



United States Department of Agriculture

Agricultural Marketing Service
National Organic Program

CERTIFICADORA MEXICANA DE PRODUCTOS Y PROCESOS ECOLOGICOS SC

**Calle 16 de Septiembre No. 204, Ejido Guadalupe Victoria, Oaxaca, Oaxaca,
68280, MEXICO**

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

7 CFR Part 205

as an Accredited Certifying Agent

for the scope of

Crops, Handling, Livestock (Apiculture only), 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 .

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CERTIFICATE OF ACCREDITATION



Certificate No: **USDA-52-22**
Effective Date: **04/14/2021**
Expiration Date: **04/14/2026**
Issue Date: **05/10/2022**


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NATIONAL ORGANIC PROGRAM: AUDIT & CORRECTIVE ACTION REPORT

GENERAL INFORMATION

- **Certifier Name** Certificadora Mexicana de Productos y Procesos Ecologicos SC, (CMEX)
- **Physical Address** Calle 16 de Septiembre No. 204, Oaxaca, Oaxaca 68280, MEXICO
- **Audit Type** Midterm Audit
- **Auditor(s) & Audit Dates** Colleen O'Brien, Kelley Belina, 04/13/2023 to 04/21/2023
- **Audit Identifier** NOP-202-23

CERTIFIER OVERVIEW

The National Organic Program (NOP) conducted an onsite Midterm Audit of Certificadora Mexicana de Productos y Procesos Ecologicos SC's (CMEX) USDA organic certification program covering the period March 12, 2021 to April 21, 2023. The purpose of the audit was to verify CMEX's compliance with the Organic Foods Production Act of 1990 (OFPA), the USDA organic regulations (7 CFR Part 205), and the NOP Handbook. Audit activities included a review of certification activities, interviews with CMEX personnel, a records audit, and two onsite witness audits. The witness audits consisted of additional onsite inspections of a handling operation and a crops operation (grower group); both operations are in Mexico.

CMEX is a non-profit organization initially accredited on April 14, 2006. CMEX is accredited to the crops, wild crops, livestock (apiculture only), and handling scopes. CMEX's office is in Oaxaca, Mexico. CMEX certifies 150 operations and offers certification services in Mexico, Colombia, Puerto Rico, and the United States of America. Certification activities are performed by 16 office personnel and 24 inspectors.

NOP DETERMINATION:

NOP reviewed the audit results to determine whether CMEX'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 audit.

Noncompliances from Prior Assessments

AIA-4008-20 - Cleared.

AIA-4012-20 - Cleared.

AIA-6100-21 - Cleared.

AIA-6101-21 - Cleared.

AIA-6150-21 - Cleared.

AIA-314-22 - Cleared.

AIA-6148-21 – Accepted. 7 C.F.R. §205.501(a)(4) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part;”

Comments: *CMEX does not consistently use adequately trained personnel to comply with and implement its USDA organic certification program. The auditor’s review of certification files found that CMEX staff approved noncompliant labels and also approved products that did not contain enough organic ingredients to qualify for the organic claim being made. The auditors found that CMEX staff approved a label stating, “with organic ingredients” instead of “made with organic (specified ingredients or food groups).” In addition, the auditors found that CMEX staff approved four products for the “100% organic” category that were only eligible for the “organic” category, based on the organic certificates of the ingredients provided by the operation.*

Corrective Action: CMEX sent notices of noncompliance to three operations regarding noncompliant labels or product formulations identified during the NOP audit and submitted the operations’ adequate corrective actions to NOP. CMEX also updated Section 6.1.1 of its “Manual of Quality Procedures, Chapter 13 - Procedures for the certification of operations” to require its reviewers to verify that labels and product formulations submitted by operations comply with §205.301 through §205.311. CMEX notified its personnel of the procedural update on August 23, 2021 and held a training event on September 3, 2021 to inform personnel of the changes. CMEX submitted an agenda and attendance list for the training.

Verification of Corrective Action: The auditors reviewed certification files and found CMEX had approved noncompliant labels. Specifically, the auditors reviewed updated labels submitted by one operation in response to CMEX’s notice of noncompliance and found that CMEX approved the updated labels although they were still not compliant. The updated labels stated, “made with organic ingredients” instead of listing out the specific organic ingredients or food groups.

2023 Corrective Action: CMEX reported that the operation with the noncompliant labels

identified by the auditors had surrendered its certification, so the labels were no longer in use. Additionally, CMEX reviewed all approved labels on file for its NOP certified operations and identified three operations with noncompliant labels. CMEX confirmed with the operations that the noncompliant labels were no longer in use, collected and reviewed compliant product labels, and notified the operations of the label approval. On August 1, 2023, CMEX emailed all certification personnel with links to NOP labeling requirements and resources for label review. CMEX staff responsible for label review completed the Organic Integrity Learning Center training “Organic Regulations and Retail Labeling.” On August 29, 2023, CMEX’s certification area coordinator conducted an NOP product label review workshop for all certification staff responsible for label review. The workshop included a review of NOP labeling requirements, CMEX’s label review procedures and forms, and evaluation of noncompliant labels identified by NOP auditors.

AIA-6149-21 - 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: *CMEX does not consistently demonstrate the ability to fully comply with the requirements for accreditation, including NOP 3012 Interim Instruction Material Review. The auditors found the following issues related to CMEX’s material review process:*

- 1. CMEX does not have adequate policies, procedures and work instructions for evaluating and approving material inputs for use in organic production or handling.*
- 2. CMEX does not accurately review pest control materials, sanitizers, processing aids and nonagricultural ingredients for compliance with the USDA organic regulations. The auditors review of certification files found that CMEX staff approved noncompliant input materials for use by its certified operations.*
- 3. CMEX staff does not use adequate information when evaluating material inputs for use in organic production or handling. The auditors found that in some cases, CMEX staff is making decisions on material inputs without having a full disclosure of its ingredients or a description of its manufacturing process.*
- 4. CMEX does not verify whether materials comply with annotations or use restrictions on the National List of Allowed and Prohibited Substances. CMEX also does not communicate any applicable National List annotations or restricted use requirements to its operations in the approved material input list it provides to them.*

Corrective Action: CMEX submitted the following corrective actions in response to the noncompliance:

1. CMEX sent notices of noncompliance to three operations regarding noncompliant labels or product formulations identified during the NOP audit and submitted the operations’ adequate corrective actions to NOP.
2. CMEX updated its “Manual of Quality Procedures, Chapter 10 - Procedure for the on-site evaluation (inspection) of operators interested in the certification of the production, processing and/or marketing of organic products” to instruct the inspector to ensure the input list in the operation’s Organic System Plan (OSP) matches the actual inputs used. CMEX also added section 8.9 which instructs the inspector to collect documentation when an operation is found to be using an input not listed in their OSP.
3. CMEX updated its “Procedure 9 - Procedure to access the certification” to state that all inputs will be reevaluated annually during review of the management plan (chapter 8.3) and to instruct the inspector to review the list of authorized inputs within the OSP (chapter 8.5).
4. CMEX updated “Procedure 13 - Procedure for the certification of operators” to

designate report reviewers and final certification managers as responsible for conducting input evaluation and to include instructions for evaluating inputs using the documents listed in section 8.9 of Procedure 10. 5.

CMEX notified review staff and inspectors of these updates in August 2021 and held a training event on September 3, 2021 to review the updated procedures. CMEX also required staff to take the OILC Input Material Review training. Nine inspectors completed the OILC training in 2021 and CMEX has required that all inspectors complete the training by the end of 2022.

Verification of Corrective Action: The auditors reviewed certification files and found CMEX does not accurately review input materials for compliance and does not always use adequate information when evaluating inputs. The auditors reviewed inspector training records and found that not all inspectors completed the OILC Input Material Review training. CMEX does not reevaluate input materials on an annual basis. When auditors requested compliance documentation for inputs currently listed as approved on an operation's input list, CMEX staff provided documents submitted two or three years ago, and in some cases, CMEX was unable to find the compliance documentation. CMEX's material review procedures do not provide clear protocols that outline the expectations regarding the depth and frequency of the review, nor do they provide clear direction for the evaluation of ingredients, sub-ingredients, processing aids, and manufacturing methodologies at all stages associated with the production of multi-ingredient inputs or products requested for certification.

2023 Corrective Action: On July 17, 2023, CMEX issued a reminder to inspection staff of CMEX's procedures for input verification during onsite inspections, including verification of required supporting documentation for each input in use. CMEX reported that as of August 5, 2023, all CMEX certification staff and inspectors had completed the OILC Input Material Review training. CMEX updated its procedure *MPC 9.1, Procedure for application and organic management plan review* to add Annex 1 outlining CMEX's review protocol for inputs and materials during OSP and inspection report review. On August 29, 2023, CMEX implemented a revised OSP form, *MCF 3.18.1.A List of Inputs Used*, which includes designated places for the application review, inspector, and final reviewer to document their compliance review for each input listed in the OSP. Certification reviewers are responsible for verifying that the operation submits current compliance documentation for each input every year and evaluating all of an operation's inputs for compliance annually. In August 2023, CMEX implemented a new central database for evaluated inputs, and reviewers are now responsible for documenting their evaluation of inputs, including the operation code, what compliance documentation was reviewed and the evaluation date, in this database. CMEX has designated folders for each operation where it stores supporting compliance documentation for inputs. On August 17, August 21, and November 1, 2023, CMEX trained certification staff on input evaluation to the NOP standards and documenting input determinations in CMEX's database of evaluated inputs.

AIA-900-22 - 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: *CMEX does not consistently carry out the provisions of the Act and regulations. A review of information submitted by CMEX found that CMEX does not consistently verify an operation's compliance with the requirements of §205.303(b)(2). Specifically, the review found that CMEX incorrectly approved the label of a package of 100% organic blackberries that does not include the required statement, "Certified organic by" The label states, "Certified by"*

Corrective Action: CMEX issued the operation a Notice of Noncompliance for the noncompliant

label and created a checklist for CMEX staff to use when reviewing labels for compliance with the USDA organic regulations. CMEX identified additional instances of approved noncompliant labels and issued Notices of Noncompliances to those operations as well. CMEX plans to conduct training for its staff in June 2022 on label review and submitted the training agenda and meeting invitation to NOP as evidence.

Verification of Corrective Action: The auditors reviewed certification files that included labels for both packaged products and nonretail containers and found several examples where CMEX approved noncompliant labels, including labels without a compliant “Certified organic by...” statement. The auditors interviewed CMEX staff and found that CMEX discontinued the use of the label review checklist in August 2022 and instead hired a staff member whose sole responsibility is to review labels.

2023 Corrective Action: CMEX reported that the operation with the noncompliant labels identified by the auditors had surrendered its certification, so the labels were no longer in use. Additionally, CMEX reviewed all approved labels on file for NOP certified operations and identified three operations with noncompliant labels. CMEX confirmed with the operations that the noncompliant labels were no longer in use, collected and reviewed compliant product labels, and notified the operations of the label approval. On August 1, 2023 CMEX emailed all certification personnel with links to NOP labeling requirements and resources for label review. CMEX staff responsible for label review completed the Organic Integrity Learning Center training “Organic Regulations and Retail Labeling.” On August 29, 2023, CMEX’s certification area coordinator conducted an NOP product label review workshop for all certification staff responsible for label review (report reviewers and designated label reviewer). The workshop included a review of NOP labeling requirements, CMEX’s label review procedures and forms, and evaluation of noncompliant labels identified by NOP auditors.

Noncompliances Identified during the Current Assessment

AIA-5021-23 - Accepted. 7 C.F.R. §205.501(a)(2) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart.”

Comments: *CMEX does not fully implement the NOP’s international organic trade arrangement policies and procedures, which are outlined in the NOP’s **International Trade Policies resources**. The auditor’s review of certification files found that CMEX does not include the statement, “Certified in accordance with the terms of the U.S.-Canada Organic Equivalency Arrangement” on organic certificates for operations with products approved for export to Canada under the U.S.-Canada Organic Equivalency Arrangement.*

Corrective Action: CMEX updated MPC-34: *Procedure for the certification of organic products in accordance with the United States-Canada equivalency arrangement* to require that the attestation statement be included on eligible organic certificates and added instructions for how to include the attestation statement on certificates issued from the Organic Integrity Database. CMEX notified staff of the revised procedure on August 11, 2023 and conducted staff training on August 21, 2023. CMEX reviewed and updated the INTEGRITY records for all certified operations with products certified in accordance with USCOEA and sent revised certificates containing the required attestation statement to the certified operations.

AIA-5022-23 - Accepted. 7 C.F.R. §205.662(a)(1) 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. Such notification shall provide: A description of each noncompliance;”

Comments: *CMEX does not consistently cite the applicable or correct regulation for the noncompliance identified in its notifications of noncompliance. The auditor's review of notifications of noncompliance found CMEX cited regulations that did not exist, such as 205.1(a)(2)(6) and 205.202(3). CMEX also cited regulations that did not apply, such as 205.206(a-e) for when a residue test of a soil sample resulted in a positive pesticide residue detection.*

Corrective Action: In August and September 2023, CMEX conducted training for certification staff and inspectors on writing findings and noncompliances with correct regulatory references. Additionally, CMEX plans to instruct the inspector field evaluators to specifically verify that inspectors are using correct regulatory citations when documenting findings.

AIA-5023-23 - Accepted. 7 C.F.R. §205.402(c) states, "The applicant may withdraw its application at any time. An applicant who withdraws its application shall be liable for the costs of services provided up to the time of withdrawal of its application. An applicant that voluntarily withdrew its application prior to the issuance of a notice of noncompliance will not be issued a notice of noncompliance. Similarly, an applicant that voluntarily withdrew its application prior to the issuance of a notice of certification denial will not be issued a notice of certification denial.

Comments: *CMEX does not consistently comply with the USDA organic regulations when an operation voluntarily withdraws its application for certification. The auditor's review of certification files found that CMEX issued an operation a notice of denial after the operation requested to withdraw their application for certification.*

Corrective Action: CMEX updated its *MPC-9 Procedure for access to certification* and *MPC-13 Procedure for certification of operators* to include requirements for applicants who withdraw their certification prior to being issued a notice of noncompliance or denial. On August 9 and August 18, 2023, CMEX notified certification personnel of the revisions to the procedures. CMEX submitted the revised procedures and copies of the communications to NOP.

AIA-5024-23 - 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: *CMEX does not consistently ensure that its inspectors have sufficient expertise in USDA organic regulations prior to performing the duties assigned. During the witness audit of a crops operation, the auditor observed the following:*

- 1. The inspector informed the operator that they must maintain records on compost temperature and turning, without taking into consideration whether manure is added to the compost, nor whether the operator applied the compost more than 90/120 days prior to harvest.*
- 2. The inspector interviewed an operator about inputs used but did not request to review any documentation to verify compliance of the inputs (such as purchase records).*

Corrective Action: CMEX updated its *MCF 3.5 Questionnaire for control of crop postharvest and handling* and *MCF 3.7.1 Form of control of coffee plantation, wet processing, packaging and storage* to add questions about compost feedstocks, compost production methods, and pre-harvest application intervals for manure. Additionally, CMEX updated its *MCF 3.5 Questionnaire for control of crop postharvest and handling* to add input compliance verification points, including verification of receipts and invoices for purchased inputs. CMEX notified certification staff and inspectors of the revisions to these inspection forms on August 18, 2023, and conducted training with inspectors on the revisions to the documents and the compost/input verification requirements

on August 21, 2023.

