

USDA

United States Department of Agriculture

Agricultural Marketing Service

National Organic Program

Bio Latina

Avenida Alfredo Benavides 330, Oficina 203, Miraflores, Lima 18, Lima, PERU

meets all the requirements prescribed in the National Organic Program Regulations

7 CFR Part 205

(Updated June 6, 2012)

as an Accredited Certifying Agent

for the scope of

Crops and 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 www.ams.usda.gov/nop

Certificate No: **NP1229ZZA**
Effective Date: **April 29, 2012**
Expiration Date: **April 29, 2017**


Miles V. McEvoy
Deputy Administrator
National Organic Program



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NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

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

GENERAL INFORMATION

Applicant Name	Bio Latina S.A.C. (BIOL)
Physical Address	Jr. Domingo Millan #852, Lima 11, Jesus Maria, Lima, Peru
Mailing Address	Same
Contact & Title	Reynaldo Chapilliquen Abad, General Manager
E-mail Address	central@biolatina.com.pe
Phone Number	0051-1-2031130
Reviewer & Auditor	Janna Howley, NOP Reviewer Mike Lopez, On-site Auditor
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP assessment review: April 7, 2015 Onsite audit: October 20-24, 2014
Audit Identifier	NP4293AKA
Action Required	None
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of BIOL's certification system.
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	BIOL's certification services in carrying out the audit criteria during the period: June 2012 through October 2014.

Bio Latina is a for-profit organization that provides certification services in Latin America. They were originally accredited by NOP on April 29, 2002 for the scopes of crops and handling, which are the same scopes they currently maintain. Bio Latina currently certifies operations to the NOP in Bolivia, Colombia, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Paraguay, and Peru. As of October 20, 2014, Bio Latina had 235 certified operations with 180 crop (142 of the certified crop operations are grower groups) and 55 handling operations. Six of the handling operations are traders; the rest are processors.

Bio Latina's main office is located in Lima, Peru with four satellite offices in Bolivia, Nicaragua, Venezuela, and Honduras. The main office and each of the local offices have a Local Representative who is responsible for certification activities in that area. Although the

representatives in the satellite offices conduct some key certification activities such as application review, initial technical reviews, inspections, report reviews, and corrective action approvals, all of these activities are done electronically through the Bio Latina website in Peru.

NOP DETERMINATION:

NOP reviewed the onsite 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 onsite audit.

Non-compliances from Prior Assessments

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP1229ZZA.NC1 – Cleared
NP1229ZZA.NC2 – Cleared
NP1229ZZA.NC3 – Cleared
NP1229ZZA.NC4 – Cleared
NP1229ZZA.NC5 – Cleared
NP1229ZZA.NC6 – Cleared

Non-compliances Identified during the Current Assessment

Any noncompliance labeled as "**Accepted**," indicates that the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP4293AKA.NC1 – 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: *Bio Latina issued a certificate for an Aloe Vera gel that contains 100% organic aloe vera, citric acid, and potassium sorbate. The certificate identifies the product as 100% organic, which is non-compliant because of the use of citric acid and potassium sorbate in the formulation. The actual labels for the product were correct, identifying the product as "organic"; however, the certificate incorrectly classifies the product as "100% organic."*

Corrective Action: In 2013 Bio Latina issued the operator a new certificate for coffee only; the operator has not since requested the organic certification of aloe vera. A copy of the 2013 certificate was provided to the NOP. In order to avoid mistakes in the classification of products, Bio Latina also instituted two trainings (December 2014 and February 2015) using the 2012 NOP Online Training Module PowerPoint presentation, "Subpart D - Labels, Labeling & Market

Information.” Copies of the completed, and signed, training forms, *MC02 PER-IE1-INS-221214* and *MC 02 CEN-IE1-INS-030215*, were provided to the NOP. In addition, Bio Latina designed a new form, *MC03 CL3-240315*, that staff is required to complete for products that contain more than one ingredient and/or utilize processing aids. A copy of the new form was provided to the NOP.

CORRECTIVE ACTION REPORT

Applicant Name:	Bio Latina
Est. Number:	N/A
Physical Address:	Av. Alfredo Benavides 330, Ofic. 203, Miraflores, Lima 18, Lima, Peru
Mailing Address:	Same
Contact & Title:	Roxana Priego Flores, Managing Director
E-mail Address:	central@biolatina.com.pe
Phone Number:	51-1-2090300
Auditor(s):	Betsy Rakola, Accreditation Manager
Program:	USDA National Organic Program (NOP)
Audit Date(s):	March 21 – May 30, 2012
Audit Identifier:	NP1229ZZA
Action Required:	No
Audit Type:	Corrective Action Audit (Renewal Assessment)
Audit Objective:	To verify continuing compliance to the audit criteria.
Audit Criteria:	7 CFR Part 205, National Organic Program, Final Rule, dated December 21, 2000; as amended August 3, 2011.
Audit Scope:	Bio Latina's quality manual including personnel, processes, procedures, facilities, and related records.
Location(s) Audited:	Desk

