United States Department of Agriculture

Agricultural Marketing Service
National Organic Program

CERTIFICATE OF ACCREDITATION

PRIMUS AUDITING OPERATIONS

2811 Airpark Drive, Santa Maria, California, 93455, U.S.A.

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 Operations

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

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

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Jennifer Tucker, Ph.D.
Deputy Administrator
National Organic Program

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

NATIONAL ORGANIC PROGRAM: AUDIT & CORRECTIVE ACTION REPORT

GENERAL INFORMATION

- **Certifier Name** Primus Auditing Operations, (PAO)
- **Physical Address** 2811 Airpark Drive, Santa Maria, California 93455, U.S.A.
- **Audit Type** Certification Office Audit
- **Auditor(s) & Audit Dates** Kelley Belina, Kendra Volk, Sam Schaefer-Joel, 05/20/2024 to 05/24/2024
- **Audit Identifier** NOP-47-24

CERTIFIER OVERVIEW

The National Organic Program (NOP) conducted an onsite certification office audit of Primus Auditing Operations' (PAO) Costa Rica office certification activities, covering the period June 20, 2020, to May 24, 2024. The purpose of the audit was to verify PAO's compliance with the USDA organic regulations. Audit activities included a review of certification activities, interviews with PAO personnel, a records audit, and two witness audits. Witness audits consisted of the annual inspections of one crop and one handling operation, both in Costa Rica.

PAO's Costa Rica certification office is a wholly owned subsidiary of PAO. PAO's Costa Rica certification office is in San Jose, Costa Rica and conducts key certification activities in Costa Rica, Guatemala, Ecuador, and Colombia. PAO's Costa Rica certification office manages certification activities of 23 operations, covering the handling and crops scopes. Certification activities are performed by five employees and contractor inspectors.

NOP DETERMINATION:

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

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

Noncompliances from Prior Assessments

None

Noncompliances Identified during the Current Assessment

AIA-2515-24 - Accepted. 7 CFR § 205.501(a)(16) states, "A private or governmental entity accredited as a certifying agent under this subpart must: 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: *PAO charged operations certification fees that were not filed with NOP. The auditors reviewed certification files and found that PAO Costa Rica charged operations certification fees that had not been filed with NOP.*

Corrective Action: PAO certification offices will send PAO USA their fee schedule annually in December. PAO USA will provide the NOP with updated documents when the change occurs. PAO updated its work instruction, "How to Update the USDA NOP Fee Schedule" in both Spanish and English. PAO reviewed the revised work instruction at a weekly staff meeting on April 1, 2025. PAO sent an internal email notifying organic staff of the changes on April 8, 2025.

AIA-2516-24 - Accepted. 7 CFR § 205.510(b)(1-2) states, "Certifying agents must maintain records according to the following schedule: (1) Records obtained from applicants for certification and certified operations must be maintained for not less than 5 years beyond their receipt; (2) 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: *PAO does not consistently comply with the USDA organic regulations and does not maintain records according to the schedule described in § 205.510(b)(1-2). The auditors reviewed certification files and found that PAO Costa Rica could not provide records of an operation's surrender request and PAO's subsequent acceptance of surrender which occurred less than three years prior to the audit.*

Corrective Action: PAO determined PAO Costa Rica staff did not understand the requirements of the surrender process. On July 23, 2024, PAO trained staff on its procedure for processing surrender requests, which includes that the operation must use the Surrender Letter Template to formally surrender an operation's certification.

AIA-2517-24 - Accepted. 7 CFR § 205.501(a)(3) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§ 205.402 through 205.406 and § 205.670;"

Comments: *PAO does not consistently carry out the provisions of the Act and regulations. The auditors reviewed certification files and found PAO Costa Rica inspectors and reviewers do not consistently cite the correct USDA organic regulations. The auditors found the following issues:*

1. *A PAO Costa Rica reviewer incorrectly cited § 205.308(b) as the applicable standard*

during a review of an organic retail label.

2. *A PAO Costa Rica inspector incorrectly cited § 205.405(e) as the applicable standard for an issue of concern on an inspection exit interview form. The issue of concern was for a handling operation failing to implement corrective actions for a prior noncompliance.*
3. *A PAO Costa Rica inspector incorrectly cited § 205.105 and § 205.600 as the applicable standard for an issue of concern on an inspection exit interview form. The issue of concern was for a crops operation failing to maintain required records.*

Corrective Action: PAO determined that the inspectors obtained the incorrect citations from a reference document. PAO Costa Rica developed a document that includes correct standard references to cite in findings at inspection. On September 10, 2024, PAO trained staff on identifying the appropriate citations are used in the Exit Interview.

AIA-2518-24 - Accepted. 7 CFR § 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: *PAO does not consistently ensure that its staff reviewing multi-ingredient organic products have sufficient expertise to successfully perform the duties assigned. The auditors reviewed certification files and found the following issues:*

1. *PAO Costa Rica certified a product as organic that contained a nonorganic agricultural ingredient not listed on the National List. PAO Costa Rica staff stated they collected commercial availability documentation and verified that the ingredient was used at less than 5% of the product composition to make this certification decision.*
2. *PAO Costa Rica staff incorrectly accepted a certified operation's statement that nonorganic ingredients (ascorbic acid and xanthan gum) were only used as processing aids in a multi-ingredient product and therefore PAO Costa Rica did not include them as a percentage of the ingredients in the overall final product formula. However, the ingredients perform a technical effect in the finished food product and do not meet the definition of processing aid at § 205.2 and should have been considered as a percentage of the ingredients in the overall final product formula.*

Corrective Action: The operation removed the product referenced in point one from its product list and PAO will verify the operation's updated formulation and labels as part of the renewal process for the products referenced in point two. On October 5, 2024 (in Spanish) and November 8, 2024 (in English), PAO had an outside consultant train staff on common practices and documents for multi-ingredient compositions. PAO will also monitor the improvement of personnel related to their multi-ingredient review expertise as part of their annual evaluation. For point two, PAO reported that the operation modified their production process to eliminate the ingredients from the final product formula.

AIA-2519-24 - Accepted. 7 CFR § 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: *PAO does not consistently demonstrate the ability to comply with the requirements for accreditation. The auditors interviewed certification staff and found that PAO Costa Rica has not identified accredited laboratories capable of performing pesticide residue analysis in some countries and therefore is not currently prepared to perform residue sampling in all countries in which they offer certification services.*

Corrective Action: PAO Costa Rica developed a list of accredited laboratories that can provide residue sampling in countries where it offers certification services called "Cert 51 List of Approved Subcontractors." PAO confirmed that the appropriate staff has been trained on the Sample Collection Procedure, SOP-23, which specifics that Cert 51 must be verified when selecting the laboratory for sample submission.

AIA-2520-24 - Accepted. 7 CFR § 205.501(a)(3) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§ 205.402 through 205.406 and § 205.670;"

Comments: *PAO does not carry out the provisions of the Act and regulations. The auditors reviewed certification files and found that PAO Costa Rica does not consistently verify an operation's compliance with the requirements of §205.303(b)(1)-(2). The auditors identified the following issues:*

1. *A retail label did not identify the ingredient as organic in the ingredient statement.*
2. *A retail label did not include the statement "Certified Organic by PAO."*
3. *A retail label used the PAO logo as the "certified organic by…" statement, however, the size of the logo meant that the "certified organic by…" statement was illegible.*

Corrective Action: The operation has since surrendered its organic certification. On September 10, 2024, PAO trained its PAO Costa Rica staff on label guidance including the proper use the "certified organic by…" statement and ingredients statement. On October 3, 2024, PAO sent its operations a letter informing them of the need for the COB statement to be legible on the labeling of the final product.

AIA-2521-24 - Accepted. 7 CFR § 205.501(a)(3) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§ 205.402 through 205.406 and § 205.670;"

Comments: *PAO does not consistently carry out the provisions of the Act and regulations. The auditors reviewed certification files and interviewed certification staff and found PAO Costa Rica does not require operations to provide sufficient information in the organic system plan (OSP) to determine compliance or the ability to comply with the USDA organic regulations. PAO Costa Rica did not require an operation to describe management practices used to prevent crop pests, weeds, and diseases as required by § 205.206(a)-(d).*

Corrective Action: On September 10, 2024, PAO trained staff responsible for conducting OSP reviews on the importance of reviewing the operation's description of management practices used to prevent crop pests, weeds, and diseases as required by § 205.206(a)-(d). PAO will monitor this issue through annual staff evaluations.

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NATIONAL ORGANIC PROGRAM: AUDIT & CORRECTIVE ACTION REPORT

GENERAL INFORMATION

- **Certifier Name** Primus Auditing Operations, (PAO)
- **Physical Address** 2811 Airpark Drive, Santa Maria, California 93455, U.S.A.
- **Audit Type** Material Review Audit
- **Auditor(s) & Audit Dates** Samuel Schaefer-Joel, 05/20/2024 to 05/23/2024
- **Audit Identifier** NOP-35-24

CERTIFIER OVERVIEW

The National Organic Program (NOP) conducted an on-site audit of Primus Auditing Operations (PAO)'s material review activities in Costa Rica. The purpose of the audit was to verify PAO's compliance with the Organic Foods Production Act of 1990 (OFPA), the USDA organic regulations (7 CFR Part 205), and the NOP Handbook. Audit activities included the assessment of PAO's material input review policies and procedures, and a review of compliance documentation for inputs used by certified clients as well as inputs on PAO's approved materials list.