AIA-5025-23 - Accepted. 7 C.F.R. §205.670(e) states, "Sample collection pursuant to paragraphs (b) and (c) of this section must be performed by an inspector representing the Administrator, applicable State organic program's governing State official, or certifying agent. Sample integrity must be maintained throughout the chain of custody, and residue testing must be performed in an accredited laboratory. Chemical analysis must be made in accordance with the methods described in the most current edition of the Official Methods of Analysis of the AOAC International or other current applicable validated methodology for determining the presence of contaminants in agricultural products."

Comments: *CMEX does not fully carry out the procedures of NOP 2610 Instruction Sampling Procedures for Residue Testing. The auditor's review of pesticide residue analysis reports and certification files found that CMEX allows non-detect pesticide residue analysis results from a counter-sample to cancel out a residue detection from the original sample.*

Corrective Action: CMEX revised its MPC-12 Procedure for taking samples for analysis of non-allowed substances to remove instructions for inspectors to leave a counter-sample with an operation, and to state that pesticide residue analysis results from samples submitted to a laboratory by an operation will not replace the analysis results from the sample submitted by CMEX. CMEX notified certification staff and inspectors of the revisions to the procedure on August 2, 2023, and conducted staff training on August 21, 2023.

AIA-5026-23 - 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: *CMEX does not fully carry out the procedures of NOP 2613 Instruction: Responding to Results from Pesticide Residue Testing. The auditor's review of pesticide residue analysis reports found CMEX did not immediately inform the operation that the product may not be sold as organic and did not immediately report the violation to the appropriate agency when residue detections exceeded the applicable tolerances.*

Corrective Action: CMEX updated its MPC-13 Procedure for certification of operators to instruct certification staff to follow **NOP 2613 Instruction: Responding to Results from Pesticide Residue Testing** when the analysis of a sample collected at an organic operation results in a detection. On August 9, 2023, CMEX emailed certification staff the revision and reminded them to follow the procedures of **NOP 2613**. On August 28, 2023, CMEX conducted training with certification staff on the revisions to the procedure and the requirements of **NOP 2613**.

AIA-5027-23 - Accepted. 7 C.F.R. §205.501(a)(7) states, "A private or governmental entity accredited as a certifying agent under this subpart must: have an annual program review of its certification activities conducted by the certifying agent's staff, an outside auditor, or a consultant who has expertise to conduct such reviews and implement measures to correct any noncompliances with the Act and the regulations in this part that are identified in the evaluation."

Comments: *CMEX does not fully carry out the procedures of the Act and NOP 2025 Instruction Internal Program Review. The auditor's review of CMEX's annual program review found that persons who conduct the annual program review also perform certification activities.*

Corrective Action: CMEX updated its *MPC-18 Internal audits procedure* to require that the internal audit team for the USDA NOP internal audit not include personnel involved in NOP certification activities. CMEX updated its *MPC-23 Procedure for qualifying candidates as internal auditors* to prohibit NOP certification staff from conducting the internal audit and allow qualified outside auditors and consultants to conduct the internal audit instead. On August 25, 2023, CMEX notified certification staff of the revisions to the procedures. CMEX submitted a list of the proposed internal audit team members for 2023 and has scheduled an internal auditor training for November 2023.

AIA-5028-23 - 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: *CMEX does not carry out the provisions of the Act and regulations. The auditor’s review of certification files found that CMEX inspectors do not consistently conduct traceability and mass balance exercises to verify compliance with § 205.103(b)(2). The following issues were identified:*

- 1. The inspector conducted a traceability exercise but did not document how records link from the finished product to the ingredient(s) purchased.*
- 2. Inspectors do not conduct mass balance or trace-back audit exercises during inspections of new applicants.*

Corrective Action: CMEX created a new form, *MCF 3.8 Control of mass balance and traceability*, for inspectors to record mass balance and traceability exercises conducted at inspections. The form includes instructions for inspectors to record the documents reviewed during traceability exercises and the data which links the documents together. On August 15, 2023, CMEX notified certification staff and inspectors of the new form to be used at inspections. On August 28, 2023, CMEX conducted training for certification staff and inspectors on use of the new form, including that mass balance and traceability exercises must be conducted and recorded at inspections of applicants.

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

GENERAL INFORMATION

- **Certifier Name** Certificadora Mexicana de Productos y Procesos Ecologicos SC, CMEX
- **Physical Address** Calle 16 de Septiembre No. 204, Oaxaca, Oaxaca 68026, MEXICO
- **Audit Type** Renewal Audit
- **Auditor(s) & Audit Dates** Sherry Aultman, Colleen O'Brien, Samuel Schaefer-Joel
03/08/2021 to 03/12/2021
- **Audit Identifier** NOP-6-21

CERTIFIER OVERVIEW

The National Organic Program (NOP) conducted a desk audit as part of its assessment of Certificadora Mexicana de Productos y Procesos Ecologicos SC's (CMEX) USDA organic certification program. The NOP assessed CMEX's conformance to the USDA organic regulations during the period September 6, 2019 to March 12, 2021.

CMEX is a non-profit organization. CMEX was initially accredited as a certifying agent on April 14, 2006. CMEX is accredited to the following scopes: Crops, Wild Crops, Livestock (Apiculture only), and Handling.

CMEX certifies 157 operations to the following certification scopes: Crops (91), Wild Crops (1), Livestock (11), and Handler/Processor/Exporters (120). CMEX certifies 122 grower groups. Certification services occur in Mexico and Colombia.

The CMEX office is in Oaxaca, Mexico. CMEX has a total of 42 staff with one Director, one Certification Manager, five Certification Reviewers/Officers, 27 inspectors and eight administrative staff.

NOP DETERMINATION:

NOP reviewed the audit results to determine whether CMEX'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 “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance. Any noncompliance labeled as “**Accepted**” indicates acceptance of the corrective actions and verification of corrective action implementation will be conducted during the next audit

Noncompliances from Prior Assessments

AIA-4009-20 – Cleared

AIA-4010-20 – Cleared

AIA-4011-20 – Cleared

AIA-4066-20 – Cleared

AIA-4008-20 - Accepted. (NOP-2-19.NC1) 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: *The auditors’ review of inspection reports found that in several instances the inspector reported noncompliances. However, CMEX did not issue a notice of noncompliance to the operations.*

2020 Corrective Action: CMEX updated its document Procedure for certification of operators (Chapter 13) to explain how certification staff should review findings identified by inspectors. The procedure states that CMEX certification staff should determine if the finding becomes a noncompliance and classify a noncompliance as either ‘minor’ or ‘serious’ based on criteria detailed in the same procedure. CMEX also updated the exit interview portion of its inspection report template (Chapter 3.18.1 B) to allow certification staff to categorize a finding as either major or minor. CMEX notified its personnel of the updates on July 13, 2020 via email.

Verification of Corrective Action: The auditors’ review of certification files found that CMEX is not consistently issuing Notices of Noncompliance when its inspectors identify noncompliant practices. In two cases, CMEX did not issue Notices of Noncompliance to the operations because the operations submitted their corrective actions to CMEX before CMEX completed its review of the inspection reports. In two other cases, CMEX’s inspectors identified noncompliant practices, but only reported them on the exit interview as findings to different standards. Because the inspectors did not report the findings in the NOP section of the exit interview, CMEX did not issue a Notice of Noncompliance, even though the findings were also violations of the USDA organic regulations.

2021 Corrective Action: CMEX updated its inspection report template “*Chapter 3.18.1.B - Manual of questionnaires and formats.*” The exit interview in the “report” sheet of the template requires the inspector to identify NOP findings. It also requires the certification staff reviewer to categorize the findings as “observation,” “minor” or “major” and make a determination on issuing a notification of noncompliance. Additionally, the sheet “*AFC-NFC Assessment*” requires

the reviewer to evaluate the received corrective actions. CMEX notified its personnel of the procedural updates on August 24, 2021 and held a training about the changes on September 3, 2021. CMEX submitted a training attendance list and agenda included instructions on the identification of findings and the classification of noncompliances. CMEX also submitted a completed inspection report with NOP findings, reviewer classification as noncompliances and a summary of corrective actions demonstrating that the updated form is in use.

AIA-4012-20 - Accepted. (NOP-2-19.NC5) 7 C.F.R. §205.404(b)(1) – (4) states, “The certifying agent must issue a certificate of organic operation which specifies the: Name and address of the certified operation; Effective date of certification; Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation; and Name, address, and telephone number of the certifying agent.”

Comments: *CMEX’s organic certificates do not fully comply with the requirements of the USDA organic regulations. The auditor’s review of certification files found the following:*

1. *CMEX’s organic certificates incorrectly state, “Organic 100%” and “7 CRF Part 205”*
2. *On one handling operation’s organic certificate, the certified honey product was incorrectly stated as “honey bee.”*

2020 Corrective Action: CMEX corrected its organic certificate template (Chapter 4.5 A) to state “100% Organic” and “7 CFR Part 205”. CMEX has also created a new document Certificate and certification notification review checklist to ensure that information is correctly presented on the organic certificates. CMEX notified its personnel via email on July 14, 2020 of the updates to the organic certificate template and the new checklist and issued the handling operation an updated organic certificate.

Verification of Corrective Action: The auditors reviewed over 20 current organic certificates and verified that all certificates (as applicable) state “100% organic” and “7 CFR Part 205.” However, the auditors found five certificates incorrectly listing a certified honey product as “Honey Bee” or “*Apis mellifera*.”

2021 Corrective Action: CMEX corrected the noncompliant certificates to identify the certified products as “honey” and submitted the updated organic certificates along with two additional certificates CMEX determined needed correction. CMEX informed personnel on November 10, 2021 that the product name must be listed as “honey” and not other derivations, such as “honey bee” or “*Apis mellifera*.” CMEX notified staff of the requirement via email on November 10, 2021. CMEX will use its “*Certificate and Certification Notice Checklist*” to verify the correct product listing prior to issuing certificates.

Non-compliances Identified during the Current Assessment and Corrective Actions

AIA-6100-21 – Accepted. 7 C.F.R. §205.403(e)(2) states, “A copy of the on-site inspection report and any test results will be sent to the inspected operation by the certifying agent.”

Comments: *CMEX does not consistently send operations a copy of their inspection report. The auditors reviewed four certification files and CMEX was unable to provide evidence that the operation received a copy of its inspection report.*

Corrective Action: CMEX updated Section 6.3 of its “Manual of Quality Procedures, Chapter 13 - Procedures for the certification of operations” to require that inspection reports be sent to operations once the certification process is completed. Additionally, CMEX reviewed all inspections conducted through July 2021 and verified that inspection reports were sent to the operations. CMEX submitted five letters with inspection reports attached and three examples of emails with unannounced inspection reports attached as evidence of implementation of the new procedures.

AIA-6101-21 - 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: *CMEX is not consistently following the requirements of NOP 2609 Unannounced Inspections. The auditors’ review of unannounced inspection files found that CMEX was unable to provide evidence that its inspectors did not provide advance notice of more than four hours to the operations prior to the unannounced inspection. Interviews with CMEX personnel found that there are many occasions when operations are notified up to four hours in advance, but the amount of notification given to the operation is not recorded by the inspector. Additionally, the current CMEX inspection procedures do not describe under what circumstances an inspector may notify an operation prior to an unannounced inspection, how much advanced notice is allowed, or how this information should be documented.*

Corrective Action: CMEX revised Section 11.2 of its “Manual of Quality Procedures- Chapter 10 - Procedure for the on-site evaluation (inspection) of operators interested in the certification of the production, processing and/or marketing of organic products” to state that operations receiving unannounced inspections must only receive up to a four-hour advance notice. CMEX also updated its “Manual of questionnaires and formats - Chapter 3.18.4 -Inspection Report Format Not Announced/Follow up” and “Chapter 3.15 Unannounced control questionnaire” to prompt inspectors to document whether the operation was notified in advance, how far in advance, under what circumstance the notification was made, and the start time of the inspection. CMEX notified its inspectors of the updates on August 20, 2021. CMEX also submitted examples of unannounced inspection documentation showing the inspector provided the required information.

AIA-6148-21 - Accepted. 7 C.F.R. §205.501(a)(4) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part;”

Comments: *CMEX does not consistently use adequately trained personnel to comply with and implement its USDA organic certification program. The auditor’s review of certification files found that CMEX staff approved noncompliant labels and also approved products that did not contain enough organic ingredients to qualify for the organic claim being made. The auditors found that CMEX staff approved a label stating, “with organic ingredients” instead of “made with organic (specified ingredients or food groups).” In addition, the auditors found that CMEX*

staff approved four products for the “100% organic” category that were only eligible for the “organic” category, based on the organic certificates of the ingredients provided by the operation.

Corrective Action: CMEX sent notices of noncompliance to three operations regarding noncompliant labels or product formulations identified during the NOP audit and submitted the operations’ adequate corrective actions to NOP. CMEX also updated Section 6.1.1 of its “*Manual of Quality Procedures, Chapter 13 - Procedures for the certification of operations*” to require its reviewers to verify that labels and product formulations submitted by operations comply with §205.301 through §205.311. CMEX notified its personnel of the procedural update on August 23, 2021 and held a training event on September 3, 2021 to inform personnel of the changes. CMEX submitted an agenda and attendance list for the training.

AIA-6149-21 - 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: *CMEX does not consistently demonstrate the ability to fully comply with the requirements for accreditation, including NOP 3012 Interim Instruction Material Review. The auditors found the following issues related to CMEX’s material review process:*

- 1. CMEX does not have adequate policies and procedures for evaluating and approving material inputs for use in organic production or handling.*
- 2. CMEX does not accurately review pest control materials, sanitizers, processing aids and nonagricultural ingredients for compliance with the USDA organic regulations. The auditors review of certification files found that CMEX staff approved noncompliant input materials for use by its certified operations.*
- 3. CMEX staff does not use adequate information when evaluating material inputs for use in organic production or handling. The auditors found that in some cases, CMEX staff are making decisions on material inputs without having a full disclosure of the input’s ingredients and a description of its manufacturing process.*
- 4. CMEX does not verify whether materials comply with annotations or use restrictions on the National List of Allowed and Prohibited Substances. CMEX also does not communicate any applicable National List annotations or restricted use requirements to its operations in the approved material input list provided to them.*

Corrective Action: CMEX submitted the following corrective actions in response to the noncompliance:

1. CMEX sent notices of noncompliance to three operations regarding noncompliant labels or product formulations identified during the NOP audit and submitted the operations’ adequate corrective actions to NOP.
2. CMEX updated its “*Manual of Quality Procedures, Chapter 10 - Procedure for the on-site evaluation (inspection) of operators interested in the certification of the production, processing and/or marketing of organic products*” to instruct the inspector to ensure the input list in the operation’s Organic System Plan (OSP) matches the actual inputs used. CMEX also added section 8.9 which instructs the inspector to collect documentation when an operation is found to be using an input not listed in their OSP.