The U.S. Department of Agriculture (USDA), Agricultural Marketing Service (AMS), Grading and Verification Division (GVD) conducted an onsite accreditation renewal assessment of Bio Latina in Lima, Peru from October 17-21, 2011. The assessment resulted in six (6) noncompliances, labeled NC1-6. The National Organic Program (NOP) sent Bio Latina a Notice of Noncompliance on February 7, 2012 requesting a response within 30 days. Bio Latina responded with corrective actions to all noncompliances on March 21, 2012. The NOP reviewed the corrective actions and requested additional corrective actions to NC2, NC4, and NC5 on April 23, 2012. Bio Latina responded with additional corrective actions on May 7, 2012. The NOP requested minor corrections on adverse actions and civil penalties on May 18, 2012. The NOP accepted these corrective actions and referred the case to the Accreditation Committee on May 30, 2012.

GENERAL INFORMATION:

Bio Latina was originally accredited on April 29, 2002. The scope of accreditation was for crops and handling operations. Bio Latina is currently certifying operations to the NOP in Central America (Honduras, El Salvador, Guatemala, Nicaragua, and Panama), South America (Bolivia and Peru), and Mexico. Bio Latina offers certification services in Columbia, Ecuador, and Venezuela; however, they do

not currently have any certified operations in these countries. The Bio Latina client list as of October 17, 2011, had 260 certified operations with 178 crop and 82 handling operations. The majority (82%) of the certified operations are grower groups. Four of the handling operations are traders and the rest of the handling operations are processors.

The Bio Latina central office (main office) is located in Lima, Peru with three other offices in Bolivia, Nicaragua, and Venezuela. The main office and each of the local offices have a Local Representative with responsibility for certification activities. The main office in Peru has a Managing Director responsible for all activities of Bio Latina, a Local Representative responsible for managing certification in Peru, two Technical Managers responsible for certification decisions, and numerous administrative staff. The Peru office conducts all certification activities which include initial inquiries, application review, initial technical reviews, cost estimates, inspection assignment, inspections, report approval, final review, corrective action approval, certification decision, and issuance of certificates. The Bolivia, Nicaragua, and Venezuela offices conduct initial inquiries, application reviews, initial technical reviews, inspection assignment (with approval/sign off by Peru Central Office), inspections, report approval, and corrective action approval. Bio Latina also has a person in Honduras that serves as a liaison with national authorities in Honduras and may conduct initial reviews and inspections only; this person does not have the same authority as the local representatives and reports to the Nicaragua office and Peru office. Based on the review of information during this assessment, the Nicaragua and Bolivia offices should be included as part of the next assessment. The Nicaragua office covers Panama, Honduras, Nicaragua, El Salvador, Guatemala, and Mexico. The Venezuela office only has one person (Bio Latina's Quality Manager) and no clients so it is not necessary to conduct an on-site assessment at this location. The Quality Manager participated in the entire assessment in Peru.

Bio Latina is authorized to certify to the Peru National Standard by Peru's Ministry of Agriculture. Bio Latina is accredited for DIN EN 45011:1998 (ISO/IEC Guide 65:1996) to perform conformity assessments in the areas of agricultural production, processing and imports of organic agricultural products according to the Bio Latina Norms, EEC, Peruvian National Standard, and Global GAP. Bio Latina also conducts review and inspections for Bio Swiss.

FEES:

The Bio Latina fee schedule is available to clients via the Bio Latina website and is sent as part of the application packet for any client that requests information. All fees are non-refundable and include base fees, inspection fees, and graduated fees based on sales. The fees appear to be reasonable and the fee schedule is clear in the amount charges and what is nonrefundable. Bio Latina sends an estimate of costs for certification to each client.

PERSONNEL:

Bio Latina has a board of directors with 4 members, a managing director, a quality manager, 4 local representatives, a Technical Manager of Certification, a Technical Sub-Manager of Certification, 3 technical assistants, 9 staff inspectors, 17 subcontracted inspectors, and 16 administrative personnel. Resumes (curriculum vitae) were provided for all staff members and inspectors which adequately documented their organic education, experience, and training. Records reviewed and interviews conducted during the on-site audit verified that personnel had the qualifications to perform their certification duties as assigned. Records reviewed verified that Bio Latina was meeting the requirements for annual performance evaluations, confidentiality, and annual conflict of interest disclosure reports for all personnel. Bio

Latina's procedures specify that supervised inspections (witness inspections) be conducted for all inspectors at least once every three years as a performance evaluation, and Bio Latina is completing these as required.

