



United States Department of Agriculture

Agricultural Marketing Service
National Organic Program

BIO LATINA S.A.C.

**Jr de La Rocca de Vergallo N° 493, Magdalena del Mar 15076, Smart Oficinas
Boutique, Oficina 1811, Lima, Lima, 17, PERU**

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>

Certificate No: **USDA-86-23**
Effective Date: **04/29/2022**
Expiration Date: **04/29/2027**
Issue Date: **06/02/2023**

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

The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, age, disability, and where applicable, sex, marital status, familial status, parental status, religion, sexual orientation, genetic information, political beliefs, reprisal, or because all or part of an individual's income is derived from any public assistance program.

CERTIFICATE OF ACCREDITATION



NATIONAL ORGANIC PROGRAM: AUDIT & CORRECTIVE ACTION REPORT

GENERAL INFORMATION

- **Certifier Name** Bio Latina S.A.C., (BIOL)
- **Physical Address** Jr de La Rocca de Vergallo N° 493, Lima, Lima 17, PERU
- **Audit Type** Renewal Audit
- **Auditors & Audit Dates** Colleen O'Brien, Alison Howard, 08/23/2021 to 08/27/2021
- **Audit Identifier** NOP-37-21

CERTIFIER OVERVIEW

A renewal audit was conducted for the Bio Latina S.A.C. (BIOL) organic program. The National Organic Program (NOP) assessed the certifier's conformance to the USDA organic regulations during the period of November 27, 2019 through August 22, 2021.

BIOL is a for-profit organization providing certification services in Latin America. BIOL has been accredited since April 29, 2002 for the accreditation categories of crops and handling. BIOL currently maintains a main office in Lima, Peru, and satellite offices in Bolivia, Honduras, and Nicaragua. BIOL conducts certification activities in Peru, Bolivia, Colombia, Nicaragua, Honduras, Panama, El Salvador, and Guatemala.

As of the renewal audit date, BIOL had 137 certified clients, including 89 crops and 135 handling operations. BIOL certifies 82 grower group operations. BIOL has 30 full time employees in various countries of operation. Employees hold several titles that may include General Manager, Quality Manager, Deputy Quality Manager, Certification Manager, Certifier, Inspector, Administrative Assistant, and Representative.

NOP DETERMINATION:

NOP reviewed the audit results to determine whether BIOL'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-3339-20 – Cleared.

AIA-5957-21 – Cleared.

AIA-5956-21 - Accepted. (NOP-57-18.NC1) 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: *BIOL is cancelling certification contracts with operators when operations do not respond to annual update requests. Certification activities are terminated by BIOL without suspension, revocation or the operation surrendering its certification. This does not comply with the requirements of 7 C.F.R. §205.404(c).*

Corrective Action: BIOL submitted a revised procedure for suspension of a NOP certificate that complies with the USDA organic regulations. It no longer states, “if an operation does not renew the certification on the anniversary date, it is mandatory to suspend or revoke its certification as of the date of the certification contract.” BIOL provided training to their certification staff on July 2, 2020.

Verification of Corrective Action: The auditors reviewed certification files and interviewed staff and verified this corrective action has not been effectively implemented. BIOL staff and certification files demonstrated that when a certified operation fails to submit their annual update or pay annual fees, BIOL maintains their certification until over a year after their anniversary date, at which point BIOL changes their status to "surrendered." BIOL does not consistently follow the noncompliance procedures, or the requirements of NOP 2601 Instruction: The Organic Certification Process, section 3.7, which states, "If the operation fails to submit its annual update and/or fees, the certifier issues a Notice of Noncompliance."

2022 Corrective Action: BIOL adopted a new management tool for tracking the progress of each operation throughout the certification cycle. This platform sends automated messages to clients and relevant BIOL staff at designated intervals prior to an operation’s anniversary date. If the operation does not submit their annual update on time, the system reminds the assigned reviewer to issue a notice of noncompliance. If the operation does not respond within 30 days, the system sends a reminder to the Certification Manager to issue a proposed adverse action notice. BIOL developed a new work instruction, ‘Platform Management Guide,’ that explains how to use the platform. BIOL notified staff of the new platform and work instruction via a memo sent out July 29, 2022. BIOL provided additional staff training on February 10, 2023 and submitted the training slides to the NOP.

