

# **United States Department of Agriculture**

Agricultural Marketing Service National Organic Program

# LACON, GmbH

Moltkestrasse 4, D-77654, Offenburg, Germany

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, Wild Crops, Livestock (Apiculture only) 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 http://www.ams.usda.gov



Certificate No: NP7177PZA
Effective Date: October 21, 2017
Expiration Date: October 21, 2022

Ruihong Guo, Ph.D.

Acting Deputy Administrator National Organic Program

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# NATIONAL ORGANIC PROGRAM: CORECTIVE ACTION REPORT

#### AUDIT AND REVIEW PROCESS

An onsite Mid-term audit of the LACON GmbH (LACON) organic program was conducted on September 25-27, 2019. The National Organic Program (NOP) reviewed the auditor's report to assess LACON's compliance to the USDA organic regulations. This report provides the results of NOP's assessment.

# **GENERAL INFORMATION**

Applicant Name	LACON GmbH (LACON)
Physical Address	Moltkestrasse 4 D-77654 Offenburg, Germany
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Contact & Title	Elisabeth Ville, Team International
E-mail Address	e.ville @lacon-institut.org
Phone Number	49 781 966 79 242
Reviewer & Auditor	Joshua Lindau, NOP Reviewer; Penny Zuck, On-site Auditor
Program	USDA National Organic Program (NOP)
Review & Audit Date	Corrective Action review: February 12, 2021
	NOP assessment review: October 4, 2019
	Onsite audit: September 25-27, 2019
Audit Identifier	NOP-35-19
Action Required	No
Audit & Review Type	Mid-Term Assessment
	To evaluate the conformance to the audit criteria; and to verify the
Audit Objective	implementation and effectiveness of LACON's certification
	system.
Audit & Determination	7 CFR Part 205, National Organic Program as amended
Criteria	
Audit & Review Scope	LACON's certification services in carrying out the audit criteria
	during the period: June 27, 2017 through September 27, 2019

LACON GmbH (LACON) is a limited liability company that conducts certification and compliance verification of agricultural products, food, and livestock feed with national, international, and private quality standards. LACON was initially accredited to the USDA National Organic Program on October 21, 2002 for the scopes of crops, wild crops, livestock, and handling. LACON currently certifies 265 operations: 180 crops, 10 wild crops, 9 livestock, and 74 handling operations. LACON certifies 15 grower groups.

LACON maintains individual or partner offices with certification bodies in Bulgaria, South Africa, and Chile. The offices serve operations in Bulgaria, South Africa, Chile, India, United Arab Emirates, Bangladesh, Indonesia, Sri Lanka, Nigeria, Nepal, Tanzania, and Uganda. The

offices provide documents and other communications in the language of the respective country. All certification reviews and decisions are conducted out of the main LACON office in Offenburg, Germany. LACON's NOP organic certification program staff consists of the General Manager, Executive Director, 10 technical staff (reviewers/inspectors), 2 administrative staff and 21 contracted inspectors.

The audit consisted of an office audit and one witness audit of a processing/handling operation located in Hamburg, Germany.

#### NOP DETERMINATION

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

# **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 "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.

NP5293OOA.NC5. Cleared NP7177PZA.NC1 – Cleared. NP7177PZA.NC2 – Cleared NP7177PZA.NC3 – Cleared NP7177PZA.NC4 – Cleared NP7177PZA.NC5 – Cleared NOP-62-17.NC1 – Cleared

# **Noncompliances Identified during the Current Assessment**

NOP reviewed corrective actions submitted as a result of noncompliances issued from Findings identified during the onsite audit. Any noncompliance labeled as "Accepted" indicates acceptance of the corrective actions and verification of corrective action implementation will be conducted during the next audit.

**AIA-2947-20** – **Accepted.** (NOP-35-19.NC1) 7 C.F.R. §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:** *LACON is charging operations located in Germany according to a certification fee schedule that is not on file with the NOP. The auditor's review of certification files revealed* 

certification fees being charged to operations located in Germany according to a fee schedule with the revision date of September 27, 2018. This fee schedule was not submitted to the NOP with LACON's 2018 annual report.