3. CMEX updated its “*Procedure 9 - Procedure to access the certification*” to state that all inputs will be reevaluated annually during review of the management plan (chapter 6.3) and to instruct the inspector to review the list of authorized inputs within the OSP (chapter 6.5).
4. CMEX updated “*Procedure 13 - Procedure for the certification of operators*” to designate report reviewers and final certification managers as responsible for conducting input evaluation and to include instructions for evaluating inputs using the documents listed in section 8.9 of Procedure 10.
5. CMEX notified review staff and inspectors of these updates in August 2021 and held a training event on September 3, 2021 to review the updated procedures. CMEX also required staff to take the OILC Input Material Review training. Nine inspectors completed the OILC training in 2021 and CMEX has required that all inspectors complete the training by the end of 2022.

AIA-6150-21 - 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: *CMEX is not fully verifying information in an operation’s organic system plan (OSP). The auditors’ review of certification files found the following:*

1. *A CMEX inspector found that an operation’s flow chart listed sodium hypochlorite and peracetic acid. These materials were not disclosed on the operation’s input list, nor was any documentation provided to CMEX on how these inputs were being used. Neither the inspector nor the final reviewer reported those as issues of concern.*
2. *An operation did not include sufficient evidence that it complied with the requirements of **NOP 5006 Processed Animal Manure in Organic Crop Production**. CMEX did not request this missing information from the operation, nor did the inspector identify it as an issue of concern.*
3. *For one operation using oak barrels to age tequila, CMEX did not require the operation to provide documentation demonstrating that the oak barrels being used were compliant.*
4. *An operation listed certain input materials throughout its OSP, and not specifically on the operation’s input list. CMEX did not review those input materials for compliance.*

Corrective Action: CMEX issued Notices of Noncompliance to the operations identified in the noncompliance and submitted evidence that the issues identified were resolved with corrective actions. CMEX sent an email to its inspectors on August 20, 2021 reminding them to verify that all inputs observed during the inspection are declared in the operations OSP. CMEX also updated its crop OSP and inspection report templates to include columns for material input use restrictions and information about inputs made on-farm. CMEX notified staff of the OSP and inspection report updates on August 24, 2021 and conducted training for inspectors on September 3, 2021 on CMEX’s Procedure 10 “*Procedure for the on-site evaluation (inspection) of operators interested in the certification of the production, processing, and/or marketing of organic products.*”

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

An onsite Mid-Term assessment of the Certificadora Mexicana de Productos y Procesos Ecologicos SC (CMEX) organic program was conducted September 3 - 6, 2019. The National Organic Program (NOP) reviewed the auditors' report to assess CMEX's compliance to the USDA organic regulations. This report provides the results of NOP's assessment.

GENERAL INFORMATION

Applicant Name	Certificadora Mexicana de Productos y Procesos Ecologicos SC (CMEX)
Physical Address	Calle 16 de Septiembre No. 204, Ejido Guadalupe Victoria, Oaxaca, 68026 Mexico
Mailing Address	Calle 16 de Septiembre No. 204, Ejido Guadalupe Victoria, Oaxaca, 68026 Mexico
Contact & Title	Taurino Reyes Santiago, Executive Director
E-mail Address	taurinoreyes@gmail.com
Phone Number	951 1832856
Reviewer & Auditor(s)	Melissa Lahullier, NOP Reviewer; Lars Crail and Karin French, On-site Auditors
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	Corrective actions review: December 8, 2020 NOP assessment review: June 12, 2020 Onsite audit: September 3 – 6, 2019
Audit Identifier	NOP-02-19
Action Required	No
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of CMEX's certification program
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	CMEX's certification services in carrying out the audit criteria during the period: December 2017 through August 2019.

CMEX is a non-profit organization. CMEX was initially accredited as a certifying agent on April 14, 2006. CMEX is accredited to the following scopes: Crops, Wild Crops, Livestock (Apiculture only), and Handling.

CMEX certifies 180 operations to the following certification scopes: Crops (112), Wild Crops (2), Livestock (12), and Handler/Processor/Exporters (146). CMEX certifies 61 grower groups. Certification services occur in Mexico.

The CMEX office is in Oaxaca, Mexico. CMEX staff (35) consists of: Senior Management (1), Certification Staff to include inspectors (28), and Administrative/support staff (6).

As part of the onsite accreditation audit activities, one witness audit was conducted of an annual inspection of a Crops and Handling/Processing operation.

NOP DETERMINATION

The NOP reviewed the audit results to determine whether CMEX's corrective actions adequately addressed previous noncompliances. The 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 "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance. Any noncompliance labeled as "**Accepted**" indicates acceptance of the corrective actions and verification of corrective action implementation will be conducted during the next audit.

Noncompliances from Prior Assessments

NP6101JZA.NC7 – Cleared.

NP6101JZA.NC8 – Cleared.

NP6101JZA.NC13 – Cleared.

NP6101JZA.NC18 – Cleared.

NOP-48-17.NC1 – Cleared.

NOP-48-17.NC2 – Cleared.

NOP-48-17.NC4 – Cleared.

NOP-48-17.NC5 – Cleared.

NOP-48-17.NC6 – Cleared.

AP-200-18.NC1 – Cleared.

AIA-4066-20 – Accepted. (NOP-48-17.NC3) 7 C.F.R. §205.662(c)(2) states, "When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance.... The notification of proposed suspension or revocation of certification shall state: ... the proposed effective date of such suspension or revocation;"

Comments: *A review of one proposed suspension notification identified that CMEX did not specify the effective date of suspension.*

2018 Corrective Actions: CMEX revised their notice of suspension to include the effective date of the suspension. CMEX provided training to their staff on August 31, 2018 that included the

requirements of §205.662 Noncompliance Procedures for Certified Operations and the updates to their notice of proposed suspension template.

2019 Verification of Corrective Actions: Three of three proposed suspension notifications reviewed by the auditors did not include an effective date of suspension.

2020 Corrective Action: CMEX previously updated its template for Notices of Proposed Suspension (Chapter 4.4.3) to include the effective date of suspension however the updated document was not maintained in CMEX's Quality Management System (QMS). Therefore, the compliant version of the Notice was not available to certification staff for use in generating Notices. CMEX added the compliant Notice template to its QMS and informed its personnel via email that the updated version of the template was now available for use.

Noncompliances Identified during the Current Assessment

AIA-4008-20 – Accepted. (NOP-2-19.NC1) 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: *The auditors' review of inspection reports found that in several instances the inspector reported noncompliances. However, CMEX did not issue a notice of noncompliance to the operations.*

Corrective Action: CMEX updated its document *Procedure for certification of operators* (Chapter 13) to explain how certification staff should review findings identified by inspectors. The procedure states that CMEX certification staff should determine if the finding becomes a noncompliance and classify a noncompliance as either ‘minor’ or ‘serious’ based on criteria detailed in the same procedure. CMEX also updated the exit interview portion of its inspection report template (Chapter 3.18.1 B) to allow certification staff to categorize a finding as either major or minor. CMEX notified its personnel of the updates on July 13, 2020 via email.

AIA-4009-20 – Accepted. (NOP-2-19.NC2) 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: *CMEX's organic system plan forms do not demonstrate that CMEX fully complies with the requirements of 205.201(a)(3). The forms do not ask operators to provide a description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented.*

Corrective Action: CMEX has implemented the following corrective actions:

- CMEX updated its organic system plan (OSP) template (Chapter 3.18.1 A) to ask operators to provide a description of the monitoring practices and procedures to be performed and maintained to verify that the OSP is effectively implemented.
- CMEX also updated Chapters 9.1 and 16 of its QMS to include the regulatory requirements of §205.201(a)(3).
- CMEX notified its personnel of the OSP template and procedure updates via email on July 10, 2020.

- CMEX notified its certified operations of the new information required in the OSP on July 12, 2020.

AIA-4010-20 – Accepted. (NOP-2-19.NC3) 7 C.F.R. §205.403(c)(2) states, “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;...”

Comments: *CMEX’s inspectors are not verifying an operation’s compliance to §205.201(a)(3), which requires the operation to have monitoring practices and procedures to verify that the operation’s organic system plan is effectively implemented.*

Corrective Action: CMEX updated its inspection report template (Chapter 3.18.1 B) to ask inspectors to verify an operation’s compliance with §205.201(a)(3) as described in the operation’s OSP. CMEX also updated its *Procedure for the on-site evaluation (inspection of operators interested in the certification of the production, processing and/or marketing of organic products* (Chapter 10) to state that an inspector must review an operation’s OSP and ensure that it has a monitoring procedure to evaluate that the activities are implemented. CMEX notified its personnel of the updates to the inspection report template and to its procedure via email on July 15, 2020.

AIA-4011-20 – Accepted. (NOP-2-19.NC4) 7 C.F.R. §205.663 states, “Any dispute with respect to denial of certification or proposed suspension or revocation of certification under this part may be mediated at the request of the applicant for certification or certified operation and with acceptance by the certifying agent. Mediation shall be requested in writing to the applicable certifying agent. If the certifying agent rejects the request for mediation, the certifying agent shall provide written notification to the applicant for certification or certified operation. The written notification shall advise the applicant for certification or certified operation of the right to request an appeal, pursuant to §205.681, within 30 days of the date of the written notification of rejection of the request for mediation. If mediation is accepted by the certifying agent, such mediation shall be conducted by a qualified mediator mutually agreed upon by the parties to the mediation. If a State organic program is in effect, the mediation procedures established in the State organic program, as approved by the Secretary, will be followed. The parties to the mediation shall have no more than 30 days to reach an agreement following a mediation session. If mediation is unsuccessful, the applicant for certification or certified operation shall have 30 days from termination of mediation to appeal the certifying agent's decision pursuant to §205.681. Any agreement reached during or as a result of the mediation process shall be in compliance with the Act and the regulations in this part. The Secretary may review any mediated agreement for conformity to the Act and the regulations in this part and may reject any agreement or provision not in conformance with the Act or the regulations in this part.”

Comments: *CMEX’s settlement agreements do not fully comply with the requirements of the USDA organic regulations. The auditor’s review of settlement agreements established by CMEX found that the settlement agreements included non-finite terms that required ongoing compliance with a USDA organic regulation.*

Corrective Action: CMEX updated its template *Settlement Agreement Format* (Chapter 4.3) to include the effective date of the settlement agreement and deadlines for each of its terms. CMEX notified its staff via email on July 13, 2020 of the update to the template.

AIA-4012-20 – Accepted. (NOP-2-19.NC5) 7 C.F.R. §205.404(b)(1) – (4) states, “The certifying agent must issue a certificate of organic operation which specifies the: Name and address of the certified operation; Effective date of certification; Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation; and Name, address, and telephone number of the certifying agent.”

Comments: *CMEX’s organic certificates do not fully comply with the requirements of the USDA organic regulations. The auditor’s review of certification files found the following:*

1. *CMEX’s organic certificates incorrectly state, “Organic 100%” and “7 CRF Part 205”*
2. *On one handling operation’s organic certificate, the certified honey product was incorrectly stated as “honey bee.”*

Corrective Action: CMEX corrected its organic certificate template (Chapter 4.5 A) to state “100% Organic” and “7 CFR Part 205”. CMEX has also created a new document *Certificate and certification notification review checklist* to ensure that information is correctly presented on the organic certificates. CMEX notified its personnel via email on July 14, 2020 of the updates to the organic certificate template and the new checklist and issued the handling operation an updated organic certificate.

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

An onsite compliance assessment of Certificadora Mexicana de Productos y Procesos Ecologicos SC (CMEX) organic program was conducted on November 12 -21, 2017. The National Organic Program (NOP) reviewed the auditor's report to assess CMEX's compliance to the USDA organic regulations. This report provides the results of NOP's assessment.

GENERAL INFORMATION

Applicant Name	Certificadora Mexicana de Productos y Procesos Ecologicos SC (CMEX)
Physical Address	Calle 16 de Septiembre No. 204, Oaxaca, 68026, Mexico
Mailing Address	Calle 16 de Septiembre No. 204, Oaxaca, 68026, Mexico
Contact & Title	Taurino Reyes, Executive Director
E-mail Address	Calidad2@certimexsc.com
Phone Number	++951 520 2687
Reviewer(s) & Auditor(s)	Graham Davis, NOP Reviewer; Jason Lopez & Lars Crail, Onsite Auditors
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP assessment: June 6, 2018 Onsite audit: November 12 – 21, 2017
Audit Identifier	NOP-48-17
Action Required	None
Audit & Review Type	Compliance Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of CMEX's certification system.
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	CMEX's certification services in carrying out the audit criteria during the period: May 2016 through November 2017

CMEX is a for-profit company initially accredited on April 14, 2006 that currently maintains the following accreditation scopes: crops, wild crops, processing/handling, livestock (apiculture only). CMEX certifies 154 operations to the following certification scopes: crops (73), livestock (7), and handlers (53). CMEX's office is in Oaxaca, Mexico, and provides certification services in Mexico. Certification services are performed by the Executive Director, fifteen office personnel including quality control, organic certification specialists, reviewers and twenty inspectors.

The auditor conducted one witness audit of an annual inspection of a grower group certified for

the production and processing/handling of coffee products.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether CMEX'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

NP6101JZA.NC1 – Cleared
NP6101JZA.NC2 – Cleared
NP6101JZA.NC3 – Cleared
NP6101JZA.NC4 – Cleared
NP6101JZA.NC5 – Cleared
NP6101JZA.NC6 – Cleared
NP6101JZA.NC9 – Cleared
NP6101JZA.NC10 – Cleared
NP6101JZA.NC11 – Cleared
NP6101JZA.NC12 – Cleared
NP6101JZA.NC14 – Cleared
NP6101JZA.NC15 – Cleared
NP6101JZA.NC16 – Cleared
NP6101JZA.NC17 – Cleared
NP6101JZA.NC19 – Cleared
NP6101JZA.NC20 – Cleared

NP6101JZA.NC7 – 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 Policy Memo 11-10, “*Grower Group Certification*,” refers to the 2008 National Organic Standards Board (NOSB) Recommendation:

- a. Producer group operations must utilize centralized processing, distribution, marketing facilities and systems.
- b. The Internal Control System (ICS) must include the application of sanctions to individual members who do not comply with the organization's OSP, the OFPA or the NOP Regulations. It must inform the ACA of the irregularities and minor non-compliances found. It must communicate back to the source of the minor non-compliance the corrective actions imposed, with agreed time for completion.
- c. For the person seeking organic certification to be in compliance with the NOP, all non-compliances detected at the production unit, site, or facility or at the sub-unit or member level are required to be reported to the certifier (not just the ICS) per 205.400 (f).
- d. The certifying agent must have policies and procedures for determining how many of the sub-units within a production unit must receive an annual inspection by the certifying

agent. In addition to the mandatory inspection of new entrants to the production unit, the certifying agent must also have policies and procedures for determining which sub-units present the greatest risks of non-compliance. Various risk assessment methods are used to both determine sample size and select the appropriate sub-units to examine.