PAO is a for-profit organization initially accredited on August 02, 2019 for the scopes of crops and handling. PAO's principal office is in Santa Maria, California with regional certification offices in Costa Rica, Chile, and Mexico. PAO certifies 788 operations in 7 countries. PAO has a separate material approval program. This program issues material approval certificates to input manufacturers and is managed from the Costa Rica office.

NOP DETERMINATION:

NOP reviewed corrective actions submitted as a result of noncompliance issued from findings identified during the audit.

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

Noncompliances from Prior Assessments

None

Noncompliances Identified during the Current Assessment and Corrective Actions

AIA-2724-24 – 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: *PAO's material review policies and procedures do not demonstrate that PAO has the ability to verify compliance with the requirements of § 205.201(a)(2) as clarified in* ***NOP 3012 Interim Instruction Material Review****. The auditors reviewed PAO's material review policy and procedures and found that these documents do not include clear written instructions outlining the expectations regarding the frequency of the review and providing clear direction for the evaluation of all ingredients, sub-ingredients, processing aids, and manufacturing methodologies at all stages associated with the production of formulated products. Additionally, PAO's procedures for their Evaluation of Inputs program do not contain expectations regarding the frequency of review for ingredient documentation.*

Corrective Action: PAO submitted a revised copy of its procedure for its input evaluation program. The changes indicate that if material compositions change, then the applicant-company must have the materials re-evaluated by PAO. In addition, PAO will conduct an annual renewal review of the product. PAO created the "Input Material Review Guidance," on October 11, 2024 which provides instructions for reviewing materials reviewed by an MRO, and for reviewing crop and handling materials not previously reviewed by an MRO. PAO conducted a training session on October 5, 2024 to cover the changes.

AIA-2725-24 – 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: *PAO does not consistently carry out the provisions of the Act and regulations. PAO's input material reviews are not always sufficient to verify compliance to §205.105 and §205.201(a)(2). The auditor reviewed certification files and found the following issues with PAO's material reviews:*

1. *PAO does not consistently copy restrictions from external material review documents to input lists in Organic System Plans. Specifically, PAO did not recognize that some material approval documents from other organizations only note restrictions by referencing the citation from the National List.*
2. *PAO incorrectly determined that an ingredient in a post-harvest coating product was nonsynthetic when the manufacturing process provided described a synthetic process. This*

ingredient is only allowed as a nonsynthetic agricultural material.

3. *PAO approved a post-harvest coating product without verifying the commercial availability of two ingredients that are only allowed when organic ingredients are not commercially available. The final product approval did not contain a restriction communicating any commercial availability requirement to the end user.*
4. *PAO incorrectly approved the use of a denatured alcohol containing diethyl phthalate as an inert in an on-farm made pesticide. Diethyl phthalate is listed on EPA list 2.*
5. *PAO approved the use of a disease control product using only an OMRI certificate showing COR compliance.*

Corrective Action: PAO contracted with a third-party expert in material review to provided staff with training on NOP 3012, NOP 5033-1 and NOP 5033-2 in October and November 2024. Training materials also included evaluating ingredients and processing aids, accepting evaluations of other certification agencies and issuing requests for information and noncompliances for material information. For points #2 and #3, PAO conducted a re-review of the material and the supplier did not provide the requested information. As a result, the material was not renewed with PAO. For points #4 and #5, PAO contacted the operation and they removed the product from their Organic System Plan.

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GENERAL INFORMATION

- **Certifier Name** Primus Auditing Operations, (PAO)
- **Physical Address** 2811 Airpark Drive, Santa Maria, California 93455, U.S.A.
- **Audit Type** Compliance Audit
- **Auditor(s) & Audit Dates** Jessica Walden, Joshua Lindau, 04/17/2023 to 04/21/2023
- **Audit Identifier** NOP-237-23

CERTIFIER OVERVIEW

The National Organic Program (NOP) conducted an onsite compliance audit, specifically focusing on certification activities conducted by Primus Auditing Operations' (PAO) Mexico satellite office. The audit of certification activities covered the period January 1, 2021 - April 16, 2023. The purpose of the audit was to verify PAO's conformance to the USDA organic regulations.

Audit activities included a review of certification activities, interviews with PAO personnel, a records audit, and three witness audits. Witness audits consisted of the annual inspections of two crop/handling operations and one handling operation in Mexico, near the city of Guadalajara.

PAO's Mexico satellite office is a wholly owned subsidiary of PAO, a for-profit business. PAO's Mexico office is located in Zapopan, Jalisco, Mexico and conducts key certification activities in Mexico. PAO's Mexico satellite office manages certification activities of 472 operations, covering the handling and crops scopes. Certification activities are performed by 21 contractors who conduct inspections and reviews and 4 staff employees.

NOP DETERMINATION:

NOP reviewed the audit results to determine whether PAO'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-1294-20 – Cleared.

AIA-1301-20 – Cleared.

AIA-1832-20 - Cleared.

AIA-1834-20 - Cleared.

AIA-1835-20 - Cleared.

AIA-6566-21 - Cleared.

AIA-8735-21 - Cleared.

AIA-8736-21 - Cleared.

AIA-533-22 - Cleared.

AIA-1291-20 - Accepted. (NP6025PZA.NC9) 7 CFR §205.501(a)(21) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary."

Comments: *During file reviews, the auditor found an operation that was providing attestation statements for organic product shipped to Canada under the U.S.-Canada organic equivalency arrangement. However, PL staff told the auditors that no operations conduct international export or import activities. The PL OSP templates do not ask applicants to describe any international activities, nor do inspection report templates instruct the inspectors to verify international activity during inspections. Additionally, PL does not have procedures for inspectors or reviewers to verify that operations comply with the requirements of USDA NOP international arrangements.*

Corrective Action: PL developed a procedure that requires an addendum be sent to all new or renewing clients; the addendum includes questions on international trade activities (import/export). The new procedure also requires the inspector to verify the answers on the addendum at the onsite inspection. For the U.S.-Canada equivalency arrangement, clients who comply with the requirements will have the attestation statement included on their organic certificate. In addition, clients will be given a self-attestation document to complete and issue with each shipment of product. PL also developed a work instruction describing compliant language for the attestation statement. PL verified that training for the certification staff members was conducted in July 2016 on the requirements for product traded under the U.S.-Canada Equivalency Arrangement.

Verification of Corrective Actions: The auditor verified that the international trade activities addendum is utilized. The addendum does not cover all of the international arrangements and does not indicate other arrangements may apply. PL's checklist does not require the inspector to verify any other arrangements except the US-Canada and the US-EU equivalency.

2017 Corrective Action: PL updated their Crop and Handling OSPs to include a section for operations to describe their international import and exporting activities. If operators are conducting import/export activities, then they are required to complete PL's International Markets OSP Addendum. PL updated the International Markets OSP Addendum to include all of the export agreements and inquire about imported products.

Inspectors are sent the operator's OSP, International Markets OSP Addendum, and a Review Report of the OSP with instructions from the reviewer to verify import/export activity. PL trained staff on the changes to the documents and the requirements of the NOP International Trade Agreements on October 14, 2017.

2018 Verification of Corrective Action: This corrective action is not completely implemented. (1) An updated Organic System Plan (OSP) template was implemented April 3, 2018. The OSP template instructs operators to indicate whether products and/or ingredients are imported or exported and instructs operators to complete an addendum describing trade activity details. The OSP addendum template was implemented June 13, 2018. (2) The inspection report template has not been updated with a section for inspectors to record verification of import and/or export activities. (3) No procedures or work instructions have been developed to guide certification personnel through the requirements of reviewing and verifying imported and exported products and/or ingredients.

2019 Corrective Action: PAO updated its crop and handling inspection checklists to include a section for inspectors to record verification of import and/or export activities and compliance with organic trade arrangements. PAO also created a work instruction "International Markets Addendum Information Guide" that instructs staff on what information should be covered in an OSP review in cases where operations are importing or exporting to equivalency countries.

2020 Verification of Corrective Action: The auditors verified that PAO implemented the use of the crop and handling inspection checklist and work instruction described in the 2019 corrective actions. However, the auditors' review of operation files with exported and imported products found that the international sections on the organic system plans (OSPs) and the inspection checklists are inconsistently completed by the operations and inspectors; therefore, there is no evidence that inspectors are verifying that operations comply with the requirements of USDA NOP international trade arrangements.

2022 Corrective Action: PAO held a training in July 2021 and August 2022 for inspectors and reviewers that addressed this topic. PAO reminded inspectors to verify that operations who import or export organic products have completed the international addendum. PAO submitted to the NOP attendance records and training materials for the trainings. PAO sent an email memo in July 2022 to inspectors and reviewers reminding inspectors to complete the ORG-058 International Equivalencies Checklist during inspections of operations that import and/or export organic products. This memo also reminded reviewers to verify that inspectors are completing this form and, if not, to notify the QA department. PAO submitted to the NOP a copy of the memo, and an example of a completed International Equivalencies Checklist, international addendum, and the documented review of an operation requesting to export organic products under an equivalency arrangement.

2023 Verification of Corrective Action: The auditors reviewed certification files and verified that the international addendum is being completed by certified crops and handling/processing operations requesting verification to the USCOEA. However, the form does not sufficiently address the requirements for handling operations and operations are completing the form

inaccurately because the questions do not correctly reflect the requirements of the USCOEA. Additionally, PAO's handling/processing inspection report templates do not prompt the inspector to verify USCOEA compliance of suppliers and ingredients.