Corrective Action: LACON submitted the current fee schedule in December 2019. LACON updated their quality manual to state "LACON will 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. USDA must be informed about any modification of those fees before these new fees are applied." LACON notified staff of the changes in the quality manual and procedures in a training conducted in December 2019 and via email November 2020.

**AIA-2948-20** – **Accepted.** (NOP-35-19.NC2) 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:** During a witness audit, LACON's inspector provided the operation with a copy of the inspection report indicating noncompliances. The auditor's review of inspection reports revealed that "issues of concern" or "potential noncompliances" are identified as "noncompliances."

**Corrective Action**: LACON updated the U-F-20 Finding checklist by replacing the words "deficiency / noncompliance" with "finding." LACON conducted a training for certification and inspection staff on the modification of the U-F-20 Finding document December 17, 2019 and March 2, 2020.

**AIA-2950-20** – **Accepted**. (NOP-35-19.NC3) 7 C.F.R. §205.403(c)(2) states, "The on-site inspection of an operation must verify: That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation;"

**Comments:** During the witness audit of a processing/handling inspection, the NOP auditor observed that the inspector did not fully verify the accuracy of the operation's organic system plan. Examples of information not verified included identification of cleaning/sanitizing materials, and pest management records. LACON's inspection report does not require the inspector to physically verify the cleaning/sanitizing materials on site during the inspection.

Corrective Action: LACON's inspection checklist now requires the inspector to verify and list the witnessed cleaning and pest materials. LACON changed its audit and certification procedures for conducting inspections so there are not separate procedures for Germany and other countries. Starting in 2020 LACON will use the same inspection checklists and OSPs in Germany that it uses in all other countries. The inspection checklist U-NOP-18 was replaced with the Inspection form Processing/ Handling U-F-15 Checklist. Trainings were conducted for inspectors on December 17, 2019 and March 2, 2020, covering the requirements of §205.403(c)(2).

AIA-2951-20 – Accepted. (NOP-35-19.NC4) 7 C.F.R. §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;"

**Comments:** According to interviews with certification staff, LACON does not submit to the NOP a copy of the notices listed in §205.501(a)(15)(i).

**Corrective Action**: LACON created a Non Compliance Procedure and staff were notified that notifications must be sent to NOPACAAdverseActions@usda.com. LACON conducted a training for certification staff on December 17, 2019, covering the requirements of §205.501(a)(15)(i).



# NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

#### AUDIT AND REVIEW PROCESS

An onsite renewal assessment of LACON GmbH's (LACON) organic program was conducted on June 26 – 28, 2017. The National Organic Program (NOP) reviewed the auditor's report to assess LACON's compliance to the USDA organic regulations. This report provides the results of NOP's assessment.

# **GENERAL INFORMATION**

Applicant Name	LACON GmbH (LACON)
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Phone Number	49 781 966 79 242
Reviewer(s) &	Cushous Davis NOD Davisayan Danay Zuah On site Auditan
Auditor(s)	Graham Davis, NOP Reviewer; Penny Zuck, On-site Auditor.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	Corrective actions review: January 11, 2017
	NOP assessment review: July 14, 2017
	Onsite audit: June 26-28, 2017
Audit Identifier	NP7177PZA
Action Required	None
Audit & Review Type	Renewal Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the
	implementation and effectiveness of LACON's certification system.
Audit & Determination	7 CFR Part 205, National Organic Program as amended
Criteria	
Audit & Review Scope	LACON's certification services in carrying out the audit criteria during the
	period: October 23, 2015 through June 26, 2017

LACON GmbH is a limited liability company that conducts certification and compliance verification of agricultural products, food, and livestock feed with national, international, and private quality standards. LACON was initially accredited to the USDA National Organic Program on October 21, 2002 for crops, wild crops, livestock, and handling. LACON currently certifies 143 operations including: 79 crops, 15 wild crops, 8 livestock (apiculture only), and 78 handling operations. LACON certifies 12 grower groups.

LACON maintains individual or partner offices with certification bodies in Austria, Brazil, Bulgaria, Cyprus, Morocco, Romania, and India. The offices serve currently certified and prospective operations. The regional offices provide documents and other communications in the language of the respective country. All certification reviews and decisions are conducted at the main LACON office in Offenburg, Germany. LACON's NOP organic certification program staff consists of the General Manager, Executive Director, 7 reviewers/certifiers, and 18 inspectors.