Comments: *Auditors observed a CMEX inspection of a certified grower group operation that revealed the following issues that do not comply with NOP Policy Memo 11-10:*

- a. *The group operation does not utilize centralized processing, distribution, and marketing system. Grower group members are marketing and selling their products individually and not as a group.*
- b. *The ICS lacked sanction procedures and processes for issuing or reporting noncompliances to CMEX.*
- c. *CMEX Procedure 10.3.1a (Inspection Procedure for Group of Small Producers) does not specify a procedure to determine the risk of group subunits and to calculate an external inspection sample.*

2016 Corrective Action: CMEX issued a notice of noncompliance to the grower group on May 31, 2016 CMEX created and submitted a policy for the certification of grower groups (Version 1 September 2016). The document specifies the conditions required for the certification of grower groups in accordance to the USDA NOP regulations. It states that the Internal Control System (ICS) should record instances of non-compliance and report findings as well as corrective measures to CMEX during on-site inspections. CMEX submitted revised procedures to calculate the risk factor of grower group sub-units (Quality Assurance Manual Chapter 10.1.1). CMEX provided evidence of training their inspection staff regarding grower groups, ICS, and calculating the risk factor on August 31, 2016.

2017 Verification of Corrective Actions: Auditors verified the following:

- a. **Cleared** – Auditors observed CMEX inspectors verify the grower group’s OSP. CMEX inspectors verified the grower group’s centralized processing, distribution, and marketing utilized exclusively by all members. Auditor interviews with CMEX reviewers revealed an adequate understanding of the NOSB 2002 and 2008 grower group recommendations. Reviewers were able to correctly apply the regulations to situational examples provided by the auditor.
- b. **Outstanding** – Auditors observed an inspection of a grower group which revealed sanctions, maps, flow charts, job descriptions, and employee lists were missing from the OSP and ICS. These elements were not part of the ICS or OSP and were not reviewed by the inspectors. A sanction policy was not defined, and a responsible grower group employee was not assigned to track or monitor existing sanctions. Sanctions that were issued were not monitored.
- c. **Outstanding** – CMEX has developed a risk factor process and document to calculate the size and composition of the external inspection sample. This process is not consistent with the 2002 and 2008 NOSB recommendations. The CMEX risk factor spreadsheet assigns a risk factor to the entire grower group instead of the individual member/subunits. CMEX’s process is to calculate the sample size, then assign percentages of that sample to four separate classes (25% at random, 30% high risk, 25% new members, 20% certified members).

2018 Corrective Actions: CMEX created an internal control system evaluation questionnaire. This is used to evaluate if the ICS has sanction policy and if ICS staff issues sanctions correctly so that they comply with the USDA organic regulations. If sanctions are issued, the questionnaire is used to determine if corrective actions have been submitted and if the corrective actions have been implemented. CMEX revised their grower group OSP. It now requires the operator to provide locations/maps of the collection centers and processing facilities. CMEX revised their grower group inspection report template. The report requires inspectors to verify that the grower group's OSP includes map of collection centers and processing facilities, traceability records are available at inspection. CMEX revised their procedure used to calculate the inspection sample size and to determine the number of high-risk sub units of a grower group. The procedure also states that all new organic sub units, all high-risk sub units, and all warehouses or collection centers of the operator are inspected. CMEX submitted the agenda from a 2-day training on Internal Control Systems presented to their staff in April and May of 2018. CMEX also submitted the agenda from a September 2018 training that covered the revisions to their grower group inspections procedure, the NOSB 2002 and 2008 recommendations on grower groups, and revisions to their procedure to calculate the risk factor of grower groups.

NP6101JZA.NC8 – Accepted. 7 C.F.R. §205.501(a)(4) states, “A private or governmental entity accredited as a certifying agent under this subpart must:... Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part;...”

Comments: *The auditors observed the following situations where CMEX personnel did not demonstrate complete knowledge and understanding of the USDA organic regulations and NOP policies:*

- a. *CMEX inspectors and reviewers are citing USDA organic regulations that do not accurately correspond to the observed noncompliance. For example, an inspector cited §205.201(a)(6) “Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations.” for a records issue that should reference §205.201, Record Keeping by certified operations.*
- b. *A CMEX inspector was unaware of the required criteria of grower group certification (as stated in NOSB recommendations 2002 and 2008) and therefore was not able to verify whether the operation was compliant.*

2016 Corrective Action: CMEX held a NOP workshop on August 30, 2016 where all CMEX personnel were trained on the USDA Organic Regulations and the NOP Handbook, specifically related to the noncompliances cited in this report. In addition, CMEX provided a comprehensive training plan that covers the NOP regulations, policies, and memorandums which began in September 2016 and runs through December 2016. CMEX created and submitted a policy for the certification of grower groups (Version 1 September 2016) requires inspections of grower groups to be compliant with the NOSB 2002 and 2008 Grower Group Recommendations. CMEX emailed all inspectors copies of NOSB 2002 and 2008 Grower Group Recommendations.

2017 Verification of Corrective Actions: The witness audit of a grower group inspection revealed that the CMEX inspectors noted several issues of concern cited to the incorrect USDA organic regulation. Specifically, the grower group's OSP or ICS did not include maps, process flow charts, an employee list, job descriptions, and defined sanctions. The inspectors inquired

about the missing documents but did not note the missing records as an issue of concern during the grower group's exit meeting.

2018 Corrective Actions: CMEX updated their procedure for the inspection of grower groups. The procedure now requires maps of the location of the operations that make up the grower group be reviewed and verified at the inspection. The revised procedure also requires the list of personnel and job descriptions of the ICS staff be reviewed and verified at inspection. CMEX provided a copy of a reviewed inspection report that includes observations of the reviewer verifying that the inspector cited the appropriate regulations. CMEX also submitted the agenda from a September 2018 training that covered the revisions to their grower group inspections procedure, the NOSB 2002 and 2008 recommendations on grower groups, and ensuring inspection findings reference the appropriate NOP regulations.

NP6101JZA.NC13 – Accepted. 7 C.F.R. §205.662(a)(1) states, "... a written notification of noncompliance shall be sent to the certified operation. Such notification shall provide...a description of each noncompliance."

Comments: *Below are three examples where CMEX is not selecting and citing the appropriate USDA organic regulations when issuing noncompliances:*

- a. A Notice of Noncompliance issued October 7, 2015, cited 205.661(a) and 205.662(a) for the presence of prohibited residues rather than 205.105(a), Allowed and prohibited substances, ... and/or 205.202(c), buffer zones.*
- b. A Notice of Noncompliance issued May 8, 2015, cited 205.403(c)(3) and 205.672(a) for the presence of prohibited residues rather than 205.105(a), and/or 205.202(c).*
- c. A Notice of Noncompliance issued November 4, 2014, cited 205.102(a) for absence of records rather than 205.103 (a – c), Recordkeeping.*

2016 Corrective Action: CMEX held a NOP workshop on August 30, 2016 where all CMEX personnel were trained on the USDA Organic Regulations and the NOP Handbook, specifically related to the noncompliances cited in this report. In addition, CMEX provided comprehensive trainings that covered the NOP regulations, policies, and handbook memorandums which began in September 2016 and runs through December 2016. CMEX submitted revised operation evaluation procedures (Quality Assurance Manual Chapter 10) which state that in order to identify a non-conformity, objective evidence must be present, and reference made to the criteria contained in the regulation.

2017 Verification of Corrective Action: The auditor reviewed two issued noncompliances. The referenced USDA organic regulations did not align with the facts of the noncompliance.

2018 Corrective Actions: CMEX provided a copy of a reviewed inspection report that includes observations of the reviewer verifying that the inspector cited the appropriate regulations. CMEX also submitted the agenda from a September 2018 training that covered ensuring inspection findings reference the appropriate NOP regulations. The training re-enforced that it is the inspector's responsibility to cite the correct NOP citation when listing findings and the reviewer's responsibility to verify that inspection reports reference the correct NOP regulation prior to issuing a noncompliance.

NP6101JZA.NC18 – Accepted. 7 C.F.R. §205.671 states, “When residue testing detects prohibited substances at levels that are greater than 5 percent of the Environmental Protection Agency’s tolerance for the specific residue detected or unavoidable residual environmental contamination, the agricultural product must not be sold, labeled, or represented as organically produced....”

Comments: *The auditor reviewed one residue analysis report where levels of the prohibited substance exceeded 5 percent of the Environmental Protection Agency’s tolerance level. CMEX did not notify the operation that the affected products could not be sold or represented as organic.*

2016 Corrective Action: CMEX created and submitted a procedure to respond to positive residue results (Version 1 August 2016) which complies NOP 2613 Responding to Results from Pesticide Residue Testing. CMEX sent information to all its inspectors on September 7, 2016 instructing them to refer to this document when samples test positive for prohibited substances. CMEX plans to train their staff on sampling procedures in December 2016.

2017 Verification of Corrective Action: The 2017 CMEX records did not indicate any product sampling with a detection level above 5% of the EPA tolerance. However, in two cases where the operations were issued noncompliances for residue detection, CMEX cited §205.671, Organic Sale Exclusion. The use of this regulatory reference was incorrect since the materials tested were not products for sale and the EPA tolerance level was not applicable. The issuance of noncompliances with reference to §205.671 indicate that CMEX personnel do not understand the purpose and proper application of §205.671.

2018 Corrective Actions: CMEX submitted a revised sampling procedure for pesticide analysis. The procedure requires CMEX to send the operation a copy of the lab results and notify the operation if the product may or may not be sold as organic based on the results. CMEX held a training on August 31, 2018 to review NOP 2613 and how to respond to the results of pesticide residue tests and the appropriate NOP citations to use when a noncompliance is issued. The training was provided to inspectors, office personnel, and report reviewers.

Non-compliances Identified during the Current Assessment and Corrective Actions

NOP-48-17.NC1 – Accepted. 7 C.F.R. §205.662(c)(4) states, “Proposed suspension or revocation. When rebuttal is unsuccessful, or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of proposed suspension ... The notification of proposed suspension or revocation of certification shall state: The right to request mediation pursuant to §205.663 or to file an appeal pursuant to §205.681.”

Comments: *CMEX accepted corrective actions to resolve a notice of proposed suspension.*

Corrective Actions: CMEX revised their procedure for gaining access to certification to state that corrective actions can only be accepted during the time period indicated in the notice of noncompliance. CMEX held a training for their staff on September 14, 2018. The training included a review of NOP 4002 "Compliance with the National Organic Program of the NOP" and the sections of the regulations 205.663 and 205.681.

NOP-48-17.NC2 – Accepted. 7 C.F.R. §205.662(a)(3) states, “Notification. When an inspection, review, or investigation of a certified operation by a certifying agent ... reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation. Such notification shall provide: The date by which the certified operation must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible.”

Comments: *CMEX notices of noncompliance do not inform operations of their right to rebut noncompliances.*

Corrective Actions: CMEX revised their notice of noncompliance template to include the operation’s right to rebut noncompliances in writing within 15 days of receiving the notice of noncompliance. CMEX’s certification procedure includes an operation’s right to rebut noncompliances within the period of time indicated in a notice of noncompliance. CMEX submitted a notice of noncompliance issued to an operation that includes the right to rebut the noncompliance. CMEX provided training to their staff on August 31, 2018 that included the requirements of §205.662 Noncompliance Procedures for Certified Operations and the updates to their notice of noncompliance template.

NOP-48-17.NC3 – Accepted. 7 C.F.R. §205.662(c)(2) states, “When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program’s governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance.... The notification of proposed suspension or revocation of certification shall state: ... the proposed effective date of such suspension or revocation;”

Comments: *A review of one proposed suspension notification identified that CMEX did not specify the effective date of suspension.*

Corrective Actions: CMEX revised their notice of suspension to include the effective date of the suspension. CMEX provided training to their staff on August 31, 2018 that included the requirements of §205.662 Noncompliance Procedures for Certified Operations and the updates to their notice of proposed suspension template.

NOP-48-17.NC4 – 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 or conditions determined by the Administrator to be necessary.” NOP 2613, Responding to Residue Results, Section 5.1.a, states that a certifier must “Notify the certified operation of the test results and indicate that the product may be sold as organic.”

Comments: *When issuing the sample results to operators, CMEX is not indicating to operators that the product may be sold as organic.*

Corrective Actions: CMEX revised their sampling procedure for pesticide analysis. It now states that CMEX will send to the operators a copy of the results and indicate if the product may be sold as organic in accordance with NOP 2613. CMEX provided training to their staff on August 31, 2018, that included an update on their sampling procedure and a review of the requirements listed in NOP 2613.

NOP-48-17.NC5 – Accepted. 7 C.F.R. §205.510(b)(2) states, “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: *Out of the three residue analysis cases reviewed by the auditor, one case did not include a record that the operation received the test results.*

Corrective Actions: CMEX submitted a copy of the email that provided the test results to the operation. CMEX submitted their sampling procedure for pesticide analysis. It states that CMEX will provide a copy of the results to the operation and indicate if the product may be sold as organic. CMEX provided training to their staff on August 31, 2018, that included an update on their sampling procedure and a review of the requirements listed in NOP 2613.

NOP-48-17.NC6 – Accepted. 7 C.F.R. §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must:… Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” NOP Policy Memo 11-10, “*Grower Group Certification*,” refers to the 2008 National Organic Standards Board (NOSB) Recommendation which provides the criteria for the certification of grower groups: Section D1 *Sampling and Risk Analysis*.

Comments: *CMEX determines the inspection sample size by taking the square root of the total number of grower group members, then divides the sample among four categories (25% random, 30% high risk, 25% new entrants, 20% organic producers). The following portions of the CMEX process for certified group sample selection do not follow the NOSB 2002 and 2008 recommendations:*

- 1. The inclusion of a group’s new entrants within the sample is incorrect. A group’s new entrants must be inspected in addition to the sample.*
- 2. High risk members must all be inspected and not limited to 30% of the sample number.*
- 3. The 25% random selection of members should not be applied to the entire sample. The 25% random selection rate is to be applied to the remaining sample size after high risk members have been subtracted from the sample total.*
- 4. All production units were not inspected.*

CMEX inspectors recalculated the risk factor onsite and reduced the sample size. The sample reduction was applied equally across all four sample categories identified above. The identified high-risk members, new entrants, and handling/processing units are not eligible to be included in a sample reduction.

Corrective Actions: CMEX revised their procedure to calculate the risk factor in the ICS of Small Producer Groups. The procedure states that all new organic producers (members), all producers considered high risk, and all warehouses/collection centers need to be inspected. The procedure also states all high-risk members will be subtracted from the sample size prior to determining 25% of randomly selected members to inspect. CMEX provided training to their staff on September 14, 2018, that included the changes to the procedure for calculating the number of producers within a grower group that need to be inspected.

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a renewal assessment of the Certificadora Mexicana de Productos y Procesos Ecologicos (CMEX). An onsite audit was conducted and the audit report reviewed to determine CMEX's capability to continue operating as a USDA accredited certifying agent. This report provides the results of the renewal assessment and review of CMEX's corrective actions.