2023 Corrective Action: PAO updated its *International Markets Addendum* and *Canadian Equivalency* documents to separate the requirements for crops operations from the requirements for handling operations. PAO updated its inspection report templates with the same questions to verify compliance at inspection. PAO notified staff on November 15, 2023 via email of the new forms. On November 13, 2023 PAO implemented the *International Markets Addendum*. On March 19, 2024, PAO implemented the use of the updated inspection report templates and *Canadian Equivalency Addendum*.

AIA-1822-20 - Accepted. 7 C.F.R. §205.670(c) states, "A certifying agent must conduct periodic residue testing of agricultural products to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))." Samples may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples. Such tests must be conducted by the certifying agent at the certifying agent's own expense."

Comments: *PAO does not fully carry out the procedures of* ***NOP 2613 Instruction Responding to Results from Pesticide Residue Testing****. The auditors' review of pesticide residue analysis reports and a combined notice of noncompliance and denial of certification identified the following:*

1. *PAO did not send a notification of the residue test results and indication that the product may be sold as organic since no prohibited pesticide residues were detected.*
2. *PAO did not follow the appropriate instructions for determining EPA tolerances for pesticide residue samples. In one case, PAO used a positive soil sample as the evidence for issuing a notice of denial on the grounds that the crop exceeded the EPA tolerance. In another case, a foliage sample instead of the edible product was tested revealing the presence of a permitted pest control material. PAO mistakenly determined that the edible portion of the crop exceeded the EPA tolerance.*

Corrective Action: PAO submitted to the NOP a "Review Report" checklist that reviewers use when evaluating pesticide residue results. The form addresses the specific questions related to the requirements of NOP 2613, including clarifying that EPA tolerances apply to the edible portion of a crop or product, not to soil or other plant material. PAO also created and submitted to the NOP a letter template that staff use to communicate the residue test results to operations. The letter template includes specific instructions to certification staff who amend the letter according to the type of sample and result. The letter template addresses the requirements of NOP 2613, including when to notify the operation that they may sell their product as organic. PAO management reviews the final letter to ensure it is accurate prior to sending it to the operation. On December 1, 2022, PAO conducted a training for QA staff, which included a segment on NOP 2613. PAO provided the NOP with the training attendance sheet. PAO will send a memo detailing the updates and implementation of the updated section within the "Review Report" document to all technical reviewers and inspectors by December 15, 2022.

Verification of Corrective Action: The auditors reviewed pesticide residue sample files and found that PAO Mexico staff are not always following NOP 2613 Instruction Responding to Results from Pesticide Residue Testing. The auditors reviewed a pesticide residue result for a sample of organic celery seedlings which indicated the presence of four pesticides, none of which have an EPA tolerance for celery. The pesticide residue levels for two pesticides were over 4 ppm. PAO Mexico issued the operation a request for information regarding two of the four

pesticides found and did not acknowledge or request information on the other two pesticides. PAO Mexico later issued a notice that stated the products may be sold as organic without carrying out a further investigation.

2023 Corrective Action: The operation discarded the contaminated celery lot and PAO conducted another inspection to verify the operation effectively implemented corrective actions. On January 21, 2024, PAO requested the operation investigate the presence of the two pesticides not included on the original request. PAO determined that the reviewer had incorrectly completed section 13 *Sample Evaluation* of its *Review Report* document and the error was duplicated on the Notice of Noncompliance. PAO provided feedback to the reviewer on the specific case. On November 3, 2023, PAO trained internal reviewers on how to correctly complete section 13 and on NOP 2613 and will train all reviewers on April 13, 2024. PAO's QA team will review all notifications prior to the notification being issued to the client.

AIA-1823-20 - 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: *PAO does not consistently demonstrate the ability to fully comply with the requirements of accreditation. Specifically, PAO is not consistently executing certification processes in a timely manner. The auditors' review of files and interviews with certification staff found the following issues:*

1. During an unannounced inspection, the inspector found that the certified operation was no longer operating out of the premises listed on the certificate and had gone bankrupt. Five months later, PAO issued a notice of noncompliance to the company for failing to renew their organic certification.

2. PAO issued a notice of suspension more than two months after the proposed effective date of suspension identified in the notice of proposed suspension.

3. PAO issued a combined notice of noncompliance and proposed suspension to an operation five months after the inspection revealed noncompliant practices.

4. PAO issued two operators notices of noncompliance more than six months after the operations failed to submit an annual update and pay certification fees.

Corrective Action: PAO implemented the use of an electronic program that logs each inspection, review, notification, and tracks them in the system via a due date. The electronic program sends alerts to PAO staff when deadlines are surpassed, triggering action by PAO to follow up with. PAO trained staff on the use of this program on April 22, 2022. PAO submitted to the NOP a detailed description of how the electronic system works as well as a copy of the training log.

Verification of Corrective Action: The auditors reviewed certification files and found that PAO Mexico is not issuing notices of noncompliance and adverse actions in a timely manner. The tracking sheet, as noted in PAO's corrective action, has not yet been implemented for the office in Mexico. The auditors found that PAO Mexico issued notices of proposed suspension to four operations more than five months after the operations failed to respond to the notices of noncompliance. Additionally, PAO has not yet issued a notice of noncompliance to two operations who failed to submit an annual update and pay certification fees by their anniversary date, which was over a year ago.

2023 Corrective Action: PAO Mexico implemented the electronic tracking system and conducted training for staff on November 3, 2023. In April 2024, PAO plans to standardize its software program so that all countries and PAO certification offices have access to the same modules. PAO will issue a notice of noncompliance to operations that send in their annual updates but do not pay their certification fees.

AIA-1830-20 - Accepted. 7 C.F.R. §205.403(a)(1) states, "A certifying agent must conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested. An on-site inspection shall be conducted annually thereafter for each certified operation that produces or handles organic products for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue."

Comments: *PAO did not conduct annual on-site inspections of all its certified operations in 2018 and 2019. The auditors identified two operations that did not receive annual inspections. PAO stated this was because they either failed to timely submit an annual update or were involved in a complaint investigation.*

Corrective Action: PAO implemented a new process and the use of an electronic tracking system. PAO sends out an anniversary reminder email to operations one month before their anniversary date. At the beginning of each month, QA staff receive a list of operations that failed to meet their annual update deadline. QA staff then generate and issue notices of noncompliance and track the notification process using the implemented electronic system. Additionally, PAO's corrective action response clarified that the operation involved in the complaint investigation would not schedule an annual inspection. In response, PAO carried out an unannounced inspection instead of issuing the operation a notice of noncompliance. PAO's new tracking system also alerts staff when inspections have not been scheduled by the deadline. QA staff generate notices of noncompliance if the operation does not allow for the timely scheduling of an inspection. If the operation does not sufficiently respond to the notice of noncompliance, PAO begins the adverse action process. PAO provided screenshots of the electronic tracking system to the NOP.

Verification of Corrective Action: The auditors reviewed certification files and found that PAO Mexico did not conduct annual on-site inspections of all its certified operations in 2021 and 2022. The tracking system, as noted in PAO's corrective action, has not yet been implemented for the office in Mexico.

2023 Corrective Action: PAO Mexico implemented the electronic tracking system and conducted training for staff on November 3, 2023. In April 2024, PAO plans to standardize its software program so that all countries and PAO certification offices have access to the same modules.

AIA-1831-20 - 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: *PAO's Quality Manual and templates do not demonstrate that PAO has the ability to fully comply with the requirements of the adverse action process in the following manner:*

1. The Quality Manual, Section D Notice of proposed suspension/revocation incorrectly states, "Once Audit Admin receives client's reply to the NoPS, then Audit Admin will forward the complete file with corrective actions to the reviewer for approval." Corrective Actions cannot resolve a Notice of Proposed Suspension according to §205.662(c).

2. The Notice of Proposed Suspension and Combined Notice of Noncompliance and Proposed Suspension templates incorrectly state, "Finally, please be advised that you may also at any time surrender your certification according to §205.404(c) by written notification to Primus Auditing Ops. Note that if you surrender your certification and apply to another certification agency, you will be required to provide this Notice of Noncompliance and Notice of Proposed Suspension and a description of the actions taken

to correct the non-compliance(s) with your application as described in §205.401(c).”An operation’s surrender does not resolve a Notice of Proposed Suspension and the adverse action process continues as stated in 205.662(e)(1).

Corrective Action: PAO submitted to the NOP screenshots of the updated Quality Manual, section D, “Notice of Proposed Suspension or Revocation §205.662(c)(d)” that reflects PAO’s adverse action process and the requirements of the USDA organic regulations. PAO also submitted an updated notice of proposed suspension and combined notice of noncompliance and proposed suspension template that now reflect the requirements of the USDA organic regulations. On December 1, 2022, PAO conducted a training for QA staff, which included a segment on quality manual and template updates. PAO provided the NOP with the training attendance sheet.

Verification of Corrective Action: The auditors found that the Quality Manual is still in draft form and has not yet been published to reflect PAO’s corrective actions.

2023 Corrective Action: PAO published its Organic Quality Manual and communicated the change to its team on November 10, 2023 via email.

AIA-1833-20 - Accepted. 7 C.F.R. §205.642 states, “Fees charged by a certifying agent must be reasonable, and a certifying agent shall charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator. The certifying agent shall provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification. The certifying agent may set the nonrefundable portion of certification fees; however, the nonrefundable fees must be explained in the fee schedule submitted to the Administrator. The fee schedule must explain what fee amounts are nonrefundable and at what stage during the certification process fees become nonrefundable. The certifying agent shall provide all persons inquiring about the application process with a copy of its fee schedule.”

