAAE.

Corrective Action: CAAE's Procedures Manual (18.3.8, doc attached) has been revised to "detail which information should be sent to the inspectors and when it should be sent."

Specifically, this update states, "inspectors will periodically receive copies of any resolutions (with the corrective measures proposed by the producer) which are issued for any inspections they carried out." CAAE also forwarded objective evidence showing a notification of this type to an inspector in 2011 in response.

NP0270MMA.NC10 – Adequately Addressed: NOP §205.510(a)(1) and (4) state, "Annual report and fees. 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) A complete and accurate update of information submitted pursuant to §§205.503 and 205.504; (4) The results of the most recent performance evaluations ..." *The 2010 annual report submitted to the Administrator did not include the results of the most recent performance reviews nor copies of 3 inspection reports and certification evaluation documents for production and handling operations certified by the applicant for each area of accreditation (NOP §205.504(d)(2)).* **Corrective Action:** CAAE's system has been updated to require that the Annual Update include performance reviews and 3 copies of inspection reports / certification evaluation documents for each area of accreditation. The Procedures Manual (21.1, doc attached) was revised to detail all information required for the Annual Update. CAAE also sent evidence of the 2010 Annual Update submission, completed in February 2011, which included required documents.

NP0270MMA.NC11 – 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 shall provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification. 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. The certifying agent shall provide all persons inquiring about the application process with a copy of its fee schedule." *Certification packages provided to applicants do not contain a copy of the CAAE fee schedule. A review of the NOP cost estimates sent by CAAE to operations indicates that the estimate/budget sent to the operator includes a charge for a risk factor that is applied to the operator based on the size of operation, number of employees, and number of sites. There is also a charge for "training" that CAAE applies to recoup expenses paid to another ACA for expenses incurred during the accreditation process. Travel expenses for inspections are also included in the estimate. None of these additional costs are described in the description of fees for NOP operators. The determination of the "risk" factor (margin) is not described in any procedure*

and is arbitrarily applied to operations. The fee schedule states that fees cannot be refunded once the subscription process has begun but does not identify the stages at which fees become non-refundable. **Corrective Action:** CAAE now sends formal pricelists to new applicants for certification. Further, CAAE revised the fee schedule to provide more transparent fees based on objective criteria. The Procedures Manual (16.1.4 and 16.1.5, docs attached) was also updated to include instructions to provide a pricelist to new applicants, as well as a quote (“estimate”) for the specific certification in question, calculated in accordance with the new pricelist. Objective evidence documents were submitted.