The audit consisted of an office audit only and did not include witness or review audits. The witness and review audits will be conducted at a later date.

# **NOP DETERMINATION:**

NOP reviewed the onsite audit results to determine whether LACON'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 "Accepted" indicates acceptance of the corrective actions and verification of corrective action implementation will be conducted during the next onsite audit.

NP2281EEA.NC3 – Cleared N5299OOA.NC1 – Cleared N5299OOA.NC2 – Cleared N5299OOA.NC3 – Cleared N5299OOA.NC4 – Cleared NP5293OOA.NC6 – Cleared NP5293OOA.NC7 – Cleared NP5293OOA.NC8 – Cleared

**NP5293OOA.NC5**. **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." The instruction NOP 2027, "Personnel Performance Evaluations, "section 3.2 (b) states "Inspectors should be evaluated during an onsite inspection by a supervisor or peer (another inspector) at least annually. This field evaluation should be conducted at the certifying agent's expense."

**Comments:** LACON's current policy for evaluating inspector field performance is on a five year cycle instead of annually. There are provisions for conducting field evaluations more frequently if deemed necessary.

**2015** Corrective Actions: LACON updated its inspector policies (U-NOP-04e r1) and now requires annual inspector field evaluations for personnel involved in USDA NOP inspection

activities. In addition, LACON provided documentation showing that six inspectors have already been subject to a field evaluation.

**2017 Verification of Corrective Action:** From the auditor's review of personnel evaluations, 4 out of 18 active NOP inspectors were not field evaluated in 2016. LACON has revised their procedure for conducting field evaluations of inspectors and intends to submit it to the NOP for review according to NOP 2027.

**2017 Corrective Actions:** LACON submitted their NOP Quality Manual which describes their proposed procedure for field evaluations of their inspectors (Section 10.6). LACON is proposing to use a risk based approach to classify their inspectors as level 'A', 'B', and 'C'. The placement of their inspectors into each of these levels will be based on various criteria (knowledge of the standards, flexibility of auditor and availability/ dedication, feedback of auditor to LACON, punctuality in sending audit checklists, use of electronic checklist/readable paper checklist, results of witness of standard setters/system providers, and results of witness audits by LACON, trainings, feedback discussion). Field evaluations for level 'A' inspectors will be conducted every 3 years, level 'B' every 2 years, and level 'C' every year.

# 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.

**NP7177PZA.NC1** – **Accepted -** 7 C.F.R. §205.662(a) states, "When an inspection, review, or investigation of a certified operation by a certifying agent or a State organic program's governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation."

NOP 2613 Section 5.3.3 (3) states, "If appropriate, consider a notice of noncompliance for the following violations:

- $\S$  205.202(b): application of prohibited substances. The notice should propose to suspend or revoke the operation's certification.
- § 205.202(c): inadequate buffer zones to prevent the unintended application of prohibited substances. The notice should require corrective actions to prevent future contamination.
- § 205.272: inadequate measures to prevent commingling or contamination of organic products. The notice should require corrective actions to prevent future contamination. If suspensions, revocations, or civil penalties are appropriate, coordinate adverse actions with the NOP."

### **Comments:**

1. Following a residue testing result without EPA or FDA levels, LACON issued a notification to the operation indicating the results; the product could not be sold, labeled, or represented as organic; and requiring measures to reduce the risk of contamination in the future. The notice was not an official Notice of Noncompliance nor did it contain the required elements according to the USDA organic regulations. After receiving insufficient corrective actions, LACON did issue a Notice of Proposed Suspension and subsequently a Notice of Suspension, however, these notices did not include the required elements according to the USDA organic regulations.

- 2. LACON provides each operation with a Review of Evaluation Report following the final certification review. This report includes measures that must be addressed by the operation, however, some of the measures reviewed by the auditor should be identified as noncompliances. LACON is not issuing Notices of Noncompliance to operations.
- 3. LACON does not have an Adverse Action process/procedure in place to demonstrate compliance with the USDA organic regulations.