Comments: *PAO does not provide certification applicants its fee schedule. The auditors’ interview with staff responsible for communicating with new applicants and a review of associated email communications confirmed that PAO’s fee schedule is only provided to applicants upon request.*

Corrective Action: PAO created an instructional document for new and renewing operations that includes a hyperlink to the most current fee schedule. PAO submitted to the NOP a copy of the instructional document and an email from PAO to a new applicant that included the instructional document containing a hyperlink to the fee schedule.

Verification of Corrective Action: The auditors interviewed certification staff and found that PAO’s use of the instructional document for operations, which includes a hyperlink to the most current fee schedule, has not been implemented by PAO Mexico.

2023 Corrective Action: PAO conducted training for PAO Mexico staff on December 1, 2023. PAO Mexico implemented the use of a fee schedule that is emailed to applicants. PAO provided NOP with an email to an applicant with the fee schedule attached as evidence of implementation.

Noncompliances Identified during the Current Assessment

AIA-5083-23 - 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: *PAO does not demonstrate the ability to fully comply with the requirements for*

accreditation. The auditors' review of certification files and interviews with staff identified the following issues:

1. PAO's notices of denial incorrectly state the operation has a right to appeal the proposed suspension.

2. PAO's *notices of noncompliance for certification applicants incorrectly state that the failure to rebut or resolve the noncompliance can lead to a proposed suspension or revocation.*

Corrective Action: On November 15, 2023, PAO implemented the use of an updated notice of denial template to remove the reference to the proposed suspension and also implemented the use of an updated notice of noncompliance template for certification applicants, which states that failure to rebut or resolve the noncompliance can lead to the issuance of a notice of denial of certification. PAO informed staff during an all-offices organic weekly meeting.

AIA-5084-23 - Accepted. 7 C.F.R. §205.406(c) states, "If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in §205.404, that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with §205.662."

Comments: *PAO Mexico does not consistently issue a notification of noncompliance to its certified operations, even though the review of the inspection report finds that the operations do not comply with the USDA organic regulations. The auditors' review of certification files found PAO Mexico did not provide operations with a written notification of noncompliance for noncompliant practices and instead issued operations a request for information requiring corrective actions and root cause analyses. The following are issues of concern identified by PAO Mexico inspectors that were not issued to operations as noncompliances:*

1. *The operation's use of restricted material inputs not in alignment with their National List use restriction;*
2. *Inadequate buffer zones;*
3. *Failure to maintain records in sufficient detail as to be readily understood and audited;*
4. *The use of non-approved labels;*
5. *Failure to demonstrate compliance with NOP's seed, seedling, and planting stock recordkeeping requirements;*
6. *Failure to implement crop rotations as described in the OSP;*
7. *Maps that did not accurately reflect the fields used for organic production; and*
8. *Pesticide residue detections above 4ppm.*

Corrective Action: PAO conducted training for reviewers on June 16, 2023 to define when an observation should be issued as a noncompliance or as a notification of required information. The training also reviewed NOP 4002 Penalty Matrix. PAO's QA staff will review all notifications to verify that observations are correctly classified.

AIA-5085-23 - 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: *PAO is not carrying out the provisions of the Act and regulations. The auditors'*

review of certification files found that PAO did not execute the terms of an NOP-established settlement agreement with a PAO-certified operation. PAO did not conduct unannounced inspections in the first year as required by the terms of the agreement and inspectors did not verify that the operation met the specific terms.

Corrective Action: PAO added the operation to its list for unannounced inspections and will verify the terms during the inspection. On January 1, 2024, PAO began using a *Master Tracking Log* that tracks the terms of all settlement agreements, starting with any executed in 2023. PAO will include all NOP-established settlement agreements under the 'Mediation and Settlement Agreements' tab of the *Master Tracking Log* as well its terms. If the agreement requires additional sampling or inspections, PAO will include this information under the 'Unannounced/Additional Inspection' tab of the *Master Tracking Log.* PAO conducted training for QA staff on the related work instruction on November 14, 2023. PAO also added "settlement agreement term" as an additional selection option under "Reason for Inspection."

AIA-5086-23 - 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: *PAO does not consistently carry out the provisions of the Act and regulations. The auditors' review of certification files found that PAO does not consistently ensure compliance of the organic system plan (OSP) with §205.105(b) and §205.203. The auditors' review of certification files and interviews with certification staff found the following issues:*

1. PAO accepted an OSP that described the use of sodium nitrate as a fertilizer for organic crop production. PAO did not verify that the material's use was restricted to no more than 20% of the crop's total nitrogen requirement, as required by §205.602(h).

2. PAO accepted an OSP that described the use of weeds and tree prunings as the sole source of fertility in organic orchards. PAO did not verify that this fertility plan met the requirements of §205.203(b).

Corrective Action: PAO implemented the following corrective actions:

1. PAO provided the reviewer with feedback. PAO trained inspectors and reviewers on the requirements for use of sodium nitrate and compliance with § 205.602(h). PAO suspended this operation for non-renewal.
2. PAO discussed the requirements of § 205.203(b) regarding fertility plans for perennial crops during its Annual Calibration Training for inspectors and reviewers on August 21, 2023. PAO requested additional information from the operation related to its fertility plan on January 12, 2024.

AIA-5087-23 - 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: *PAO does not consistently demonstrate the ability to fully comply with the requirements for accreditation. The auditors' review of PAO's crop organic system plan (OSP) and crop inspection report templates found that the crop OSP does not require operations to document if plastic mulch is removed at the end of the growing season or if the plastic mulch is manufactured in accordance with the National List of Allowed and Prohibited Substances, §205.601(b)(2)(ii). PAO crop inspection report templates do not prompt inspectors to verify compliance with these requirements.*

Corrective Action: PAO updated its crops OSP and inspection report templates to include questions about plastic mulch usage. PAO conducted Annual Calibration Training for inspectors and reviewers on August 21, 2023. The training covered the compliance criteria regarding plastic mulch usage and removal and PAO's procedure for requesting supplementary information about the materials used for the plastic mulch.

AIA-5088-23 - 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: *PAO does not consistently demonstrate the ability to fully comply with the requirements for accreditation. The auditors' review of PAO's crops inspection report templates and inspector mass balance worksheets found that the inspector instructions on the forms are not relevant to crops operations. The forms instruct inspectors to conduct mass balances on product/ ingredients received versus final product produced and sold, which is only applicable to handling operations.*

Corrective Action: PAO implemented a revised Mass Balance and Traceability form on March 19, 2024, that includes instructions for conducting mass balance and traceability exercises for crops operations. PAO trained inspectors on February 10, 2024.

AIA-5089-23 - 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: *PAO does not consistently demonstrate the ability to fully comply with the requirements for accreditation. The auditors' review of information submitted prior to the audit and certification files during the audit found the following issues:*

1. PAO does not consistently update the certification status of certified operations in the Organic Integrity Database (OID). The auditors found that several operations that were listed as certified at the time of the audit had surrendered their certification in 2020 and 2021.

2. PAO does not maintain certification files in a manner that is readily available and auditable. Certification files provided to the auditors prior to the audit included inspection reports that were not formatted in a manner that could be understood and audited, out of date certificates, and product labels that were inconsistent with private label agreements. While PAO was able to locate the information during the audit, the information was not readily available.

Corrective Action: PAO implemented the following corrective actions:

1. As of January 2024, PAO Mexico staff are required to update its operation statuses in OID within three days of the issuance of a notification. Other countries will be responsible for their own updates. On November 30, 2023, PAO trained PAO Mexico QA staff on updating OID.
2. On November 29, 2023, PAO trained PAO Mexico staff on standardizing the organization of PAO Mexico's client folders. The training also reminded PAO Mexico staff to keep the latest versions of documents on file.

AIA-5090-23 - 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: *PAO does not fully implement the National Organic Program's (NOP) international organic trade arrangement policies and procedures, which are outlined in the NOP's International Trade Policies resources. The auditors identified the following issues during certification file reviews and witness audits:*

1. The auditors identified several operations, who were not eligible or approved by PAO to export under the U.S.-Canada Organic Equivalence Arrangement, packing into bilingual retail private labels that are specific to marketing USDA organic product in Canada. In order to be sold, labeled, or represented as organic in Canada, USDA organic products must meet specific requirements.

2. The auditors identified one operation, who was not eligible for the US/Japan Organic Equivalence Arrangement, packing into bilingual retail labels that are specific to marketing organic product in Japan. The US/Japan Organic Equivalence Arrangement is limited to products certified to the USDA organic regulations that are produced or have had their final processing occur within the U.S.

Corrective Action: PAO updated their process to not approve bilingual labels if the operation does not meet the specific requirements of the relevant equivalency arrangement. When making a certification decision involving an operation that has submitted a bilingual label, PAO will notify the operator to either update the label or to demonstrate compliance with the applicable equivalency arrangement. PAO trained inspectors and reviewers on the topic of verification of equivalency and bilingual labeling on February 10, 2024.

AIA-5091-23 - 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: *During witness audits of crops inspections, the auditors observed that the inspector did not identify potential noncompliances resulting from the inspections as issues of concern. Examples of potential noncompliances that the inspectors did not identify as issues of concern include:*

1. Plastic or other synthetic mulches were not removed from the field at the end of the growing or harvest season, as required by § 205.206(c)(6).