Noncompliances Identified during the Current Assessment

AIA-7284-21 - Accepted. 7 C.F.R. §205.501(a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670;”

Comments: *BIOL does not fully carry out the provisions of §205.201 in the following manner:*

- 1. BIOL does not ensure that Organic System Plans (OSPs) describe practices and procedures to comply with international equivalency arrangements.*
- 2. BIOL does not ensure that OSPs describe how an operation meets the requirements of §205.200 and NOP 5020 Guidance Natural Resources and Biodiversity. OSP forms provide space for producers to describe their practices only related to soil conservation and water use but do not address all aspects of natural resources as defined by 205.2.*

Corrective Action: BIOL updated its Organic System Plan forms for production (AB4-AAA_050822 v10) and handling (AB4-BBB_050822 v9) to prompt the operation to describe their compliance with the requirements of the US-Canada Organic Equivalence Arrangement (USCOEA). Additionally, BIOL updated section 5 of its production Organic System Plan to include questions related to natural resources and biodiversity. In August of 2022, BIOL began using the new forms, and all clients will be using the new forms by August of 2023. BIOL intends to incorporate guidance from both the NOP Handbook and the Organic Integrity Learning Center into future BIOL training sessions. BIOL has taken steps to ensure that the Quality Management team receives updates from the NOP so that any new guidance or directives are taken into consideration and incorporated into training and changes to controlled documents or procedures. BIOL sent a training memo describing these changes to certification personnel on August 3, 2022.

AIA-7285-21 - Accepted. 7 C.F.R. §205.670(g) states, “If test results indicate a specific agricultural product contains pesticide residues or environmental contaminants that exceed the Food and Drug Administration's or the Environmental Protection Agency's regulatory tolerances, the certifying agent must promptly report such data to the Federal health agency whose regulatory tolerance or action level has been exceeded. Test results that exceed federal regulatory tolerances must also be reported to the appropriate State health agency or foreign equivalent.”

Comments: *BIOL does not fully carry out the requirements of §205.670(g) and procedures outlined in NOP 2613 Instruction Responding to Results from Pesticide Residue Testing. The auditor's review of pesticide residue analysis files found BIOL does not always inform operations that their product may be sold as organic when residues are not detected, or does not immediately notify operations that their product may not be sold as organic when the residues exceed 5% of the EPA tolerance for that product. In addition, BIOL does not report the violation to the appropriate authority if testing determines regulatory tolerance or action levels have been exceeded.*

Corrective Action: BIOL updated their ‘Guide for Taking, Preservation, and Shipment of Samples’ (GMP-INT-MUE_300722 v8). Section 7 was added to cover all requirements outlined in NOP 2613. BIOL created a new instruction document, ‘Communication Templates’ (TEM_300722 v1) to provide reviewers with standard language when responding to results from pesticide residue tests. When laboratory results are received by BIOL, an automated message is sent to the responsible reviewer to remind them to notify the operation about the results. BIOL trained staff on this change on August 22, 2022, and also outlined the details in an email to staff on August 31, 2022 and via a newsletter announcement to staff. The email and newsletter were submitted to the NOP.

AIA-7286-21 - Accepted. 7 C.F.R. §205.501(a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670;”

Comments: *BIOL does not carry out the provisions of the Act and regulations. BIOL incorrectly issued NOP noncompliances for concerns that were outside the purview of the USDA organic regulations, such as cases in which personnel in a processing facility did not use proper sanitary protection, and where electrical cords were observed near standing water. BIOL incorrectly noted these issues to be violations of §205.406.*

Corrective Action: BIOL developed two courses for their review staff on writing noncompliances and appropriately addressing regulatory requirements. BIOL required all staff to take these courses and submitted the training records to the NOP. Additionally, BIOL sent a memo to all certification staff on August 10, 2022 to inform them of the issues identified in this noncompliance and remind them of the importance of connecting issues identified during inspection with applicable regulatory

requirements. To monitor the efficacy of their corrective action, BIOL updated the performance evaluation forms for reviewers and inspectors (LA10_300722 v5 and LA11_300722 v3) to evaluate the accuracy of the findings pursuant to regulatory requirements.

AIA-7288-21 – Accepted. 7 C.F.R. §205.662(c) states, “Proposed suspension or revocation. When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance. When correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation of certification may be combined in one notification.”

Comments: *BIOL does not consistently follow the noncompliance procedures as required in §205.662(c). The auditor’s review of certification files found the following:*

- 1. BIOL does not combine the notification of noncompliance and the proposed suspension or revocation of certification into one notification when correction of a noncompliance is not possible.*
- 2. BIOL issued a notification of noncompliance and a notification of proposed suspension on the same date, to the same operation, for the same issue of concern. These notifications contained conflicting instructions.*
- 3. BIOL issues a combined notice of noncompliance and proposed suspension for correctable violations. BIOL classifies multiple noncompliances as not correctable; however, the violations are correctable because they do not indicate a systemic failure in the operation’s system.*

Corrective Action: BIOL developed two new adverse action forms, ‘Combined notice of Noncompliance and Proposed Suspension or Revocation’ (ME7_300722 v1) and ‘Combined notice of non-compliance and denial of certification’ (ME8_300722 v1). BIOL developed an online self-paced course for technical staff on when to issue combined notices. BIOL submitted training results and training content to NOP along with the new forms. BIOL updated their ‘Procedures Manual’ (GMP_100822 v47); section 3.7 describes the conditions under which combined notifications may be issued. To monitor the efficacy of their corrective action, BIOL updated the performance evaluation forms for reviewers (LA10_300722 v5) to evaluate correct application of noncompliance levels and notifications.