**2017 Corrective Actions:** LACON revised their letter templates used to respond to certifiers for a positive test result of a prohibited substance. Notice of noncompliance templates have been revised to include the required elements according to 7 C.F.R. §205.662 and NOP 2613. Notice of proposed suspension/proposed revocation and notice of suspension/revocation templates have been revised to include the required elements according to 7 C.F.R. §205.662. LACON created a noncompliance and adverse action flow chart that includes hyperlinks to their letter templates for the steps of the chart and procedures for reviewing pesticide residue test results. LACON conducted training on their flow chart and letter templates on July 24, 2017. LACON will conduct an additional training on their flow chart and corresponding letters upon acceptance of their corrective actions. LACON will evaluate the implementation of these documents during their annual internal audit and annual management review.

**NP7177PZA.NC2** – **Accepted.** 7 C.F.R. §205.501(a)(11)(v) states, "A private or governmental entity accredited as a certifying agent under this subpart must:.. Prevent conflicts of interest by:.. Requiring all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent to complete an annual conflict of interest disclosure report."

**Comments:** Three LACON inspectors did not have Conflict of Interest statements on file for 2016 or 2017.

**2017 Corrective Actions:** LACON submitted signed conflict of interest statements received from the three inspectors. LACON indicated that conflict of interest statements will collected at the beginning of the year, and that an inspector will not be allowed to conduct inspections if LACON does not have a conflict of interest statement for that inspector on file.

NP7177PZA.NC3 – Accepted. 7 C.F.R. §205.401(a) states, "A person seeking certification of a production or handling operation under this subpart must submit an application for certification to a certifying agent. The application must include the following information: An organic production and handling system plan, as required in §205.200; "NOP 2615 provides details of how producers and handlers can comply with these requirements. Organic System Plan (OSP) templates are available in the NOP Handbook. 7 C.F.R. §205.201(a)(3) states, "The producer or handler of a production or handling operation,...must develop an organic production or handling system plan that is agreed to by the producer or handler and an accredited certifying agent. An organic system plan must meet the requirements set forth in this section for organic production or handling. An organic production or handling system plan must include:...A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented;..."

**Comments:** LACON's OSPs do not include the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify

the plan is effectively implemented. LACON's inspection reports do not provide verification of the monitoring practices and procedures.

**2017 Corrective Actions:** LACON revised their OSPs & Inspection Checklists to include a section on monitoring practices and procedures. LACON informed their inspectors in August of 2017 that a section on monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, was added in each OSP and their respective inspector checklist. LACON informed their inspectors to verify that the answers in the OSP are being implemented by the client. LACON intends to verify the use of the latest version of their checklists during their annual internal audit.

**NP7177PZA.NC4** – **Accepted** - 7 C.F.R. §205.501(a)(18) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Provide the inspector, prior to each on-site inspection, with previous on-site inspection reports and notify the inspector of its decision regarding certification of the production or handling operation site inspected by the inspector and of any requirements for the correction of minor noncompliances;..."

**Comments:** *LACON is not notifying inspectors of its decision regarding certification of the operations inspected and any requirements for the correction of minor noncompliances.* 

**2017 Corrective Actions:** LACON will send a copy of the results of the audit (certificate, review report and inspection report) to each inspector. LACON provided training to their staff in July of 2017 regarding this change to their procedure. Training slides were sent to LACON staff who could not take part in the training. LACON updated their NOP Quality Manual to include this change to their procedure. LACON intends to verify the implementation of the corrective actions during their annual internal audit.

**NP7177PZA.NC5** – **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; and..."

**Comments:** LACON is not consistently providing copies of inspection reports to operations from the LACON office. On some occasions, the inspector provides the operator with a copy during the inspection.

**2017 Corrective Actions:** After a certification decision, LACON will send an e-mail to the client and the inspector with the complete package (audit checklists and certification decision). LACON updated their Quality Manual (Section 3.9) to include this procedure. LACON provided training to their staff in July of 2017 regarding this change to their procedure. Training slides were sent to LACON staff who could not take part in the training. LACON intends to verify the implementation of the corrective actions during their annual internal audit.