2. The operation's maps of its production areas were inaccurate.

Corrective Action: PAO implemented the following corrective actions:

1. PAO updated its crops OSP and inspection report templates to include questions about plastic mulch usage. PAO conducted Annual Calibration Training for inspectors and reviewers on August 21, 2023, that covered the compliance criteria regarding plastic mulch usage and removal and PAO's procedure for requesting supplementary information about the materials used for the plastic mulch.
2. PAO updated its crops OSP template to include a question about whether the total field and crop acreage is consistent with the operation's maps and other information. PAO received an updated map from the operation.

AIA-5092-23 - Accepted. 7 C.F.R. §205.403(c)(1) states, "The onsite inspection of an operation must verify: The operation's compliance or capability to comply with the Act and the regulations in this part;"

Comments: *During witness audits of crops inspections, the auditor observed that the inspectors did not fully verify the operation's compliance with the USDA organic regulations and the National Organic Program Handbook. The auditor identified the following:*

1. The inspector did not verify that the specific growing medium product used by the operation complied with the applicable National List use restrictions.

2. The inspectors did not verify the operation's compliance with ***NOP 5020 Guidance Natural Resources and Biodiversity Conservation****.*

Corrective Action: PAO implemented the following corrective actions:

1. The operation indicated to PAO that the product would not be marketed as organic. PAO provided feedback to the inspector following the witness audit to go through the checklist and request information on the planting material from the operation.
2. PAO updated its crops organic system plan (OSP) template to include a section on Natural Resources and Biodiversity Conservation. PAO implemented the use of the updated OSP template on February 1, 2024. PAO conducted Annual Calibration Training on August 21, 2023 for inspectors and reviewers which included the topic of biodiversity.

AIA-5093-23 - 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: *PAO does not consistently ensure inspectors have sufficient expertise in organic production or handling techniques prior to performing the duties assigned. During a witness audit of a crops inspection, the auditor observed the following:*

1. The inspector informed the operation the organic certificates of suppliers whose anniversary date had recently passed were "no longer valid" and reported this as an issue of concern in the exit interview. Organic certificates do not expire.

2. The inspector did not identify that erosion was evident throughout the operation.

Corrective Action: PAO implemented the following corrective actions:

1. PAO determined this was a translation issue and, in the future, will contract with a translator that has technical knowledge and a strong understanding of both English and Spanish.
2. PAO updated its crops organic system plan (OSP) template to include a section on Natural Resources and Biodiversity Conservation that includes questions about erosion. PAO conducted Annual Calibration Training on August 21, 2023 for inspectors and reviewers. PAO implemented the use of the updated OSP template on February 1, 2024.

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

NATIONAL ORGANIC PROGRAM: AUDIT & CORRECTIVE ACTION REPORT

GENERAL INFORMATION

- **Certifier Name** Primus Auditing Operations (PAO)
- **Physical Address** 1265 Furukawa Way, Santa Maria, California 93458, U.S.A.
- **Audit Type** Initial Audit
- **Auditor(s) & Audit Dates** Jessica Walden, Sherry Aultman, 06/15/2020 to 06/19/2020
- **Audit Identifier** NOP-32-20

CERTIFIER OVERVIEW

The National Organic Program (NOP) conducted an initial audit of Primus Auditing Operations' (PAO) certification activities during the period July 14, 2018 to June 19, 2020. The purpose of the audit was to verify PAO's conformance to the USDA organic regulations.

PAO is a for-profit corporation and was initially accredited on August 2, 2019. PAO's main office is in Santa Maria, California, with satellite offices in Mexico and Costa Rica. PAO is accredited to the following scopes: crops and handling. Prior to achieving their own accreditation, PAO conducted certification activities for Primus Labs Inc. (PL) under contract since 2015.

PAO certifies 415 operations under the crops (207) and handling (208) scopes. These operations are certified in Colombia, Costa Rica, Mexico, Ecuador, Guatemala, Peru and domestically in Arizona, California, Florida, Georgia, Illinois, Massachusetts, New Jersey, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, South Carolina, Texas, and Wisconsin. Certification services are performed by the five program directors, 12 inspection coordinators, one scheme manager, two quality managers, 22 inspectors, 12 reviewers and one external assessor.

NOP DETERMINATION:

NOP reviewed the audit results to determine whether PAO'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-1292-20 - Cleared
AIA-1293-20 - Cleared
AIA-1295-20 - Cleared
AIA-1296-20 - Cleared
AIA-1297-20 - Cleared
AIA-1298-20 - Cleared
AIA-1299-20 - Cleared
AIA-1300-20 - Cleared
AIA-1302-20 - Cleared
AIA-1303-20 - Cleared

AIA-1291-20 - Accepted. (NP6025PZA.NC9) 7 CFR §205.501(a)(21) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary."

Comments: *During file reviews, the auditor found an operation that was providing attestation statements for organic product shipped to Canada under the U.S.-Canada organic equivalency arrangement. However, PL staff told the auditors that no operations conduct international export or import activities. The PL OSP templates do not ask applicants to describe any international activities, nor do inspection report templates instruct the inspectors to verify international activity during inspections. Additionally, PL does not have procedures for inspectors or reviewers to verify that operations comply with the requirements of USDA NOP international arrangements.*

2016 Corrective Action: PL developed a procedure that requires an addendum be sent to all new or renewing clients; the addendum includes questions on international trade activities (import/export). The new procedure also requires the inspector to verify the answers on the addendum at the onsite inspection. For the U.S.-Canada equivalency arrangement, clients who comply with the requirements will have the attestation statement included on their organic certificate. In addition, clients will be given a self-attestation document to complete and issue with each shipment of product. PL also developed a work instruction describing compliant language for the attestation statement. PL verified that training for the certification staff members was conducted in July 2016 on the requirements for product traded under the U.S.-Canada Equivalency Arrangement.

2017 Verification of Corrective Actions: The auditor verified that the international trade activities addendum is utilized. The addendum does not cover all of the international arrangements and does not indicate other arrangements may apply. PL's checklist does not

require the inspector to verify any other arrangements except the US-Canada and the US-EU equivalency.

2017 Corrective Action: PL updated their Crop and Handling OSPs to include a section for operations to describe their international import and exporting activities. If operators are conducting import/export activities, then they are required to complete PL's International Markets OSP Addendum. PL updated the International Markets OSP Addendum to include all of the export agreements and inquire about imported products.

Inspectors are sent the operator's OSP, International Markets OSP Addendum, and a Review Report of the OSP with instructions from the reviewer to verify import/export activity. PL trained staff on the changes to the documents and the requirements of the NOP International Trade Agreements on October 14, 2017.

2018 Verification of Corrective Action: This corrective action is not completely implemented. (1) An updated Organic System Plan (OSP) template was implemented April 3, 2018. The OSP template instructs operators to indicate whether products and/or ingredients are imported or exported and instructs operators to complete an addendum describing trade activity details. The OSP addendum template was implemented June 13, 2018. (2) The inspection report template has not been updated with a section for inspectors to record verification of import and/or export activities. (3) No procedures or work instructions have been developed to guide certification personnel through the requirements of reviewing and verifying imported and exported products and/or ingredients.

2019 Corrective Action: PAO updated its crop and handling inspection checklists to include a section for inspectors to record verification of import and/or export activities and compliance with organic trade arrangements. PAO also created a work instruction "International Markets Addendum Information Guide" that instructs staff on what information should be covered in an OSP review in cases where operations are importing or exporting to equivalency countries.

2020 Verification of Corrective Action: The auditors verified that PAO implemented the use of the crop and handling inspection checklist and work instruction described in the 2019 corrective actions. However, the auditors' review of operation files with exported and imported products found that the international sections on the organic system plans (OSPs) and the inspection checklists are inconsistently completed by the operations and inspectors; therefore, there is no evidence that inspectors are verifying that operations comply with the requirements of USDA NOP international trade arrangements.

2022 Corrective Action: PAO held a training in July 2021 and August 2022 for inspectors and reviewers that addressed this topic. PAO reminded inspectors to verify that operations who import or export organic products have completed the international addendum. PAO submitted to the NOP attendance records and training materials for the trainings. PAO sent an email memo in July 2022 to inspectors and reviewers reminding inspectors to complete the ORG-058 International Equivalencies Checklist during inspections of operations that import and/or export organic products. This memo also reminded reviewers to verify that inspectors are completing this form and, if not, to notify the QA department. PAO submitted to the NOP a copy of the memo, and an example of a completed International Equivalencies Checklist, international addendum, and the documented review of an operation requesting to export organic products under an equivalency arrangement.

AIA-1294-20 - Accepted. (NOP-83-17.NC2) 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: *PAO inspectors are not consistently conducting or recording in-out balance and trace-back audits as a part of onsite inspections. During the witness audit of a crops operation, the inspector did not conduct an in-out balance or trace-back audit. Additionally, a review of previous inspection reports revealed no evidence that in-out balance and trace-back audits were conducted.*

2019 Corrective Action: PAO issued a notice to all inspectors and reviewers on March 1, 2019 clarifying the policy that in-out balance and traceability exercises should be conducted at all inspections. PAO developed a guidance for reviewers (Org-R008) to instruct them on how to verify that the exercises were conducted properly. PAO updated the mass-balance sections on inspection checklists to make the requirements clearer for inspectors. PAO also added sections to the crops and handling OSP templates that explain to the producer that all documentation must be kept and available for the inspector to complete successful mass-balance and traceability exercises. This will help ensure that operations are ready with the information that inspectors need and alleviate the time pressure for these activities during inspections.