CERTIFICATION PROCESS:

Requests for certification are received via telephone, emails, and visits to the office. New applicants are sent a certification packet with Bio Latina's quality manual and certification procedures, an application form, a fee schedule, general requirements for certification and continuation of certification, appropriate organic system plan forms, and the NOP Rule. The initial review for completeness and compliance of the application materials is conducted by one of the four local representatives or an assigned technical assistant all of which are employees. Inspectors are then assigned by the local representative based on the category of inspection (producer/handler), qualifications, conflicts of interest, and travel time; however, the final decision and approval for assigned inspectors is by the Peru office. Inspections are conducted by staff or subcontracted inspectors. The inspection reports and files are first reviewed by the local representatives and then forwarded to the Peru office for the certification decision. All final reviews, certification decisions, and issuance of certificates are made by the Peru Office. The Technical Manager of Certification or Sub-Manager of Certification review the complete file and inspection reports to make the certification decision. The two Technical Managers are members of the Certification Committee; however, only one person is necessary to make the certification decision. Their decision is documented on the certification decision form and provided to the Managing Director (General Manager) for issuance of the certificate. In previous years, the Managing Director made the certification decision; however, in May 2011, Bio Latina changed their certification process to have the Technical Managers make the certification decision and have the Managing Director focus on the administrative side of certification; however, their procedures and forms were not updated to reflect the change (see NC6).

ADMINISTRATIVE PROCEDURES:

Records reviewed verified that notification of denial of certification, notification of proposed suspension, and notification of suspension were not in accordance with the NOP Rule (see NC2, 3, and 4). Bio Latina has not been forwarding notices of non-compliances, non-compliance correction, or proposed suspension to the NOP Appeals Team as required (see NC1).

Bio Latina has conducted an annual program review and annual updates are submitted to the Administrator as required.

WITNESS INSPECTIONS:

The assessment included observation of a renewal inspection at a grower group certified for crops and handling in Piura, Peru. The grower group produces and processes tropical fruits (mangos, passion fruit, limes, oranges, etc.), coffee, cocoa, and sugar cane; however, the witness inspection was observed for the production, harvesting, and processing of sugar cane. The grower group is managed by an Internal Control System with 100% annual on-site inspections. The Bio Latina inspector was very knowledgeable of the NOP Rule and the additional requirements for grower group certification. All areas of the NOP Rule were addressed and an exit interview was conducted with the operation representative at the end of the inspection.

FINDINGS

Observations made, interviews conducted, and procedures and records reviewed verified that Bio Latina is

currently operating in compliance with the requirements of the audit criteria, except as noted in the non-compliances below. Six non-compliances were identified during the assessment.

NP1229ZZA.NC1 – Accepted. NOP §205.501(a)(15)(i) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Submit to the Administrator a copy of: Any notice of denial of certification issued pursuant to §205.405, notification of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, and notification of suspension or revocation sent pursuant to §205.662 simultaneously with its issuance. *Bio Latina has not submitted any notices of noncompliance or notification of noncompliance correction to the Administrator since the last assessment; although, they have issued them to certified operations. Bio Latina issued three notices of denial of certification in 2011; however, these were not submitted to the Administrator. Bio Latina issued one notice of noncompliance and notice of proposed suspension in July 2011, and these were not submitted to the Administrator. Bio Latina did submit their one notice of suspension to their Regional Accreditation Manager on October 14, 2011; however, it was not submitted to the NOP Appeals e-mail address or physical address as required.* **Corrective Actions:** Bio Latina began sending all adverse action notices to the NOP in November 2011. The NOP confirmed receipt of these notices.

NP1229ZZA.NC2 – Accepted. NOP §205.662(c)(3)(4) states, “The notification of proposed suspension or revocation of certification shall state: (3) The impact of suspension or revocation on future eligibility for certification; and (4) The right to request mediation pursuant to §205.663 or to file an appeal pursuant to §205.681.” *Bio Latina’s template form (ME4) for proposed suspension or proposed revocation does not correctly distinguish between the impact of suspension and revocation. Bio Latina proposed suspension (and ultimately enacted suspension) for one certified operation and the Notice of Proposed Suspension did not adequately include the impact of suspension on future eligibility for certification or the rights to request mediation or to file an appeal. The notice of proposed suspension did not correctly distinguish between the impact of suspension and revocation; stated that if the suspension goes into effect and the certified operation does not provide corrective actions within 10 working days then their certification will be revoked; stated the certified operation had 15 working days to file an appeal; and did not provide the address for submitting the appeal.* **Corrective Actions:** Bio Latina revised its adverse action procedures in its quality manual and also revised its templates to comply with NOP regulations. Information now states a 30 day period to file an appeal, includes the correct address for NOP Appeals, and explains the difference between suspension and revocation. Training was held on November 30, 2011 to inform staff of the modifications.