GENERAL INFORMATION

Applicant Name	Certificadora Mexicana de Productos y Procesos Ecologicos SC (CMEX)
Physical Address	Calle 16 de Septiembre No. 204, Ejido Guadalupe Victoria Oaxaca, Oaxaca 68026 Mexico
Mailing Address	Calle 16 de Septiembre No. 204, Ejido Guadalupe Victoria Oaxaca, Oaxaca 68026 Mexico
Contact & Title	Juan Felipe Ortega Valdez, Quality Manger
E-mail Address	calidad@CMEXsc.com
Phone Number	951 5200617/951 5202687
Reviewer(s) & Auditor(s)	Graham Davis, NOP Reviewer; Jason Lopez (Lead), Lars Crail, Onsite Auditors.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	Corrective actions review: October 18, 2016 NOP assessment review: August 12, 2016 Onsite audit: May 8, 2016
Audit Identifier	NP6101JZA
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 CMEX's certification system.
Audit & Determination Criteria	7 CFR Part 205, National Organic Program as amended
Audit & Review Scope	CMEX's certification services in carrying out the audit criteria during the period: October 2013 through May 2016

Certificadora Mexicana de Productos y Procesos Ecologicos S.C.'s (CMEX) office is in Oaxaca, Mexico. Certification services are provided throughout Mexico and for one operation in Columbia. CMEX was initially accredited as a USDA National Organic Program (NOP) certifying agent on April 14, 2006 for the scopes of Crops, Wild Crops, and Handling. On October 16, 2014, the USDA NOP issued a Notice of Accreditation Scope Extension for livestock (apiculture only) to CMEX. The current list of NOP certified operations indicates 97

operations: 66 (crops), 81 (handling), and 7 (livestock – only apiculture), and 3 (wild crops). Some of the operations are certified in more than one scope (i.e., crops and handling).

NOP DETERMINATION:

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

NP3133LCA.NC1-3 – Withdrawn by NOP.

NP3133LCA.NC4 – Cleared.

NP3133LCA.NC5 – 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.

NP6101JZA.NC1 – Accepted. 7 C.F.R. §205.501(a)(21) states, "A private or governmental entity accredited as a certifying agent under this subpart must:... Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary." NOP 5022, *Wild Crop Harvesting*, Section 4, states that management practices such as introduction of new plants is considered an indicator of crop production and not a wild crop. Sustainable harvesting of the wild crops should support the long-term viability of the habitat. §205.207 states, "A wild crop must be harvested in a manner that ensures that such harvesting or gathering will not be destructive to the environment and will sustain the growth and production of the wild crop."

Comments: *CMEX incorrectly certified an operation to the Wild Crops scope; whereas, the operation is conducting agriculture practices applicable to the certification scope of Crops:*

- 1. The operation is transplanting nursery grown stock to replace those harvested in order to maintain a five year rotational harvest cycle. The operation's organic system plan states that yucca nursery stock will be transplanted after the harvest. The auditors did observe production and transplanting of yucca nursery stock during the witness audit.*
- 2. The large amount of yucca plants harvested from the area is not consistent with a natural and sustainable regeneration process. Removal of the majority of large yucca plants has*

a significant impact on the eco-system and could be considered destructive to the environment reducing the habitat for native fauna and flora.

2016 Corrective Action: CMEX issued a notice of noncompliance to the operation that was replacing harvested plants with transplanted nursery stock. CMEX created and submitted a wild crop policy (Version 1 August 2016) which complies the requirements for this certification scope in NOP 5022 and §205.207. CMEX updated their OSP to include the minimum management activities that can be performed under the wild crop certification scope. CMEX also provided training to their inspection staff regarding wild crop certification on September 23, 2016. CMEX plans to review the other two operations they certified under the wild crops scope to determine if they operations are in compliance.

NP6101JZA.NC2 – 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;…” §205.100(a) states, “Except for operations exempt or excluded in §205.101, each production or handling operation or specified portion of a production or handling operation that produces or handles crops, livestock, livestock products, or other agricultural products that are intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” must be certified according to the provisions of subpart E of this part and must meet all other applicable requirements of this part.”

Comments: *CMEX allows certified operations to contract with uncertified operations to produce and handle agricultural products that are marketed and sold as organic. The auditors witnessed an inspection of a wild crop operation where the wild crop harvest was conducted by an uncertified organic operation on property controlled by the uncertified entity.*

2016 Corrective Action: CMEX issued a notice of noncompliance to the operation on August 24, 2016 for contracting with an uncertified operation to handle a certified product. CMEX submitted a revised procedure for gaining access to certification (Quality Assurance Manual Chapter 9), which states that any working relation between the processor, marketer and operator of product(s), specify clearly the commitment of each party to ensure the compliance with the USDA Organic Regulations. CMEX provided training to their certification and inspection staff regarding contract agreements and requirements in October of 2016. CMEX reviewed all of their clients and found two additional operations that were contracting with uncertified organic operations and issued corrective actions.

NP6101JZA.NC3 – Accepted. 7 C.F.R. §205.403(c)(2) states, “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;…”

Comments: *In two of three witness audits conducted by the auditors, CMEX inspectors did not completely verify the organic system plan (OSP). Onsite inspections assessed organic integrity control points, but did not verify the OSP’s described practices to actual activities. In one observed case, grower group members were marketing and selling their products individually and not as a group as stated in the OSP. In another observed case, an inspection focused exclusively on one certified product and did not verify compliance to the other fourteen produced and handled organic products listed in the OSP.*

2016 Corrective Action: CMEX submitted a revised inspection procedure (Quality Assurance Manual Chapter 10) that states on-site inspections must verify compliance with §205.403. It also states that grower group operations must use centralized processing, distribution, service commercialization and systems. CMEX sent a copy of the revised inspection procedures to all of its inspectors. CMEX sent a memo to all of its inspectors informing them to verify that the practices described in the OSP precisely reflect the actions of the operation and to determine if the materials used at the processing unit are allowed, restricted, or forbidden. CMEX provided evidence of training to all inspectors in September 2016.

NP6101JZA.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:… 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;…”

Comments: *CMEX’s organic system plan (OSP) template does not provide grower group compliance information, nor a reference to the 2002 and 2008 National Organic Standards Board (NOSB) recommendations allowing operations to accurately describe activities to comply with the USDA organic regulations and NOP policy (PM 10-11, Grower Group Certification).*

2016 Corrective Action: CMEX revised their OSP to include the requirements for grower group certification according to NOSB 2002 and 2008 recommendations. CMEX submitted a revised inspection procedure (Quality Assurance Manual Chapter 10.1) requiring inspections of producer groups to be compliant with the NOSB 2002 and 2008 recommendations. CMEX emailed all its inspectors copies of NOSB 2002 and 2008 producer group recommendations, the updated procedure 10.1, and revised OSP template in August of 2016. CMEX provided training to their inspection staff regarding grower group certification in August 30 - 31, 2016.

NP6101JZA.NC5 – Accepted. 7 C.F.R. §205.403(d) states, “The inspector must conduct an exit interview with an authorized representative of the operation who is knowledgeable about the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The inspector must also address the need for any additional information as well as any issues of concern.”

Comments: *CMEX inspectors identify and issue noncompliances to operations during the exit interview. Inspectors request, obtain, and assess corrective actions of the operation during the exit interview. These noncompliances and corrective actions are recorded in the inspection report submitted to CMEX. USDA organic regulations allow inspectors to request additional information and address issues of concern during the exit interview; however, the certifier determines and issues noncompliances to the operation. Also, the certifier, not the inspector, assesses any provided corrective actions or rebuttals by the operation.*

2016 Corrective Action: CMEX submitted a revised certification procedure (Quality Assurance Manual Chapter 13). The revised procedure has separate instructions for inspections of operations that are seeking certification to the USDA Organic Regulations that comply with NOP 2601 “*The Organic Certification Process.*” CMEX created and submitted an exit interview form (3.18. B) that requires the inspector to list observations, findings, and issues of concerns (not noncompliances) along with the corresponding regulation. CMEX sent information to all of its inspectors on September 14, 2016 instructing them to review the revised inspection policy.

CMEX provided training to its inspectors on October 24, 2016, to explain how NOP inspections differ from inspections to other regulations.

NP6101JZA.NC6 – Accepted. 7 C.F.R. §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must:… Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” NOP 2603 *Organic Certificates*, Section 3.1, Elements of the Organic Certificate, states that certificates are to be in English, list the certification scope, and display an anniversary date.

Comments: *The auditors’ review of issued organic certificates found the following discrepancies:*

- a. *Organic certificates are not consistently issued in English.*
- b. *“Commercialization” or “Marketing” is listed as a certification scope.*
- c. *The term “Update” is used rather than the term “Anniversary Date.”*

2016 Corrective Action: CMEX revised their NOP certificate template so that all the information is provided in English. CMEX replaced “Update/Actualizacion” with “Anniversary Date/fechas de aniversario” and “Processing/Comercialization” to “Handling/Procesamiento” CMEX submitted a copy of a certificate they issued and it complies with NOP 2603. CMEX also submitted evidence of training on August 31, 2016.

NP6101JZA.NC7 – 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 Policy Memo 11-10, “*Grower Group Certification*,” refers to the 2008 National Organic Standards Board (NOSB) Recommendation:

- a. Producer group operations must utilize centralized processing, distribution, marketing facilities and systems.
- b. The Internal Control System must include the application of sanctions to individual members who do not comply with the organization’s OSP, the OFPA or the NOP Regulations. It must inform the ACA of the irregularities and minor non-compliances found. It must communicate back to the source of the minor non-compliance the corrective actions imposed, with agreed time for completion.
- c. For the person seeking organic certification to be in compliance with the NOP, all non-compliances detected at the production unit, site, or facility or at the sub-unit or member level are required to be reported to the certifier (not just the ICS) per 205.400 (f).
- d. The certifying agent must have policies and procedures for determining how many of the sub-units within a production unit must receive an annual inspection by the certifying agent. In addition to the mandatory inspection of new entrants to the production unit, the certifying agent must also have policies and procedures for determining which sub-units present the greatest risks of non-compliance. Various risk assessment methods are used to both determine sample size and select the appropriate sub-units to examine.

Comments: *Auditors observed a CMEX inspection of a certified grower group operation that revealed the following issues that do not comply with NOP Policy Memo 11-10:*

- a. *The group operation does not utilize centralized processing, distribution, and marketing system. Grower group members are marketing and selling their products individually and not as a group.*
- b. *The Internal Control System lacked sanction procedures and processes for issuing or reporting noncompliances to CMEX.*
- c. *CMEX Procedure 10.3.1a (Inspection Procedure for Group of Small Producers) does not specify a procedure to determine the risk of group subunits and to calculate an external inspection sample.*

2016 Corrective Action: CMEX issued a notice of noncompliance to the grower group on May 31, 2016 CMEX created and submitted a policy for the certification of grower groups (Version 1 September 2016). The document specifies the conditions required for the certification of grower groups in accordance to the USDA NOP regulations. It states that the Internal Control System (ICS) should record instances of non-compliance and report findings as well as corrective measures to CMEX during on-site inspections. CMEX submitted revised procedures to calculate the risk factor of grower group sub-units (Quality Assurance Manual Chapter 10.1.1). CMEX provided evidence of training their inspection staff regarding grower groups, ICS, and calculating the risk factor on August 31, 2016.

NP6101JZA.NC8 - Accepted. 7 C.F.R. §205.501(a)(4) states, “A private or governmental entity accredited as a certifying agent under this subpart must:... Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part;...”

Comments: *The auditors observed the following situations where CMEX personnel did not demonstrate complete knowledge and understanding of the USDA organic regulations and NOP policies:*

- a. *CMEX inspectors and reviewers are citing USDA organic regulations that do not accurately correspond to the observed noncompliance. For example, an inspector cited §205.201(a)(6) “Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations.” for a records issue that should reference §205.201, Record Keeping by certified operations.*
- b. *A CMEX inspector was unaware of the required criteria of grower group certification (as stated in NOSB recommendations 2002 and 2008) and therefore was not able to verify whether the operation was in compliance.*

2016 Corrective Action: CMEX held an NOP workshop on August 30, 2016 where all CMEX personnel were trained on the USDA Organic Regulations and the NOP Handbook, specifically related to the noncompliances cited in this report. In addition, CMEX provided a comprehensive training plan that covers the NOP regulations, policies, and memorandums which began in September 2016 and runs through December 2016. CMEX created and submitted a policy for the certification of grower groups (Version 1 September 2016) requires inspections of grower groups to be compliant with the NOSB 2002 and 2008 Grower Group Recommendations. CMEX emailed all its inspectors copies of NOSB 2002 and 2008 Grower Group Recommendations.

NP6101JZA.NC9 - Accepted. 7 C.F.R. §205.403(a)(2)(i) states, “A certifying agent may conduct additional on-site inspections of applicants for certification and certified operations to determine compliance with the Act and the regulations in this part.”

Comments: *The auditors determined that CMEX inspection instructions to inspectors do not sufficiently convey the scope and purpose of each inspection. When the auditors interviewed an inspector during a Witness Audit, the inspector explained the onsite inspection was a demonstration for the NOP auditors because the annual inspection had occurred. CMEX personnel were unaware that certifiers may conduct additional onsite inspections to verify continued compliance with the regulations.*

2016 Corrective Action: CMEX submitted revised inspection procedures (Quality Assurance Manual Chapter 10) which now states that a certifier may carry out additional inspections at the work site of operations applying for certification or of operations already certified, in order to ensure compliance with the NOP regulations. It also states that additional inspections may or may not be announced at the discretion of CMEX or as required by the manager. CMEX created and submitted an organic inspection policy (Version 1 August 2016) which outlines the conditions and requirements of inspections to the NOP regulations. CMEX sent a copy of the revised inspection procedures and organic inspection policy to all of its inspectors. CMEX provided evidence of training to all inspectors in September 2016.

NP6101JZA.NC10 - Accepted. 7 C.F.R. §205.662(c)(2) states, “When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program’s governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance.... The notification of proposed suspension or revocation of certification shall state: ... 2) the proposed effective date of such suspension or revocation;”

Comments: *The auditors’ review of a proposed suspension notification found that CMEX specified that the suspension would begin on the same date the notice of proposed suspension was issued.*

2016 Corrective Action: CMEX submitted revised certification procedures (Quality Assurance Manual Chapter 13). The revised procedure has separate instructions for issuing notices of proposed suspension and notices of suspension to operations certified to the USDA organic regulations that comply with §205.662(c). CMEX sent information to all of its inspectors on September 14, 2016 instructing them to review the revised certification policy. CMEX provided training to its inspectors on October 24, 2016 that included a review of the NOP regulations and NOP 2601.

NP6101JZA.NC11 - Accepted. 7 C.F.R. §205.501(a)(16) states, “Charge applicants for certification and certified production and handling operations only those fees and charges for certification activities that it has filed with the Administrator;”

Comments: *CMEX updated and implemented their fee schedule on March 17, 2016 and did not submit it to the NOP. The updated fee schedule was submitted to the NOP after being identified by the auditors during the onsite audit.*

2016 Corrective Action: CMEX submitted a fee schedule (Quality Assurance Manual Chapter 2.14.1) that complies with §205.501(a)(16). In addition, CMEX will notify the NOP every time their fee schedule and/or their procedure regarding fees changes. CMEX will revise their quality assurance manual (Chapter 16) to reflect the changes in the procedures. CMEX held an NOP workshop on August 30, 2016 where all CMEX personnel were trained on the USDA Organic Regulations and the NOP Handbook, specifically related to the noncompliances cited in this report.