2020 Verification of Corrective Action: The auditors reviewed the notice sent to inspectors on March 1, 2019, the guidance for reviewers (Org R008), and inspection report templates for both crops and handling operations. The documents provide accurate and clear guidance to inspectors and reviewers. However, the auditors' review of certification files found that inspectors are inconsistently and inaccurately completing mass balance and traceback exercises.

2022 Corrective Action: PAO held a training in July 2021 and August 2022 for inspectors and reviewers that addressed how to complete traceback and mass balance exercises at inspection. Additionally, PAO reminded reviewers to verify that these sections of the inspection report are completed. PAO developed, and submitted to the NOP, the Org-056 R0 Mass Balance and Traceability Form, which is a guide to carrying out these exercises during inspections. PAO submitted to the NOP the attendance records and training material for the 2021 and 2022 trainings.

AIA-1301-20 - Accepted. (NOP-83-17.NC9) 7 C.F.R. §205.402(b)(2) states, "The certifying agent shall within a reasonable time: Provide the applicant with a copy of the on-site inspection report, as approved by the certifying agent, for any on-site inspection performed."

Comments: *In the case of the unannounced inspection where the operator refused to complete the full inspection, PAO did not issue an unannounced inspection report to the operation.*

2019 Corrective Action: PAO conducted a staff training on March 7, 2019 on audit reports and unannounced inspections. The training instructed staff that an inspection report must always be provided to the operation regardless of whether the inspector was able to do a complete inspection. PAO also develop a template for letters that will be issued to operations following unannounced inspections with the inspection report as an attachment.

2020 Verification of Corrective Action: The auditors reviewed unannounced inspection files and found that PAO did not provide two operations with copies of the inspection reports.

2022 Corrective Action: PAO developed a Master Tracking Log, which verifies that inspection reports are provided to operations following all unannounced inspections. PAO submitted to the NOP a screenshot of the Master Tracking Log, which logs the inspected operation and verification that the inspection report and Org-T025 Unannounced Certification Resolution Letter has been sent to the operation. On December 1, 2022, PAO conducted a training for QA staff as a refresher on the Master Tracking Log. The training included a

reminder that an unannounced inspection report is to accompany Org-T025. PAO provided the NOP with the training attendance sheet.

Noncompliances Identified during the Current Assessment

AIA-1822-20 - Accepted. 7 C.F.R. §205.670(c) states, "A certifying agent must conduct periodic residue testing of agricultural products to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))." Samples may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples. Such tests must be conducted by the certifying agent atthe certifying agent's own expense."

Comments: *PAO does not fully carry out the procedures of **NOP 2613 Instruction Responding to Results from Pesticide Residue Testing**. The auditors' review of pesticide residue analysis reports and a combined notice of noncompliance and denial of certification identified the following:*

1. *PAO did not send a notification of the residue test results and indication that the product may be sold as organic since no prohibited pesticide residues were detected.*
2. *PAO did not follow the appropriate instructions for determining EPA tolerances for pesticide residue samples. In one case, PAO used a positive soil sample as the evidence for issuing a notice of denial on the grounds that the crop exceeded the EPA tolerance. In another case, a foliage sample instead of the edible product was tested revealing the presence of a permitted pest control material. PAO mistakenly determined that the edible portion of the crop exceeded the EPA tolerance.*

Corrective Action: PAO submitted to the NOP a "Review Report" checklist that reviewers use when evaluating pesticide residue results. The form addresses the specific questions related to the requirements of NOP 2613, including clarifying that EPA tolerances apply to the edible portion of a crop or product, not to soil or other plant material. PAO also created and submitted to the NOP a letter template that staff use to communicate the residue test results to operations. The letter template includes specific instructions to certification staff who amend the letter according to the type of sample and result. The letter template addresses the requirements of NOP 2613, including when to notify the operation that they may sell their product as organic. PAO management reviews the final letter to ensure it is accurate prior to sending it to the operation. On December 1, 2022, PAO conducted a training for QA staff, which included a segment on NOP 2613. PAO provided the NOP with the training attendance sheet. PAO will send a memo detailing the updates and implementation of the updated section within the "Review Report" document to all technical reviewers and inspectors by December 15, 2022.

AIA-1823-20 - 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: *PAO does not consistently demonstrate the ability to fully comply with the requirements of accreditation. Specifically, PAO is not consistently executing certification processes in a timely manner. The auditors' review of files and interviews with certification staff found the following issues:*

1. *During an unannounced inspection, the inspector found that the certified operation was no longer operating out of the premises listed on the certificate and had gone bankrupt. Five months later, PAO issued a notice of noncompliance to the company for failing to renew their organic certification.*

2. *PAO issued a notice of suspension more than two months after the proposed effective date of suspension identified in the notice of proposed suspension.*
3. *PAO issued a combined notice of noncompliance and proposed suspension to an operation five months after the inspection revealed noncompliant practices.*
4. *PAO issued two operators notices of noncompliance more than six months after the operations failed to submit an annual update and pay certification fees.*

Corrective Action: PAO implemented the use of an electronic program that logs each inspection, review, notification, and tracks them in the system via a due date. The electronic program sends alerts to PAO staff when deadlines are surpassed, triggering action by PAO to follow up with. PAO trained staff on the use of this program on April 22, 2022. PAO submitted to the NOP a detailed description of how the electronic system works as well as a copy of the training log.

AIA-1830-20 - Accepted. 7 C.F.R. §205.403(a)(1) states, "A certifying agent must conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested. An on-site inspection shall be conducted annually thereafter for each certified operation that produces or handles organic products for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue."

Comments: *PAO did not conduct annual on-site inspections of all its certified operations in 2018 and 2019. The auditors identified two operations that did not receive annual inspections. PAO stated this was because they either failed to timely submit an annual update or were involved in a complaint investigation.*

Corrective Action: PAO implemented a new process and the use of an electronic tracking system. PAO sends out an anniversary reminder email to operations one month before their anniversary date. At the beginning of each month, QA staff receive a list of operations that failed to meet their annual update deadline. QA staff then generate and issue notices of noncompliance and track the notification process using the implemented electronic system. Additionally, PAO's corrective action response clarified that the operation involved in the complaint investigation would not schedule an annual inspection. In response, PAO carried out an unannounced inspection instead of issuing the operation a notice of noncompliance. PAO's new tracking system also alerts staff when inspections have not been scheduled by the deadline. QA staff generate notices of noncompliance if the operation does not allow for the timely scheduling of an inspection. If the operation does not sufficiently respond to the notice of noncompliance, PAO begins the adverse action process. PAO provided screenshots of the electronic tracking system to the NOP.

AIA-1831-20 - 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: *PAO's Quality Manual and templates do not demonstrate that PAO has the ability to fully comply with the requirements of the adverse action process in the following manner:*

1. *The Quality Manual, Section D Notice of proposed suspension/revocation incorrectly states, "Once Audit Admin receives client's reply to the NoPS, then Audit Admin will forward the complete file with corrective actions to the reviewer for approval." Corrective Actions cannot resolve a Notice of Proposed Suspension according to §205.662(c).*
2. *The Notice of Proposed Suspension and Combined Notice of Noncompliance and Proposed Suspension templates incorrectly state, "Finally, please be advised that you may also at any*

time surrender your certification according to §205.404(c) by written notification to Primus Auditing Ops. Note that if you surrender your certification and apply to another certification agency, you will be required to provide this Notice of Noncompliance and Notice of Proposed Suspension and a description of the actions taken to correct the non-compliance(s) with your application as described in §205.401(c).”An operation’s surrender does not resolve a Notice of Proposed Suspension and the adverse action process continues as stated in 205.662(e)(1).

Corrective Action: PAO submitted to the NOP screenshots of the updated Quality Manual, section D, “Notice of Proposed Suspension or Revocation §205.662(c)(d)” that reflects PAO’s adverse action process and the requirements of the USDA organic regulations. PAO also submitted an updated notice of proposed suspension and combined notice of noncompliance and proposed suspension template that now reflect the requirements of the USDA organic regulations. On December 1, 2022, PAO conducted a training for QA staff, which included a segment on quality manual and template updates. PAO provided the NOP with the training attendance sheet.

AIA-1832-20 - Accepted. 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: *PAO’s organic certificates are missing elements identified in **NOP 2603 Organic Certificates**. The auditors’ review of certification files found that certificates do not specify the certifier’s address. In addition, certificates do not display the statement, “Certified to the USDA organic regulations, 7 CFR Part 205.”*

Corrective Action: PAO updated its organic certificate template to include the previously missing elements identified in NOP 2603. PAO submitted to the NOP the updated template and examples of two compliant organic certificates issued in May 2022 as evidence that issued certificates include PAO’s address and the correct statement. To ensure there is no reoccurrence of this issue, PAO is now using an electronic system that generates the accurate template. PAO eliminated all previous templates, so they are no longer available for use.

AIA-1833-20 - Accepted. 7 C.F.R. §205.642 states, “Fees charged by a certifying agent must be reasonable, and a certifying agent shall charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator. The certifying agent shall provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification. The certifying agent may set the nonrefundable portion of certification fees; however, the nonrefundable fees must be explained in the fee schedule submitted to the Administrator. The fee schedule must explain what fee amounts are nonrefundable and at what stage during the certification process fees become nonrefundable. The certifying agent shall provide all persons inquiring about the application process with a copy of its fee schedule.”

Comments: *PAO does not provide certification applicants its fee schedule. The auditors’ interview with staff responsible for communicating with new applicants and a review of associated email communications confirmed that PAO’s fee schedule is only provided to applicants upon request.*

Corrective Action: PAO created an instructional document for new and renewing operations

that includes a hyperlink to the most current fee schedule. PAO submitted to the NOP a copy of the instructional document and an email from PAO to a new applicant that included the instructional document containing a hyperlink to the fee schedule.