NP1229ZZA.NC3 – Accepted. NOP §205.405(d)(1)-(3) states, “A notice of denial of certification must state... the applicant’s right to: (1) Reapply for certification pursuant to §§205.401 and 205.405(e); (2) Request mediation pursuant to §205.663...; or (3) File an appeal of the denial of certification pursuant to §205.681....” *Bio Latina issued three notices of denial of certification and none of them contained the required information about the applicant’s right to reapply for certification; the information regarding the right to request mediation or appeal was incomplete, and the notice specified they had 15 working days to appeal. Bio Latina’s appeal procedure (3-9), which is provided to clients at the time of application, correctly addresses the mediation and appeal process for NOP; however, this information was not included in the notices of denial of certification. In addition, the address provided in the appeal procedure for submitting the appeal to the Administrator was incorrect.* **Corrective Action:** Bio Latina modified two documents: its Denial of Certification template to include information on appeals, and its procedure on complaints and appeals to note the unique procedures for NOP Appeals.

NP1229ZZA.NC4 – Accepted. NOP §205.662(e)(1) states, “If the certified operation fails to correct the noncompliance, to resolve the issue through rebuttal or mediation, or to file an appeal of the proposed suspension or revocation of certification, the certifying agent...shall send the certified operation a written notification of suspension or revocation.” *Bio Latina issued a Notice of Suspension which incorrectly states the certified operation may submit an appeal of the suspension to the NOP. According to NOP 205.681(a), certified operations may only appeal a notice of proposed suspension not a notice of suspension. NOP 205.662(f)(1) specifies the request for reinstatement of certification for a certified operation whose certification has been suspended may be submitted to the Secretary.* **Corrective Action:** Bio Latina modified its adverse action policies and templates to remove any references to appeal rights for notices of revocation and suspension. The template for the Notice of Proposed Suspension/Revocation still contains language regarding the right to mediation or appeal.

NP1229ZZA.NC5 – Accepted. NOP §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms or conditions determined by the Administrator to be necessary.” NOP Policy Memo (PM) 11-10 (dated 1/21/11) states, “accredited certifying agents should use the National Organic Standards Board (NOSB) recommendations of October 2002 and November 2008 as the current policies.” NOSB Recommendation, November 2008, section III.D requires, “...all new entrants to a production unit must be inspected in their first year with the group...Once the annual sampling percentage rate is determined by the ACA, the highest risk sub-units are identified and inspected. Of the remaining sample to be inspected annually, at least 25% of these the sub-units should be selected at random.”

1. *Bio Latina’s grower group procedure (3-1B, Application of the certification system for collective operators) does not require mandatory inspection of new entrants into the production unit by Bio Latina and interviews with Bio Latina confirmed they do not inspect all new entrants; although, they might select some new entrants based on risk. Bio Latina’s procedures do require the Internal Control System (ICS) to be conducting 100% annual inspections on all producers and inspections on new entrants.*
2. *Bio Latina’s grower group procedures do not specify the criteria used to determine and select high-risk producers; although, interviews and files reviewed verified it is based on the similar criteria to that listed in the NOSB recommendations.*
3. *Bio Latina’s procedures do not specify that “Of the remaining sample to be inspected annually, at least 25% of these the sub-units should be selected at random.” Files reviewed and interviews verified the remaining sub-units selected (after high risk chosen) are selected at random and the number is at least 25%.*

Corrective Action: Bio Latina updated its grower group policy to mandate 100% inspections during the first visit, to establish criteria by which to select high-risk producers for inspection, and to include requirement that an additional 25% of producers must be inspected at random, per the NOSB recommendation.

NP1229ZZA.NC6 – Accepted. Bio Latina’s Procedure 3-8 Organic Certification and Other Related Certification, Section 4.3 Certification, specifies the General Manager makes the certification decision. *Bio Latina’s certification procedure (3-8) and certification decision form (Solicitud de Certificación y Dictamen de certificación, Form DD3, Version 10, 01.05.11) do not accurately reflect their current certification decision process and responsibilities. Based on interviews with the General Manager, Quality Manager, and Technical Manager, it was determined that in May 2011 Bio Latina changed their procedure to have*

*the Technical Managers (Certification Committee Members) make the certification decision instead of the General Manager and for the General Manager to only have responsibility to ensure the certification certificate is issued (administrative function). Bio Latina did not update the certification procedure (3-8) or form (DD3) to reflect this change. The DD3 Form still documents that General Manager makes the certification based on the recommendation of the Technical Manager when in fact the Technical Manager or Technical Sub-Manager make the certification decision and the General Manager is simply documenting that the certificate should be issued. **Corrective Action:** Bio Latina modified its quality manual to reflect the current procedures.*