NP6101JZA.NC12 - 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, “Personnel Performance Evaluation,” Section 3.2b states, “Inspectors should be evaluated during an onsite inspection by a supervisor or peer (another inspector) at least annually.”

Comments: *Field evaluations for three of 17 inspectors were not conducted during 2015. For one of the three inspectors, there was no evaluation conducted in 2015 of any inspection activities (e.g. inspection report writing or timeliness).*

2016 Corrective Action: CMEX created and submitted an inspector evaluation form (6.2.1 Rev 1 09/2016). CMEX submitted a spreadsheet that lists all of their inspectors, when they will be evaluated, and who will be conducting their field evaluations in 2016/2017. CMEX provided training to its inspectors on September 21, 2016 that included a review of the form used to evaluate the performance of their inspectors.

NP6101JZA.NC13 - Accepted. 7 C.F.R. §205.662(a)(1) states, “... a written notification of noncompliance shall be sent to the certified operation. Such notification shall provide...a description of each noncompliance.”

Comments: *Below are three examples where CMEX is not selecting and citing the appropriate USDA organic regulations when issuing noncompliances:*

- a. *A Notice of Noncompliance issued October 7, 2015, cited 205.661(a) and 205.662(a) for the presence of prohibited residues rather than 205.105(a), Allowed and prohibited substances, ... and/or 205.202(c), buffer zones.*
- b. *A Notice of Noncompliance issued May 8, 2015, cited 205.403(c)(3) and 205.672(a) for the presence of prohibited residues rather than 205.105(a), and/or 205.202(c).*
- c. *A Notice of Noncompliance issued November 4, 2014, cited 205.102(a) for absence of records rather than 205.103 (a – c), Recordkeeping.*

2016 Corrective Action: CMEX held an NOP workshop on August 30, 2016 where all CMEX personnel were trained on the USDA Organic Regulations and the NOP Handbook, specifically related to the noncompliances cited in this report. In addition, CMEX provided comprehensive trainings that covered the NOP regulations, policies, and handbook memorandums which began in September 2016 and runs through December 2016. CMEX submitted revised operation evaluation procedures (Quality Assurance Manual Chapter 10) which state that in order to identify a non-conformity, objective evidence must be present and reference made to the criteria contained in the regulation.

NP6101JZA.NC14 - 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 or conditions determined by the Administrator to be necessary.” NOP 2613, Responding to Residue Results, Section 5.3.1, states that a certifier must assess why the residue is present prior to considering and issuing a noncompliance.

Comments: *In one of the three residue samples reviewed by the auditor indicated a detection above the 5% EPA tolerance level. The operation was issued a noncompliance prior to CMEX assessing why the residue was present.*

2016 Corrective Action: CMEX created and submitted a procedure to respond to positive residue results (Version 1 August 2016) which is compliant with NOP 2613 “*Responding to Results from Pesticide Residue Testing*”. CMEX sent information to all of its inspectors on September 7, 2016 instructing them to refer to this document when samples test positive for prohibited substances. CMEX plans to train all of its staff on sampling procedures and the actions certifiers need to take when prohibited substance are detected in December 2016.

NP6101JZA.NC15 - Accepted. 7 C.F.R. §205.670 (e) states, “Sample collection pursuant to paragraphs (b) and (c) of this section must be performed by an inspector representing the Administrator, applicable State organic program’s governing State official, or certifying agent....”

Comments: *The auditor reviewed certification suspension records and found in one instance, the operation was issued a combined notice partly based on laboratory analysis results from samples collected by the operation’s vendor, not a CMEX representative.*

2016 Corrective Action: CMEX created and submitted a collection procedure for lab testing. (Version 1 August 2016) which states that CMEX should take their own samples if residues of prohibited substances are detected in other analyzed samples. CMEX sent this information to all of its inspectors on September 7, 2016 informing them of the new procedure. CMEX plans to train all of their staff on sampling procedures in December 2016.

NP6101JZA.NC16 - 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: *In two cases reviewed by the auditors where CMEX issued a notification of suspension, the notice indicated the operations could file an appeal with the Administrator. Operations may not file an appeal after the issuance of suspension, operations may file an appeal during the period of proposed suspension (§205.662 (c)).*

2016 Corrective Action: CMEX submitted a revised procedure for gaining access to certification procedures (Quality Assurance Manual Chapter 9), revised certification procedures (Quality Assurance Manual Chapter 13), and revised procedures for appeals, complaints, and amendments (Quality Assurance Manual Chapter 14). The procedures state that notices of proposed suspension may be appealed and provide separate instructions for issuing Notices of Suspension of NOP certification which comply with §205.662(c) and (e)(1). CMEX provided

training to all of their staff on October 24, 2016 that included a review of the NOP regulations and NOP 2601.

NP6101JZA.NC17 - Accepted. 7 C.F.R. §205.662 (c)(4) states, “....The notification of proposed suspension or revocation of certification shall state:... The right to request mediation pursuant to §205.663 or to file an appeal pursuant to §205.681.”

Comments: *The auditor reviewed one combined noncompliance and proposed suspension notification (the Spanish version) did not include statements informing the operation that it could request mediation with the certifier or file an appeal with the Administrator. The English version filed with the NOP did include the correct statements regarding mediation and appeal options.*

2016 Corrective Action: CMEX reviewed and updated their Notice of Noncompliance and Notice of Proposed Suspension templates. The templates now include information on mediation and appeals. CMEX provided training to its inspectors on October 24, 2016 that included a review of the NOP regulations and NOP 2601.

NP6101JZA.NC18 - Accepted. 7 C.F.R. §205.671 states, “When residue testing detects prohibited substances at levels that are greater than 5 percent of the Environmental Protection Agency’s tolerance for the specific residue detected or unavoidable residual environmental contamination, the agricultural product must not be sold, labeled, or represented as organically produced....”

Comments: *The auditor reviewed one residue analysis report where levels of the prohibited substance exceeded 5 percent of the Environmental Protection Agency’s tolerance level. CMEX did not notify the operation that the affected products could not be sold or represented as organic.*

2016 Corrective Action: CMEX created and submitted a procedure to respond to positive residue results (Version 1 August 2016) which complies NOP 2613 Responding to Results from Pesticide Residue Testing. CMEX sent information to all of its inspectors on September 7, 2016 instructing them to refer to this document when samples test positive for prohibited substances. CMEX plans to train their staff on sampling procedures in December 2016.

NP6101JZA.NC19 - Accepted. 7 C.F.R. §205.403(e)(1) states, “At the time of the inspection, the inspector shall provide the operation's authorized representative with a receipt for any samples taken by the inspector.”

Comments: *The auditor reviewed three separate operations records involving the collection and analysis of residue samples. In each of the cases, there was no record that the operators were given a receipt for the samples taken. An interview of CMEX certification staff revealed that receipts are not provided to operations for samples obtained.*

2016 Corrective Action: CMEX created and submitted an in situ sampling receipt template (3.30 Revision 0 May 20, 2016) which complies with §205.403(e)(1). CMEX submitted a revised procedure for sample collection for pesticide analysis (Quality Assurance Manual Chapter 12) that states the inspector must complete a receipt for the sample and provide a copy to the operation’s representative. CMEX emailed its inspectors on June 1, 2016 instructing them

to fill out this form and provide a copy to the operation after the inspector takes a sample. CMEX plans to train their staff on sampling procedures in December 2016.

NP6101JZA.NC20 - Accepted. 7 C.F.R. §205.402(a)(2) states, “Determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part;...” § 205.206(e) states that an Organic System Plan must include, “Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations.”

Comments: *The auditor, when conducting a sampling review of CMEX approved material inputs, identified a material listed in an operation’s organic system plan that did not list the material’s restrictions (i.e. annotations) for the use of micro-nutrient Boron as specified at §205.601(j)(6)(i).*

2016 Corrective Action: CMEX submitted a revised procedure for applying for certification (Quality Assurance Manual Chapter 9) and a revised certification procedure (Quality Assurance Manual Chapter 13). CMEX’s Material Review Template contains additional columns to note evaluations, restrictions, and observations for all materials used in production. CMEX sent a memo to its certification staff informing them to verify the materials listed in the OSP are allowed, restricted, or forbidden. CMEX provided evidence of training to all certification staff in September 2016.

Applicant Name:	Certificadora Mexicana de Productos y Procesos Ecologicos SC (CERTIMEX)
Physical Address:	Calle 16 de Septiembre Num. 204; Ejido Guadalupe Victoria; Oaxaca, Oaxaca, Mexico, C.P. 68026
Mailing Address:	Calle 16 de Septiembre Num. 204; Ejido Guadalupe Victoria; Oaxaca, Oaxaca, Mexico, C.P. 68026
Contact & Title:	Taurino Reyes Santiago, Executive Director
E-mail Address:	certimex@certimexsc.com
Phone Number:	951 520 2687
Auditor(s):	Betsy Rakola, Accreditation Manager
Program:	USDA National Organic Program (NOP)
Audit Date(s):	August 15 – September 19, 2013
Audit Identifier:	NP3133LCA
Action Required:	No
Audit Type:	Corrective Action Audit
Audit Objective:	To review and categorize the certifier’s response to the non-compliances issued in the Notice of Noncompliance of August 1, 2013.
Audit Criteria:	7 CFR Part 205, National Organic Program; Final Rule, dated December 21, 2000; revised January 1, 2013.
Audit Scope:	CERTIMEX’s August 26, 2013 response to the Notice of Noncompliance issued on August 1, 2013.
Location(s) Audited:	Desk

GENERAL INFORMATION

Certificadora Mexicana de Productos y Procesos Ecologicos S.C. (CERTIMEX) was initially accredited as a USDA National Organic Program (NOP) certifying agent on April 14, 2006 for crops, wild crops, and handling operations. CERTIMEX consists of the main office in Oaxaca, Mexico. All NOP certification activities are carried out from the main office with certification provided throughout Mexico. The CERTIMEX list of NOP certified operations included 85 operations with 70 certified for crops, 21 for handling, and no wild crop. Of the 85 certified operations there were 13 distributors/traders and 49 grower groups.

AUDIT INFORMATION

The NOP conducted a mid-term accreditation assessment of Certimex from May 13 – 17, 2013. The assessment also reviewed CERTIMEX’s application to expand their scope of accreditation to include livestock, assessing whether CERTIMEX demonstrated the capacity to carry out livestock certification according to the USDA organic regulations. The auditor reviewed CERTIMEX’s main office in Oaxaca, Mexico. The auditor also observed organic inspections of a handling operation in Soledad Etna, Oaxaca, Mexico and a livestock operation in Chignahuapan, Puebla, Mexico. The NOP issued CERTIMEX a Notice of Noncompliance on August 1, 2013, which included the findings listed below.

This report summarizes the NOP's assessment of CERTIMEX's response to the Notice of Noncompliance. The NOP sent CERTIMEX a Notice of Noncompliance summarizing these findings on August 1, 2013. CERTIMEX responded with corrective actions on August 16, August 26, and September 9, 2013.

FINDINGS

Observations made, interviews conducted, and procedures and records reviewed verified that CERTIMEX is currently operating in compliance to the requirements of the audit criteria. The auditor identified one (1) new non-compliance and one (1) outstanding non-compliance during the on-site audit. The auditor also identified three non-compliances related to CERTIMEX's application for livestock accreditation.

2013 Livestock Scope Expansion Findings:

NP3133LCA.NC1 – Not accepted. NOP §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." *Observations from the witness audits and file reviews showed that CERTIMEX inspection and review staff did not fully understand or correctly implement the USDA organic regulations for livestock, including pasture practice standards in §205.240, health care standards in §205.238, and material reviews in §205.603. CERTIMEX Corrective Action:* CERTIMEX sent inquiries to six parties regarding organic livestock training in Spanish. These parties included certifying agents, training organizations, and the NOP. Since none of them were able to provide training, CERTIMEX will conduct its own internal training on November 7-8, 2013, including a review of the USDA livestock regulations, a review of revised livestock forms, and a visit to an organic livestock operation in Mexico. CERTIMEX sent a copy of the training agenda as evidence.

NP3133LCA.NC2 – Not accepted. NOP § 205.403(c)(1) states, "The on-site inspection of an operation must verify: The operation's compliance or capability to comply with the Act and the regulations in this part." *During the witness inspection of a livestock applicant, the inspector did not verify the operation's compliance to §205.240 (b), "to comply a minimum of 30 percent DMI, on average, over the course of the grazing season." The inspector did not identify the operation's shortcomings regarding the lack of records, adequate pasture, or the operator's understanding of the standard in order to comply with §205.240(b). CERTIMEX Corrective Action:* In addition to scheduling a training session the USDA organic livestock standards for November 2013, CERTIMEX revised its training policies to set minimum standards for inspectors. CERTIMEX will use the results of performance evaluations, internal and external audits, and other observations to identify training needs. Inspectors must pass with an 80% success rate in order to be considered successful. CERTIMEX submitted a revised training policy as evidence.

NP3133LCA.NC3 – Not accepted. NOP § 205.501(a)(4) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply

with and implement the organic certification program established under the Act and the regulations in subpart E of this part.” *Below is evidence that CERTIMEX staff and contract inspectors do not fully comprehend or understand various technical standards of the USDA organic regulations.*

- a. During the livestock inspection of a dairy, the inspector identified that an antibiotic (Oxycillin) was used to treat the goats; however, the inspector was unaware that this medical treatment would effectively render the animal noncompliant indefinitely. The inspector stated that the animal was compliant to §205.238(b)(2) if the animal’s milk or products were not sold or labeled as organic for 90 days. §205.238(b)(2) only applies to parasiticides allowed listed in §205.603.*
- b. During a file review of a bee keeping cooperative, both the CERTIMEX initial review of the OSP and the inspection did not identify the use the medication Oxalic Acid (used as a miticide against Varroa mite) as non-compliant with USDA organic regulations and not on the National List. During the post-inspection review, the input was identified as non-compliant.*
- c. During the initial OSP review and subsequent inspection of a goat dairy, both the initial reviewer and inspector did not identify that livestock feed of uncertified organic soy paste, canola oil and molasses as noncompliant with §205.237.*
- d. During the livestock inspection of a dairy, the inspector identified compost as noncompliant to § 205.203(c) (i.e. turning, temp, c/n ration, etc...); however, the compost or material was compliant because it was not intended for human consumption (§205.203(c)(1)(i)).*

CERTIMEX Corrective Action: CERTIMEX scheduled a livestock standards training course for November 2013. CERTIMEX also revised its policies for evaluating training needs and assessing its employees’ knowledge, skills and abilities.

2013 Mid-Term Assessment Findings:

NP0319MMA.NC4 – Rebutted and cleared. 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... simultaneously with its issuance.” *The records reviewed and interviews conducted verified that notifications of noncompliance and notifications of adverse actions were not being submitted to the USDA Administrator simultaneously with their issuance.*

Corrective Action: After the audit, CERTIMEX revised their procedures to require notification to NOP Appeals for notices of non-compliance and adverse action. CERTIMEX submitted copy of email confirmation of notice of adverse action submitted to NOP Appeals as objective evidence (Annex 4-A), as well as a copy of the revised Quality Manual (page 10) that demonstrates the system change requiring NOP Appeals notification. If effectively implemented, the corrective action plan demonstrates CERTIMEX’s capability to comply with NOP accreditation requirements.