AIA-1834-20 - 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: *PAO's annual program review (APR) does not fully comply with* ***NOP 2025 Instruction Internal Program Review*** *or the USDA organic regulations. The auditors' review of PAO's 2019 APR found the following issues:*

1. *The APR was conducted by someone directly involved in the following certification activities: drafting Notices of Noncompliance, Notices of Proposed Suspensions, and Settlement Agreements. This does not comply with NOP 2025, which states that the review is to be conducted by personnel different from those who perform certification activities.*
2. *The APR was not a review of PAO's certification activities. The review focused only on accepted corrective actions for prior noncompliances.*

Corrective Action: PAO created a job description for the APR reviewer position that it uses to determine whether a particular person meets the NOP Requirements for conducting an APR. The job description specifies that the person completing the APR must not be directly involved in certification decisions and that their responsibilities include conducting an APR that complies with all requirements of NOP 2025. Moving forward, PAO's APR will follow the NOP 2005 checklist and include all PAO's certification activities. PAO submitted to the NOP the new job description and the designated annual program reviewer's resume.

AIA-1835-20 - Accepted. 7 C.F.R. §205.663 states, "Any dispute with respect to denial of certification or proposed suspension or revocation of certification under this part may be mediated at the request of the applicant for certification or certified operation and with acceptance by the certifying agent... 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 anyagreement or provision not in conformance with the Act or the regulations in this part."

Comments: *PAO's settlement agreements do not comply with the requirements of the USDA organic regulations. The auditors' review of settlement agreements established by PAO found the following:*

1. *The terms of the settlement agreements do not always include actions the operation must take in order to correct the noncompliance that led to the Notice of Proposed Suspension. The terms for operations who failed to submit timely annual updates do not address the root cause of the noncompliance.*
2. *The settlement agreements include non-finite terms that require ongoing compliance with a USDA organic regulation. PAO settlement agreements do not indicate deadlines allowing for PAO to verify settlement agreement terms for adequate implementation and closure.*

Corrective Action: PAO submitted an updated Settlement Agreement template that instructs certification staff to state terms that include actions the operator must take to correct the

noncompliance that led to the notice of proposed suspension, terms for operations to address the root cause of the noncompliance, and terms that indicate specified timeframes. On December 1, 2022, PAO conducted a training for QA staff, which included the updates made to the Settlement Agreement template. PAO provided the NOP with the training attendance sheet.

USDA Agricultural Marketing Service

1400 Independence Avenue, SW.
Room 2642-S, STOP 0268
Washington, DC 20250-0201

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

National Organic Program (NOP) auditors conducted a pre-decisional on-site assessment of the Primus Auditing Ops (PAO) organic program on July 8 - 14, 2018. The National Organic Program (NOP) reviewed the auditor's report to assess PAO's compliance to the USDA organic regulations. This report provides the results of NOP's assessment.

GENERAL INFORMATION

Applicant Name	JS Auditing Group Inc. d.b.a. Primus Auditing Ops (PAO)
Physical Address	1259 Furukawa Way, Santa Maria, CA 93458
Mailing Address	1259 Furukawa Way, Santa Maria, CA 93458
Contact & Title	Josie Quevedo, NOP Scheme Manager
E-mail Address	JQuevedo@pao-usa.com
Phone Number	501-312-2962
Reviewer(s) & Auditor(s)	Bridget McElroy, NOP Reviewer; Jason Lopez, Lars Crail, On-site Auditors.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP assessment review: October 3, 2018 Onsite audit: July 8 – 14, 2018
Audit Identifier	NOP 83-17
Action Required	Yes
Audit & Review Type	Pre-Decisional Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of PAO's certification
Audit & Determination Criteria	*7 CFR Part 205, National Organic Program as amended*.
Audit & Review Scope	PAO's implementation of USDA NOP certification services.

JS Auditing Group Inc. d.b.a. Primus Auditing Ops (PAO) is a for-profit corporation applying for accreditation to the USDA National Organic Program (NOP) for the scopes of crops and handling. PAO has conducted certification activities for Primus Labs Inc. (PL) under contract since 2015.

The PAO NOP certification program provides certification services to 304 operations under the crops (150) and handler (154) scopes. These operations are certified in Colombia, Costa Rica, Mexico, and domestically in Arizona, California, Florida, Georgia, Illinois, Massachusetts, Missouri, New Jersey, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Texas, and Wisconsin.

PAO's main office is located in Santa Maria, California with satellite offices in Mexico and Costa Rica. Certification services are performed by the 5 program directors, 12 inspection coordinators, 1 scheme manager, 2 quality managers, 20 inspectors, 12 reviewers and an external assessor.

As part of the pre-decisional assessment NOP auditors conducted two witness audits, observing an annual inspection of a crops operation and an initial inspection of a handling operation.

NOP DETERMINATION

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

Noncompliances from Prior Assessments

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

NP6025PZA.NC14 – Cleared.
NP7128JZA.NC1 – Cleared.
NP7128JZA.NC3 – Cleared.
NP7128JZA.NC4 – Cleared.
AIA7264RC.NC1 – Cleared.
AP-54-18.NC1 – Cleared.
NOP-69-17.NC1 – Cleared.
NOP-69-17.NC2 – Cleared.
NOP-69-17.NC3 – Cleared.
NOP-69-17.NC4 – Cleared.

NP6025PZA.NC9 – Accepted. – 7 CFR §205.501(a)(21) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary."

Comments: *During file reviews, the auditor found an operation that was providing attestation statements for organic product shipped to Canada under the U.S.-Canada organic equivalency arrangement. However, PL staff told the auditors that no operations conduct international export or import activities. The PL OSP templates do not ask applicants to describe any international activities, nor do inspection report templates instruct the inspectors to verify international activity during inspections. Additionally, PL does not have procedures for*

inspectors or reviewers to verify that operations comply with the requirements of USDA NOP international arrangements.

2016 Corrective Action: PL developed a procedure that requires an addendum be sent to all new or renewing clients; the addendum includes questions on international trade activities (import/export). The new procedure also requires the inspector to verify the answers on the addendum at the onsite inspection. For the U.S.-Canada equivalency arrangement, clients who comply with the requirements will have the attestation statement included on their organic certificate. In addition, clients will be given a self-attestation document to complete and issue with each shipment of product. PL also developed a work instruction describing compliant language for the attestation statement. PL verified that training for the certification staff members was conducted in July 2016 on the requirements for product traded under the U.S.-Canada Equivalency Arrangement.

2017 Verification of Corrective Actions: The auditor verified that the international trade activities addendum is utilized. The addendum does not cover all of the international arrangements and does not indicate other arrangements may apply. PL's checklist does not require the inspector to verify any other arrangements except the US-Canada and the US-EU equivalency.

2017 Corrective Action: PL updated their Crop and Handling OSPs to include a section for operations to describe their international import and exporting activities. If operators are conducting import/export activities, then they are required to complete PL's International Markets OSP Addendum. PL updated the International Markets OSP Addendum to include all of the export agreements and inquire about imported products. Inspectors are sent the operator's OSP, International Markets OSP Addendum, and a Review Report of the OSP with instructions from the reviewer to verify import/export activity. PL trained staff on the changes to the documents and the requirements of the NOP International Trade Agreements on October 14, 2017.

Verification of Corrective Action: This corrective action is not completely implemented. (1) An updated Organic System Plan (OSP) template was implemented April 3, 2018. The OSP template instructs operators to indicate whether products and/or ingredients are imported or exported and instructs operators to complete an addendum describing trade activity details. The OSP addendum template was implemented June 13, 2018. (2) The inspection report template has not been updated with a section for inspectors to record verification of import and/or export activities. (3) No procedures or work instructions have been developed to guide certification personnel through the requirements of reviewing and verifying imported and exported products and/or ingredients.

2019 Corrective Action: PAO updated its crop and handling inspection checklists to include a section for inspectors to record verification of import and/or export activities and compliance with organic trade arrangements. PAO also created a work instruction "International Markets Addendum Information Guide" that instructs staff on what information should be covered in an OSP review in cases where operations are importing or exporting to equivalency countries.

NP7128JZA.NC2 – Accepted. 7 C.F.R. §205.670(d) states, "A certifying agent must, on an annual basis, sample and test from a minimum of five percent of the operations it certifies, rounded to the nearest whole number…"

Comments: *PL did not sample and test from a minimum of 5% of total 2016 certified operations.*

2017 Corrective Action: PL developed an unannounced sampling procedure (SOP 22-27) stating that PL must sample from 5% of their certified operations annually. PL conducted a training with the staff responsible for scheduling the sample testing inspections on May 2, 2017. PL also set up bi weekly check-ins with Quality Assurance (QA), to ensure the sampling inspections are on schedule for the year. PL submitted the training log and evidence that bi-weekly meetings are on QA's calendar.

Verification of Corrective Action: PAO has not effectively implemented the corrective action. PAO did not conduct residue sampling and testing of at least 5% of the total amount of certified operations during 2017.

2019 Corrective Action: PAO identified further improvements were necessary for its residue testing tracking system in each country to ensure that the sampling requirement was fulfilled. Previously, QA in the U.S. was responsible for contacting each country's coordinators to ensure that samples were scheduled. At times, communication was difficult or delayed, particularly when scheduled samples could not be done and alternatives had to be found. Beginning in 2019, each country's manager is required to report directly to QA on the status during monthly meetings. PAO's annual sampling list will also now include alternate operations that managers can use in cases where planned sampling can't take place. PAO conducted sampling of at least 5% of certified operations in 2018 and is on track to meet this requirement in 2019.