AIA-7394-21 - Accepted. 7 C.F.R. §205.501(a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670;”

Comments: *BIOL does not consistently carry out the provisions of the Act and the regulations by verifying compliance with the labeling requirements described in Subpart D of the USDA organic regulations. The auditors reviewed certification files and found the following issues with labels on packaged agricultural products:*

- 1. Each ingredient in the ingredient statement was not identified with the word, “organic,” as described in §205.303(b)(1).*
- 2. The statement, “Certified organic by * * *,” or similar phrase, as described in §205.303(b)(2) was missing from the label.*
- 3. The USDA seal displayed on the label was not as described in §205.311(b).*

Corrective Action: BIOL updated ‘Labeling of Organic Products Guide’ (GMP-INT-ETI_300722 v3) to provide a comprehensive guide for the NOP labeling requirements, including all the

requirements under Subpart D. BIOL developed an online self-paced course for technical staff on labeling requirements. Staff took the training in August and September of 2022, and BIOL submitted training records for all staff. Also, BIOL updated the 'Evaluation Form of Label and Labeling for Organic Product USDA-NOP' (LA1-ETI-USA_300722 v3) to provide a more inclusive list of NOP-USDA labeling requirements for reviewers in charge of evaluating the labels. BIOL replaced the outdated versions with the new evaluation form and labeling guide on the online document-storage platform accessed by staff and updated the labeling guide on the BioLatina website to be accessed by applicants and certified operations. BIOL submitted the updated labeling guide and evaluation form to the NOP.

AIA-7411-21 - Accepted. 7 C.F.R. §205.501(a)(2) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart."

Comments: *BIOL does not consistently demonstrate the ability to fully comply with the requirements for accreditation, including NOP 3012 Interim Instruction Material Review. The auditors reviewed certification files and conducted interviews with certification staff and found the following issues:*

1. *BIOL does not maintain documentation to support its determinations about the status of a product's compliance with the regulations.*
2. *BIOL does not have written protocols and procedures outlining the depth and frequency of input review, or the evaluation of ingredients and manufacturing processes.*

Corrective Action: BIOL updated the 'Guide for Input Evaluation in Organic Agriculture' (GMP-INT-EIN_300722 v2) to include the requirements of NOP 3012. This instruction includes the requirement to maintain documentation related to material reviews. In February of 2022, BIOL implemented use of a cloud-based input registry that where the required supporting documentation is kept. Additionally, material review status is stored in a folder for each operator. Input authorization expires after one year; after that, BIOL will require a re-review of current information.

BIOL developed an online, self-paced course for technical staff, incorporating NOP 3012 and OILC-120. BIOL technical staff took this training in August and September of 2022. Additionally, BIOL updated 'Form for Exceptional Authorizations' (KA1_300722 v6) to remind reviewers that for materials used with NOP, they must reference NOP 3021. This revised form and the related input review guide were submitted to the NOP. BIOL also submitted to the NOP a training email sent to technical staff in December of 2022.

AIA-7412-21 - Accepted. 7 C.F.R. §205.501(a)(2) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart."

Comments: *BIOL does not accurately report the certification status of its certified operations in the Organic Integrity Database. The auditor's review of certification files found operations identified as "Certified" in the Organic Integrity Database over a year after BIOL accepted the operation's surrender of organic certification.*

Corrective Action: BIOL developed a 'Voluntary Surrender of Organic Certificate form (RET_041121 v1), which they began using in September of 2022, to ensure the operator provides necessary surrender details in a timely manner. BIOL's new automated message system will track surrendering operations once the reviewer enters the effective date of surrender when the volunteer surrender form is received from the operation. Once the date passes, the platform will send periodic, repeated reminders to relevant BIOL personnel to update the Organic Integrity Database and BIOL's internal database. The reminders will continue until the internal database is updated. BIOL developed the work instruction 'Platform Management Guide' (GMP-INT-MON_050822) to standardize the automations to be implemented on the platform and describe

their relationship with BIOL's procedures and forms. BIOL update their 'Procedures Manual' (GMP_100822 v47); Section 7.1 describes OID management procedures. BIOL trained staff on the new form and procedures on August 22, 2022. BIOL submitted the new surrender form and related work instruction, as well as related training content to the NOP.