2013 Mid-Term Assessment Finding: The NOP auditor reviewed several certified postal receipts as evidence that copies were submitted by CERTIMEX and received by the NOP; however, the examples presented to the NOP auditor were only for the two operations that were issued adverse actions in April 2013. Further review revealed and confirmed by NOP Appeals that NOP did not receive any notices during 2012 (via email,

post or fax). Shortly afterwards on 31 May 2013, CERTIMEX sent the NOP auditor six notices that were issued in 2012. Three notices were Notices of Non-compliances and three notices were combined notices of noncompliance and proposed suspensions. NOP Appeals subsequently responded to the NOP auditor and stated that NOP Appeals did not receive the notices. The evidence reviewed by the NOP auditor indicates that the corrective actions are not fully implemented and therefore, the non-compliance is outstanding.

2013 CERTIMEX response: CERTIMEX stated that they had sent all adverse action notices to NOP Appeals. As evidence, CERTIMEX provided receipts from a courier service from 2012 and 2013 showing NOP Appeals as the addressee. Based on this additional evidence, the NOP has cleared this finding.

NP3133LCA.NC4 – Accepted. NOP § 205.510 (a)(4) states, “An accredited certifying agent must submit annually to the Administrator, on or before the anniversary date of the issuance of the notification of accreditation, the following reports and fees: The results of the most recent performance evaluations and annual program review and a description of adjustments to the certifying agent's operation and procedures implemented or to be implemented in response to the performance evaluations and program review.” *The 2012 Annual Review was conducted using ISO standards criteria, not the NOP regulations. Certifier Annual Reviews must assess compliance 7 CFR Subparts E, F, and G (§§205.400, 500, and 600) in order to satisfy this requirement.* **CERTIMEX Corrective Action:** CERTIMEX submitted revised internal audit procedures, which state that the internal audit must review compliance with sections 205.400-600 of the USDA organic regulations. The internal audit will include administrative and program activities, and it may include on-site witness audits. The resulting report will use the NOP 2005 checklist as a guide. CERTIMEX also submitted evidence of its July 2013 internal audit report, which utilized the NOP checklist to identify issues of concern.

NP3133LCA.NC5 – Accepted. NOP § 205.501(a)(4) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part.” *During a review of client files, several OSPs identified the Crop Rotation Standard, §205.205, as “not applicable” due to the presence of perennial crops. According to the definitions in §205.2, Crop Rotation: “Perennial cropping systems employ means such as alley cropping, intercropping, and hedgerows to introduce biological diversity in lieu of crop rotation.” CERTIMEX is currently not requiring this information from its clients.* **CERTIMEX Corrective Action:** CERTIMEX sent information to all of its inspectors on September 3, 2013 instructing them to review perennial crop rotations on all inspections. CERTIMEX submitted a copy of its modified inspection report. The revised report includes a section which specifically asks about crop rotation practices on perennial crops and provides examples of such practices.

Applicant Name:	Certimex, Certificadora Mexicana de Productos y Procesos Ecologicos S.C.
Est. Number:	N/A
Physical Address:	16 de Septiembre Num. 204; Ejido Guadalupe Victoria; C.P. 68026, Oaxaca, Oax. Mexico
Mailing Address:	16 de Septiembre Num. 204; Ejido Guadalupe Victoria; C.P. 68026, Oaxaca, Oax. Mexico
Contact & Title:	Hernan Martinez Morales, Head of Quality Control
E-mail Address:	certimex@certimexsc.com
Phone Number:	++951 52 00 617, 951 52 02 687
Auditor(s):	Meg Kuhn, RAM – East Region
Program:	USDA National Organic Program (NOP)
Audit Date(s):	April 8 – May 13, 2011
Audit Identifier:	NP0319MMA
Action Required:	No
Audit Type:	Corrective Action Audit
Audit Objective:	To verify review and approve corrective actions addressing the non-compliances identified during the Surveillance-Accreditation Renewal Audit.
Audit Criteria:	7 CFR Part 205, National Organic Program; Final Rule, dated December 21, 2000; revised February 17, 2010.
Audit Scope:	Certimex corrective action response letter dated 03/21/11 to the Renewal Audit non-compliance report.
Location(s) Audited:	Desk

AUDIT INFORMATION

During the Surveillance-Accreditation Renewal audit, the corrective actions for the non-compliances identified during the 2007 Initial On-Site audit (NP7071GGA) were verified and found to be implemented and effective and the non-compliances were cleared. There were seven (7) non-compliances identified during this Surveillance-Accreditation Renewal audit. Certimex (CMEX) was notified of these findings in a notice from the NOP on February 15, 2011. CMEX sent their corrective action response on March 21, 2011. Additional information and submission of objective evidence documents was requested of CMEX on April 08, 2011; CMEX responded April 27, 2011. Review of corrective action plans and supporting objective evidence submitted, if effectively implemented, demonstrates CMEX's capability to comply with NOP accreditation requirements.

FINDINGS

NP0319MMA.NC1 – Adequately Addressed: NOP §205.402 (a)(2) states “Upon acceptance of an application for certification, a certifying agent must: Determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part.” *Certimex does not have an adequate process in place to verify labels that meet the NOP labeling requirements as confirmed by the following:*

NP0319MMA Corrective Action Audit Certimex Oaxaca, Mexico

- a) *Certimex initially approves labels but does not require revised labels to be submitted for review. After labels are approved, the operation has to submit a correspondence of the intent to revise labels and there is no further review.*
- b) *There is no product profile used to calculate the percentage of organic ingredients in formulations and ensure products meet the minimum organic ingredient percentage requirements to be labeled as “Organic”.*
- c) *A review of labels approved for NOP products in six files verified that the information panels did not contain the statement “Certified Organic by” or a similar phrase as required under §205.303(b)(2).*

Corrective Action: For point a), CMEX updated their system to include a labeling procedure (Annex 1-A. – Procedure for Labeling), which requires all labels – new and revised – to be reviewed against NOP requirements prior to approval. For point b), CMEX established and implemented a product profile document (Annex 1-B. – Request Format for the use of stamp), which includes the requirement to provide all ingredients / materials within the formulated product, as well as percentages at which the ingredient(s) appear in the product. For point c), CMEX provided objective evidence demonstrating review of labels after this reaccreditation review display the “certified organic by...” statement appropriately (Annex 1-C – Example Label). The “Procedure for Labeling” also includes the NOP labeling requirements. If effectively implemented, the corrective action plan demonstrates CMEX’s capability to comply with NOP accreditation requirements.

NP0319MMA.NC2 – Adequately Addressed: NOP §205.403(a)(1) states, “A certifying agent must conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested.” The *2002 NOSB Recommendation on Criteria for Certification of Grower Groups* accepted by the NOP on an interim basis, Recommendation #1 states, “Grower groups must establish and implement an internal control system (quality system), with supervision and documentation of production practices and inputs used at each producer's operation to insure compliance with the USDA’s National Organic Standard.” *Interviews conducted and records reviewed during the grower group witness inspection verified that the approved internal control system (ICS) was not inspecting all parcels of all producers. Internal inspectors of the ICS inspect all producers each year. However, the parcel inspected by the ICS inspector is rotated from year to year instead of inspecting all parcels every year.* **Corrective Action:** At the client level, CMEX issued a letter to all producers indicating that each farmer and each farmer’s parcel(s) must be inspected annually through the ICS (Annex 2-A – Letter for Small Farmer Groups). At the certification level, CMEX updated its Production Plan for Organic Agriculture NOP (Annex 2-B) to require specific information about the ICS, including the confirmation of 100% of all farmers and 100% of all parcels / plots, etc, inspected within the annual ICS auditing cycle. If implemented effectively, the corrective action plan demonstrates CMEX’s capability to comply with NOP accreditation requirements, including the 2002 NOSB Recommendation on Criteria for Certification of Grower Groups.

NP0319MMA.NC3 – WITHDRAWN: NOP §205.404(b)(2) states, “The certifying agent must issue a certificate of organic operation which specifies the: Effective date of certification.” *On at least twelve certificates issued, the effective date of certification placed on the certificates was the date the operation was certified by a previous certifier and not the date certified by Certimex.*

NOP response: This non-compliance has been withdrawn at this time, as this policy issue is being reviewed by the NOP.

NP0319MMA.NC4 –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... simultaneously with its issuance.” *The records reviewed and interviews conducted verified that notifications of noncompliance and notifications of adverse actions were not being submitted to the USDA Administrator simultaneously with their issuance.*

Corrective Action: After the audit, CMEX revised their procedures to require notification to NOP Appeals for notices of non-compliance and adverse action. CMEX submitted copy of email confirmation of notice of adverse action submitted to NOP Appeals as objective evidence (Annex 4-A), as well as a copy of the revised Quality Manual (page 10) that demonstrates the system change requiring NOP Appeals notification. If effectively implemented, the corrective action plan demonstrates CMEX’s capability to comply with NOP accreditation requirements.

NP0319MMA.NC5 – Adequately Addressed: NOP §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.” *All notifications of noncompliance, notifications of denial of certification, and notifications of suspensions issued by Certimex were sent to applicants and certified operations by electronic mail or regular mail.* **Corrective Action:** After the audit, CMEX began using a delivery service that provides dated return receipts, demonstrated by the examples of letters and receipt notices attached as objective evidence of this specific action. CMEX submitted a copy of the revised Quality Manual (page 9) that requires the use of a service that provides dated return receipts, as applicable. If effectively implemented, the corrective action plan demonstrates CMEX’s capability to comply with NOP accreditation requirements.

NP0319MMA.NC6 –Adequately Addressed: NOP §205.662(c) states, “When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program’s governing State official shall send the certified operation a written notification of proposed suspension” and §205.662(c)(4) states, “The notification of proposed suspension or revocation of certification shall state: The right to request mediation pursuant to §205.663 or to file an appeal pursuant to §205.681.” *Certimex issued two combined notifications of noncompliance/notification of suspensions to two certified operations without following the required process. In both instances, Certimex issued the notifications of suspension without first issuing a notification of proposed suspension. Additionally, both notifications stated the clients could appeal in writing directly to Certimex as opposed to the NOP Administrator.* **Corrective Action:** CMEX responded showing changes to the NoNC and Notice of Proposed Suspension format letters, which demonstrate the requirements of §205.662 are met. CMEX provided a copy of the Quality Manual change (page 8) that demonstrates proposed suspension notices must be sent prior to suspension. If effectively implemented, the corrective action plan demonstrates CMEX’s capability to comply with NOP accreditation requirements.

NP0319MMA.NC7 – Adequately Addressed: NOP §205.670(b) states, “The Administrator, applicable State organic program's governing State official, or the certifying agent may require preharvest or postharvest testing... Such tests must be conducted by the applicable State organic program's governing State official or the certifying agent at the official's or certifying agent's own expense.” *A review of samples taken and invoices issued, verified Certimex was charging clients for sample testing.* **Corrective Action:** Annex 7.A demonstrates CMEX's understanding to the requirements of §205.670, specific to the responsibility of paying lab costs for residue testing. This annex (a letter to the Administrator of CMEX) has also been given to all certification personnel for their reference. If effectively implemented, the corrective action plan demonstrates CMEX's capability to comply with NOP accreditation requirements.

NATIONAL ORGANIC PROGRAM: AUDIT & CORRECTIVE ACTION REPORT

GENERAL INFORMATION

- **Certifier Name** Certificadora Mexicana de Productos y Procesos Ecologicos SC, (CMEX)
- **Physical Address** Calle 16 de Septiembre No. 204, Oaxaca, Oaxaca 68280, MEXICO
- **Audit Type** Midterm Audit
- **Auditor(s) & Audit Dates** Colleen O'Brien, Kelley Belina, 04/13/2023 to 04/21/2023
- **Audit Identifier** NOP-202-23

CERTIFIER OVERVIEW

The National Organic Program (NOP) conducted an onsite Midterm Audit of Certificadora Mexicana de Productos y Procesos Ecologicos SC's (CMEX) USDA organic certification program covering the period March 12, 2021 to April 21, 2023. The purpose of the audit was to verify CMEX's compliance with the Organic Foods Production Act of 1990 (OFPA), the USDA organic regulations (7 CFR Part 205), and the NOP Handbook. Audit activities included a review of certification activities, interviews with CMEX personnel, a records audit, and two onsite witness audits. The witness audits consisted of additional onsite inspections of a handling operation and a crops operation (grower group); both operations are in Mexico.

CMEX is a non-profit organization initially accredited on April 14, 2006. CMEX is accredited to the crops, wild crops, livestock (apiculture only), and handling scopes. CMEX's office is in Oaxaca, Mexico. CMEX certifies 150 operations and offers certification services in Mexico, Colombia, Puerto Rico, and the United States of America. Certification activities are performed by 16 office personnel and 24 inspectors.

NOP DETERMINATION:

NOP reviewed the audit results to determine whether CMEX'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 audit.

Noncompliances from Prior Assessments

AIA-4008-20 - Cleared.

AIA-4012-20 - Cleared.

AIA-6100-21 - Cleared.

AIA-6101-21 - Cleared.

AIA-6150-21 - Cleared.

AIA-314-22 - Cleared.

AIA-6148-21 – Accepted. 7 C.F.R. §205.501(a)(4) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part;”

Comments: *CMEX does not consistently use adequately trained personnel to comply with and implement its USDA organic certification program. The auditor’s review of certification files found that CMEX staff approved noncompliant labels and also approved products that did not contain enough organic ingredients to qualify for the organic claim being made. The auditors found that CMEX staff approved a label stating, “with organic ingredients” instead of “made with organic (specified ingredients or food groups).” In addition, the auditors found that CMEX staff approved four products for the “100% organic” category that were only eligible for the “organic” category, based on the organic certificates of the ingredients provided by the operation.*

Corrective Action: CMEX sent notices of noncompliance to three operations regarding noncompliant labels or product formulations identified during the NOP audit and submitted the operations’ adequate corrective actions to NOP. CMEX also updated Section 6.1.1 of its “Manual of Quality Procedures, Chapter 13 - Procedures for the certification of operations” to require its reviewers to verify that labels and product formulations submitted by operations comply with §205.301 through §205.311. CMEX notified its personnel of the procedural update on August 23, 2021 and held a training event on September 3, 2021 to inform personnel of the changes. CMEX submitted an agenda and attendance list for the training.

Verification of Corrective Action: The auditors reviewed certification files and found CMEX had approved noncompliant labels. Specifically, the auditors reviewed updated labels submitted by one operation in response to CMEX’s notice of noncompliance and found that CMEX approved the updated labels although they were still not compliant. The updated labels stated, “made with organic ingredients” instead of listing out the specific organic ingredients or food groups.