Noncompliances Identified during the Current Assessment

NOP-83-17.NC1 – 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: *PAO's OSP templates do not require enough information about the operation for the reviewer or inspector to assess and verify compliance with the act and regulations. The OSP does not allow or prompt the operation to describe its activities (i.e. all organic or mixed operation). Additionally, the use of site-specific OSPs has led to operations limiting their activity descriptions to only the specific site and excluding information about parallel/split production activities causing the OSP to be misleading.*

Corrective Action: PAO submitted updated crops and handling OSP templates that now include sections where applicants are required indicate whether they are involved in nonorganic production and to describe any nonorganic production activities and sites.

NOP-83-17.NC2 – 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: *PAO inspectors are not consistently conducting or recording in-out balance and trace-back audits as a part of onsite inspections. During the witness audit of a crops operation, the inspector did not conduct an in-out balance or trace-back audit. Additionally, a review of previous inspection reports revealed no evidence that in-out balance and trace-back audits were conducted.*

Corrective Action: PAO issued a notice to all inspectors and reviewers on March 1, 2019 clarifying the policy that in-out balance and traceability exercises should be conducted at all inspections. PAO developed a guidance for reviewers (Org-R008) to instruct them on how to verify that the exercises were conducted properly. PAO updated the mass-balance sections on inspection checklists to make the requirements clearer for inspectors. PAO also added sections to the crops and handling OSP templates that explain to the producer that all documentation must be kept and available for the inspector to complete successful mass-balance and traceability exercises. This will help ensure that operations are ready with the information that inspectors need and alleviate the time pressure for these activities during inspections.

NOP-83-17.NC3 – Accepted. – 7 C.F.R. §205.406(a)(1) states, "To continue certification, a certified operation must annually pay the certification fees and submit the following information, as applicable, to the certifying agent: An updated organic production or handling system plan …"

Comments*: The auditor found annual update OSPs to be incomplete and inaccurate. Missing and inaccurate information was found in the following OSP sections: equipment lists, material input lists and annotations, disclosure of parallel production, undisclosed sites, pest control inputs, seed verification records, and procedures for the prevention of comingling.*

Corrective Action: Previously, reviewers did not have adequate guidance to ensure that OSP reviews were being done in a thorough manner. PAO developed and submitted a guidance for reviewers (Org-R008) to use during OSP reviews. The guidance covers every section of the OSP and provides examples of the types of information that PAO expects operators to provide in each section.

NOP-83-17.NC4 – 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: *The PAO annual program review was conducted by an individual whose documented qualifications on file were insufficient to demonstrate adequate knowledge and expertise of the USDA organic regulations and NOP Policy. The individual's qualifications noted in the annual review were ISO based certifications. The reviewer was not available for interview at the time of the audit to determine any additional qualifications.*

Corrective Action: PAO created and submitted a job description for the person who conducts the certifier's internal audit to ensure that they have the proper qualifications. The job description requires that the auditor have a minimum of two years working in organic agriculture and be familiar with and demonstrate updated training on the USDA organic regulations. The job description was implemented for PAO's 2019 internal audit and the auditor's qualifications were documented.

NOP-83-17.NC5 – 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.

Comments: *The auditor found that PAO's grower group certification procedures do not comply with NOP Policy Memo 11-10 in the following ways:*

- *PAO does not require or request Grower Group Internal Control System (ICS) documents as part of the OSP for review.*
- *PAO does not implement consistent procedures for determining the external inspection sample size for grower groups and documenting the protocol used. For example, PAO does not determine an overall group risk factor to apply in calculating external inspection sample size, though this is stipulated in PAO's work instruction. Additionally, PAO's inspection reports do not document the reason why operations were selected for external inspection (i.e. high risk, random, new member), resulting in protocol that is not transparent.*

Corrective Action: PAO submitted a revised Review Report template (Org-008) which includes a question on grower groups so that the reviewer is reminded to request ICS documentation when reviewing a grower group OSP. PAO also updated its grower group addendum for inspections reports to include: 1) an example for inspectors on how to calculate the number of subunits that need to be inspected; 2) a definition for inspectors of "high risk operations" as growers who have been issued non-compliances, growers identified in complaints to the ICS, and new entrants; 3) a section where inspectors mush document the name of each subunit selected for inspection and the reason for selection.

NOP-83-17.NC6 – Accepted. – 7 C.F.R. §205.501(a)(21) states, "Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary." NOP 2603, Organic Certificates, Section 3.4, states, "Certifying agents should issue a new organic certificate each year."

Comments: *PAO did not issue an organic certificate to an operation in 2017.*

Corrective Action: PAO's protocol for issuing certificates did not take into account situations where the renewal process takes longer than one year. PAO submitted a new work instruction (Org-WI-028) on Annual Organic Certificates. As described in the instruction, each October, PAO's QA will do a full review of all certified operations to verify that all have been issued a certificate for the year. In cases where operations have not received a certificate and the annual update process is still underway, QA will instruct CR Support to issue an updated certificate and

will follow up with the flagged operations to ensure they complete the annual update process or surrender their certification.

NOP-83-17.NC7 – Accepted. – 7 C.F.R. §205.663 states, "Any dispute with respect to denial of certification or proposed suspension or revocation of certification under this part may be mediated at the request of the applicant for certification or certified operation and with acceptance by the certifying agent. … If the certifying agent rejects the request for mediation, the certifying agent shall provide written notification. … 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. …The parties to the mediation shall have no more than 30 days to reach an agreement following a mediation session. …"

Comments: *PAO did not respond to an operation's January 2018 written mediation request.*

Corrective Action: PAO QA personnel had never received formal training on the mediation process. QA personnel and the NOP scheme manager received training on September 26, 2018 which covered all aspects of adverse actions and mediation, including timeframes and regulatory requirements. PAO also created a Mediation Approval/Denial template and a Mediation Settlement Agreement template to ensure the proper process is followed. PAO submitted documentation with its corrective action showing an example of a compliant mediation and settlement process with a client after staff training and new templates were developed.

NOP-83-17.NC8 – Accepted. – 7 C.F.R. §205.501(a)(21) states, "A private or governmental entity accredited as a certifying agent under this subpart must:…Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary." NOP 2601 The Organic Certification Process Section 3.4 states, "Once the inspector finishes the inspection report, he or she sends the report to the certifier for review."

Comments: *In the case of the unannounced inspection where the operator refused to complete the full inspection, the inspector did not submit an inspection report. Instead, the inspector submitted a statement of the events which described how the inspection was terminated before it was complete.*

Corrective Action: PAO updated its unannounced inspection work instruction to include a section on what inspectors should do in cases where the operation does not allow the inspection, the operator is not onsite at the time of inspection, or there are other inspection challenges. The updated work instruction states that in these cases, inspectors must complete an inspection report describing the events that took place even when an inspection is not possible. PAO issued a notice to all inspectors on March 15, 2019 clarifying this requirement.

NOP-83-17.NC9 – Accepted. – 7 C.F.R. §205.402(b)(2) states, "The certifying agent shall within a reasonable time: Provide the applicant with a copy of the on-site inspection report, as approved by the certifying agent, for any on-site inspection performed."

Comments: *In the case of the unannounced inspection where the operator refused to complete the full inspection, PAO did not issue an unannounced inspection report to the operation.*

Corrective Action: PAO conducted a staff training on March 7, 2019 on audit reports and unannounced inspections. The training instructed staff that an inspection report must always be provided to the operation regardless of whether the inspector was able to do a complete

inspection. PAO also develop a template for letters that will be issued to operations following unannounced inspections with the inspection report as an attachment.

NOP-83-17.NC10 – Accepted. – 7 C.F.R. §205.504(b)(1) states, "A private or governmental entity seeking accreditation as a certifying agent must submit the following documents and information to demonstrate its expertise in organic production or handling techniques; its ability to fully comply with and implement the organic certification program established in §§205.100 and 205.101, §§205.201 through 205.203, §§205.300 through 205.303, §§205.400 through 205.406, and §§205.661 and 205.662; and its ability to comply with the requirements for accreditation set forth in §205.501: …A copy of the procedures to be used to evaluate certification applicants, make certification decisions, and issue certification certificates."

Comments: *There are no written work instructions or procedures established for reviewing inputs and retaining supporting records of material decision outcomes. The auditor reviewed several inputs that were approved and/or denied, but records were not consistently maintained to support these decisions.*

Corrective Action: PAO submitted a new work instruction for reviewers to use when reviewing inputs for crops and handling. Reviewers were made aware of this new resource via a notice sent to them on March 15, 2019. To ensure documentation of outcomes, PAO updated its review report with a table where reviewers are to document the name of the input reviewed, whether it has already been approved by a recognized MRO, restrictions, additional review observations and the final review determination.

NOP-83-17.NC11 – 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: *Inspectors are inconsistently verifying whether the list of allowed inputs in the Organic System Plan (OSP) includes any inputs with applicable restrictions (annotations) for their use. The auditor identified several OSP input tables that were missing a description of the applicable input restrictions.*

Corrective Action: PAO updated its review report with a table where reviewers are to document the name of the input reviewed, whether it has already been approved by a recognized MRO, restrictions, additional review observations and the final review determination. PAO also revised its inspection checklists to include a question for inspectors to verify compliance with the listed annotations (in the review report) for each input used.