2023 Corrective Action: CMEX reported that the operation with the noncompliant labels

identified by the auditors had surrendered its certification, so the labels were no longer in use. Additionally, CMEX reviewed all approved labels on file for its NOP certified operations and identified three operations with noncompliant labels. CMEX confirmed with the operations that the noncompliant labels were no longer in use, collected and reviewed compliant product labels, and notified the operations of the label approval. On August 1, 2023, CMEX emailed all certification personnel with links to NOP labeling requirements and resources for label review. CMEX staff responsible for label review completed the Organic Integrity Learning Center training “Organic Regulations and Retail Labeling.” On August 29, 2023, CMEX’s certification area coordinator conducted an NOP product label review workshop for all certification staff responsible for label review. The workshop included a review of NOP labeling requirements, CMEX’s label review procedures and forms, and evaluation of noncompliant labels identified by NOP auditors.

AIA-6149-21 - 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: *CMEX does not consistently demonstrate the ability to fully comply with the requirements for accreditation, including NOP 3012 Interim Instruction Material Review. The auditors found the following issues related to CMEX’s material review process:*

- 1. CMEX does not have adequate policies, procedures and work instructions for evaluating and approving material inputs for use in organic production or handling.*
- 2. CMEX does not accurately review pest control materials, sanitizers, processing aids and nonagricultural ingredients for compliance with the USDA organic regulations. The auditors review of certification files found that CMEX staff approved noncompliant input materials for use by its certified operations.*
- 3. CMEX staff does not use adequate information when evaluating material inputs for use in organic production or handling. The auditors found that in some cases, CMEX staff is making decisions on material inputs without having a full disclosure of its ingredients or a description of its manufacturing process.*
- 4. CMEX does not verify whether materials comply with annotations or use restrictions on the National List of Allowed and Prohibited Substances. CMEX also does not communicate any applicable National List annotations or restricted use requirements to its operations in the approved material input list it provides to them.*

Corrective Action: CMEX submitted the following corrective actions in response to the noncompliance:

1. CMEX sent notices of noncompliance to three operations regarding noncompliant labels or product formulations identified during the NOP audit and submitted the operations’ adequate corrective actions to NOP.
2. CMEX updated its “Manual of Quality Procedures, Chapter 10 - Procedure for the on-site evaluation (inspection) of operators interested in the certification of the production, processing and/or marketing of organic products” to instruct the inspector to ensure the input list in the operation’s Organic System Plan (OSP) matches the actual inputs used. CMEX also added section 8.9 which instructs the inspector to collect documentation when an operation is found to be using an input not listed in their OSP.
3. CMEX updated its “Procedure 9 - Procedure to access the certification” to state that all inputs will be reevaluated annually during review of the management plan (chapter 8.3) and to instruct the inspector to review the list of authorized inputs within the OSP (chapter 8.5).
4. CMEX updated “Procedure 13 - Procedure for the certification of operators” to

designate report reviewers and final certification managers as responsible for conducting input evaluation and to include instructions for evaluating inputs using the documents listed in section 8.9 of Procedure 10. 5.

CMEX notified review staff and inspectors of these updates in August 2021 and held a training event on September 3, 2021 to review the updated procedures. CMEX also required staff to take the OILC Input Material Review training. Nine inspectors completed the OILC training in 2021 and CMEX has required that all inspectors complete the training by the end of 2022.

Verification of Corrective Action: The auditors reviewed certification files and found CMEX does not accurately review input materials for compliance and does not always use adequate information when evaluating inputs. The auditors reviewed inspector training records and found that not all inspectors completed the OILC Input Material Review training. CMEX does not reevaluate input materials on an annual basis. When auditors requested compliance documentation for inputs currently listed as approved on an operation's input list, CMEX staff provided documents submitted two or three years ago, and in some cases, CMEX was unable to find the compliance documentation. CMEX's material review procedures do not provide clear protocols that outline the expectations regarding the depth and frequency of the review, nor do they provide clear direction for the evaluation of ingredients, sub-ingredients, processing aids, and manufacturing methodologies at all stages associated with the production of multi-ingredient inputs or products requested for certification.

2023 Corrective Action: On July 17, 2023, CMEX issued a reminder to inspection staff of CMEX's procedures for input verification during onsite inspections, including verification of required supporting documentation for each input in use. CMEX reported that as of August 5, 2023, all CMEX certification staff and inspectors had completed the OILC Input Material Review training. CMEX updated its procedure *MPC 9.1, Procedure for application and organic management plan review* to add Annex 1 outlining CMEX's review protocol for inputs and materials during OSP and inspection report review. On August 29, 2023, CMEX implemented a revised OSP form, *MCF 3.18.1.A List of Inputs Used*, which includes designated places for the application review, inspector, and final reviewer to document their compliance review for each input listed in the OSP. Certification reviewers are responsible for verifying that the operation submits current compliance documentation for each input every year and evaluating all of an operation's inputs for compliance annually. In August 2023, CMEX implemented a new central database for evaluated inputs, and reviewers are now responsible for documenting their evaluation of inputs, including the operation code, what compliance documentation was reviewed and the evaluation date, in this database. CMEX has designated folders for each operation where it stores supporting compliance documentation for inputs. On August 17, August 21, and November 1, 2023, CMEX trained certification staff on input evaluation to the NOP standards and documenting input determinations in CMEX's database of evaluated inputs.

AIA-900-22 - 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: *CMEX does not consistently carry out the provisions of the Act and regulations. A review of information submitted by CMEX found that CMEX does not consistently verify an operation's compliance with the requirements of §205.303(b)(2). Specifically, the review found that CMEX incorrectly approved the label of a package of 100% organic blackberries that does not include the required statement, "Certified organic by" The label states, "Certified by"*

Corrective Action: CMEX issued the operation a Notice of Noncompliance for the noncompliant

label and created a checklist for CMEX staff to use when reviewing labels for compliance with the USDA organic regulations. CMEX identified additional instances of approved noncompliant labels and issued Notices of Noncompliances to those operations as well. CMEX plans to conduct training for its staff in June 2022 on label review and submitted the training agenda and meeting invitation to NOP as evidence.

Verification of Corrective Action: The auditors reviewed certification files that included labels for both packaged products and nonretail containers and found several examples where CMEX approved noncompliant labels, including labels without a compliant “Certified organic by...” statement. The auditors interviewed CMEX staff and found that CMEX discontinued the use of the label review checklist in August 2022 and instead hired a staff member whose sole responsibility is to review labels.

2023 Corrective Action: CMEX reported that the operation with the noncompliant labels identified by the auditors had surrendered its certification, so the labels were no longer in use. Additionally, CMEX reviewed all approved labels on file for NOP certified operations and identified three operations with noncompliant labels. CMEX confirmed with the operations that the noncompliant labels were no longer in use, collected and reviewed compliant product labels, and notified the operations of the label approval. On August 1, 2023 CMEX emailed all certification personnel with links to NOP labeling requirements and resources for label review. CMEX staff responsible for label review completed the Organic Integrity Learning Center training “Organic Regulations and Retail Labeling.” On August 29, 2023, CMEX’s certification area coordinator conducted an NOP product label review workshop for all certification staff responsible for label review (report reviewers and designated label reviewer). The workshop included a review of NOP labeling requirements, CMEX’s label review procedures and forms, and evaluation of noncompliant labels identified by NOP auditors.

Noncompliances Identified during the Current Assessment

AIA-5021-23 - Accepted. 7 C.F.R. §205.501(a)(2) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart.”

Comments: *CMEX does not fully implement the NOP’s international organic trade arrangement policies and procedures, which are outlined in the NOP’s **International Trade Policies resources**. The auditor’s review of certification files found that CMEX does not include the statement, “Certified in accordance with the terms of the U.S.-Canada Organic Equivalency Arrangement” on organic certificates for operations with products approved for export to Canada under the U.S.-Canada Organic Equivalency Arrangement.*

Corrective Action: CMEX updated MPC-34: *Procedure for the certification of organic products in accordance with the United States-Canada equivalency arrangement* to require that the attestation statement be included on eligible organic certificates and added instructions for how to include the attestation statement on certificates issued from the Organic Integrity Database. CMEX notified staff of the revised procedure on August 11, 2023 and conducted staff training on August 21, 2023. CMEX reviewed and updated the INTEGRITY records for all certified operations with products certified in accordance with USCOEA and sent revised certificates containing the required attestation statement to the certified operations.

AIA-5022-23 - Accepted. 7 C.F.R. §205.662(a)(1) 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. Such notification shall provide: A description of each noncompliance;”

Comments: *CMEX does not consistently cite the applicable or correct regulation for the noncompliance identified in its notifications of noncompliance. The auditor's review of notifications of noncompliance found CMEX cited regulations that did not exist, such as 205.1(a)(2)(6) and 205.202(3). CMEX also cited regulations that did not apply, such as 205.206(a-e) for when a residue test of a soil sample resulted in a positive pesticide residue detection.*

Corrective Action: In August and September 2023, CMEX conducted training for certification staff and inspectors on writing findings and noncompliances with correct regulatory references. Additionally, CMEX plans to instruct the inspector field evaluators to specifically verify that inspectors are using correct regulatory citations when documenting findings.

AIA-5023-23 - Accepted. 7 C.F.R. §205.402(c) states, "The applicant may withdraw its application at any time. An applicant who withdraws its application shall be liable for the costs of services provided up to the time of withdrawal of its application. An applicant that voluntarily withdrew its application prior to the issuance of a notice of noncompliance will not be issued a notice of noncompliance. Similarly, an applicant that voluntarily withdrew its application prior to the issuance of a notice of certification denial will not be issued a notice of certification denial.

Comments: *CMEX does not consistently comply with the USDA organic regulations when an operation voluntarily withdraws its application for certification. The auditor's review of certification files found that CMEX issued an operation a notice of denial after the operation requested to withdraw their application for certification.*

Corrective Action: CMEX updated its *MPC-9 Procedure for access to certification* and *MPC-13 Procedure for certification of operators* to include requirements for applicants who withdraw their certification prior to being issued a notice of noncompliance or denial. On August 9 and August 18, 2023, CMEX notified certification personnel of the revisions to the procedures. CMEX submitted the revised procedures and copies of the communications to NOP.

AIA-5024-23 - 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: *CMEX does not consistently ensure that its inspectors have sufficient expertise in USDA organic regulations prior to performing the duties assigned. During the witness audit of a crops operation, the auditor observed the following:*

- 1. The inspector informed the operator that they must maintain records on compost temperature and turning, without taking into consideration whether manure is added to the compost, nor whether the operator applied the compost more than 90/120 days prior to harvest.*
- 2. The inspector interviewed an operator about inputs used but did not request to review any documentation to verify compliance of the inputs (such as purchase records).*

Corrective Action: CMEX updated its *MCF 3.5 Questionnaire for control of crop postharvest and handling* and *MCF 3.7.1 Form of control of coffee plantation, wet processing, packaging and storage* to add questions about compost feedstocks, compost production methods, and pre-harvest application intervals for manure. Additionally, CMEX updated its *MCF 3.5 Questionnaire for control of crop postharvest and handling* to add input compliance verification points, including verification of receipts and invoices for purchased inputs. CMEX notified certification staff and inspectors of the revisions to these inspection forms on August 18, 2023, and conducted training with inspectors on the revisions to the documents and the compost/input verification requirements

on August 21, 2023.

AIA-5025-23 - Accepted. 7 C.F.R. §205.670(e) states, "Sample collection pursuant to paragraphs (b) and (c) of this section must be performed by an inspector representing the Administrator, applicable State organic program's governing State official, or certifying agent. Sample integrity must be maintained throughout the chain of custody, and residue testing must be performed in an accredited laboratory. Chemical analysis must be made in accordance with the methods described in the most current edition of the Official Methods of Analysis of the AOAC International or other current applicable validated methodology for determining the presence of contaminants in agricultural products."

Comments: *CMEX does not fully carry out the procedures of NOP 2610 Instruction Sampling Procedures for Residue Testing. The auditor's review of pesticide residue analysis reports and certification files found that CMEX allows non-detect pesticide residue analysis results from a counter-sample to cancel out a residue detection from the original sample.*

Corrective Action: CMEX revised its MPC-12 Procedure for taking samples for analysis of non-allowed substances to remove instructions for inspectors to leave a counter-sample with an operation, and to state that pesticide residue analysis results from samples submitted to a laboratory by an operation will not replace the analysis results from the sample submitted by CMEX. CMEX notified certification staff and inspectors of the revisions to the procedure on August 2, 2023, and conducted staff training on August 21, 2023.

AIA-5026-23 - 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: *CMEX does not fully carry out the procedures of NOP 2613 Instruction: Responding to Results from Pesticide Residue Testing. The auditor's review of pesticide residue analysis reports found CMEX did not immediately inform the operation that the product may not be sold as organic and did not immediately report the violation to the appropriate agency when residue detections exceeded the applicable tolerances.*

Corrective Action: CMEX updated its MPC-13 Procedure for certification of operators to instruct certification staff to follow **NOP 2613 Instruction: Responding to Results from Pesticide Residue Testing** when the analysis of a sample collected at an organic operation results in a detection. On August 9, 2023, CMEX emailed certification staff the revision and reminded them to follow the procedures of **NOP 2613**. On August 28, 2023, CMEX conducted training with certification staff on the revisions to the procedure and the requirements of **NOP 2613**.

AIA-5027-23 - Accepted. 7 C.F.R. §205.501(a)(7) states, "A private or governmental entity accredited as a certifying agent under this subpart must: have an annual program review of its certification activities conducted by the certifying agent's staff, an outside auditor, or a consultant who has expertise to conduct such reviews and implement measures to correct any noncompliances with the Act and the regulations in this part that are identified in the evaluation."

Comments: *CMEX does not fully carry out the procedures of the Act and NOP 2025 Instruction Internal Program Review. The auditor's review of CMEX's annual program review found that persons who conduct the annual program review also perform certification activities.*

Corrective Action: CMEX updated its *MPC-18 Internal audits procedure* to require that the internal audit team for the USDA NOP internal audit not include personnel involved in NOP certification activities. CMEX updated its *MPC-23 Procedure for qualifying candidates as internal auditors* to prohibit NOP certification staff from conducting the internal audit and allow qualified outside auditors and consultants to conduct the internal audit instead. On August 25, 2023, CMEX notified certification staff of the revisions to the procedures. CMEX submitted a list of the proposed internal audit team members for 2023 and has scheduled an internal auditor training for November 2023.

AIA-5028-23 - 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: *CMEX does not carry out the provisions of the Act and regulations. The auditor’s review of certification files found that CMEX inspectors do not consistently conduct traceability and mass balance exercises to verify compliance with § 205.103(b)(2). The following issues were identified:*

- 1. The inspector conducted a traceability exercise but did not document how records link from the finished product to the ingredient(s) purchased.*
- 2. Inspectors do not conduct mass balance or trace-back audit exercises during inspections of new applicants.*

Corrective Action: CMEX created a new form, *MCF 3.8 Control of mass balance and traceability*, for inspectors to record mass balance and traceability exercises conducted at inspections. The form includes instructions for inspectors to record the documents reviewed during traceability exercises and the data which links the documents together. On August 15, 2023, CMEX notified certification staff and inspectors of the new form to be used at inspections. On August 28, 2023, CMEX conducted training for certification staff and inspectors on use of the new form, including that mass balance and traceability exercises must be conducted and recorded at inspections of applicants.