### **AUDIT INFORMATION**

Applicant Name:	LACON GmbH
Est. Number:	N/A
Physical Address:	Brünnlesweg 19, 77654; Offenburg, Germany
Mailing Address:	Postfach 1909, 77609; Offenburg, Germany
Contact & Title:	Fabienne Verzeletti, NOP Quality Manager
E-mail Address:	f.verzeletti@lacon-institut.com
Phone Number:	0049 781 919 37 42
Auditor(s):	Renee Mann, Accreditation Manager
Program:	USDA National Organic Program (NOP)
Audit Date(s):	April 10 – November 5, 2013
Audit Identifier:	NP2281EEA
Audit Type:	Corrective Action Assessment, Renewal of Accreditation
Audit Objective:	To verify adequate corrective actions in response to the notice of noncompliance issued in response to noncompliances identified during the renewal assessment.
Audit Criteria:	7 CFR Part 205, National Organic Program, Final Rule, dated December 21, 2000; updated March 15, 2012.
Audit Scope:	The corrective actions submitted on April 10 through November 5, 2013.
<b>Location(s) Audited:</b>	Desk audit

The USDA National Organic Program (NOP) conducted a Renewal of Accreditation Assessment of LACON GmbH (LACON) from October 8-12, 2012. The NOP issued LACON a Notice of Noncompliance based on the findings from this assessment on February 4, 2013.

# **GENERAL INFORMATION:**

LACON GmbH is an independent service organization that carries out inspection activities for the purpose of verifying compliance of agricultural produce, foods, food products, and feed with national, international, and private standards. LACON was initially accredited to the USDA National Organic Program as an authorized certifying agent for the scopes of crops, wild crops, livestock, and processing/handling on October 21, 2002. The LACON current list of certified operations, dated January 02, 2012, included a total of 86 operations certified to the National Organic Program; which included 48 crop, 17 wild crop, 7 livestock (bees only), and 66 handling (21 processors & 4 traders) operations. LACON also has 26 grower groups listed on the certified operations list. LACON conducts certification activities in the following countries: Germany, Azerbaijan, Brazil, Egypt, Nepal, Dubai, Sudan, Morocco, Burkina Faso, Madagascar, South Africa, Poland, Bulgaria, India, Bangladesh, Lithuania, and Cypress.



LACON either staffs or partners with other certification bodies with offices in Brazil (Sao Paulo), Bulgaria, Morocco and India. The offices are maintained as a contact for currently certified and prospective clients and provide communication and documents in the language of the country. Inspectors from the office in India are utilized for inspections in Bangladesh and Nepal. The India office issues certificates for operations within India based on the NOP agreement; however, for any inspections outside of India (e.g. Bangladesh and Nepal) the certification activities and decision on certification is made by LACON Germany who issues the certificate. The partner in Egypt is ECOA and the ECOA inspectors (3) are used. The office in Brazil and Bulgaria operate as LACON Brazil and LACON Bulgaria respectively. These offices do not process any applications but only provide information and perform inspections. The office in Morocco is a one person office dealing mostly with EU organic and Global Gap certifications. There are no certification activities in foreign offices other than inspections.

#### **FINDINGS**

Observations made, interviews conducted, and procedures and records reviewed verified that LACON GmbH is currently operating in compliance to the requirements of the audit criteria, except as noted below. The corrective actions for the four non-compliances identified during the 2010 Mid-term Audit were verified and found to be implemented and effective and the non-compliances were cleared. There were four new non-compliances identified during the 2012 renewal assessment.

NP0263EEA.NC1 – Cleared NP0263EEA.NC2 – Cleared NP0263EEA.NC3 – Cleared NP0263EEA.NC4 – Cleared

NP2281EEA.NC1 – Accepted. §205.404(b) and NOP §205.406(d) specifies the information which must appear on organic certificates. The NOP 2603, Section 4, states, "NOP organic certificates should be issued in English and specify the: ... 5. Anniversary date (the date when the certified operation is required to submit their next annual update); ... 9. The statement – "Certified Organic under the US National Organic Program 7 CFR Part 205"; and 10. The statement - "Once certified, a production or handling operation's organic certification continues in effect until surrendered, suspended or revoked"." A review of each of the certificates in the 10 files reviewed confirmed that the LACON certificate "template" does not provide all of the information required by the NOP Instruction 2603. The Anniversary date; the statement - "Certified Organic under the US National Organic Program 7 CFR Part 205"; and the statement - "Once certified, a production or handling operation's organic certification continues in effect until surrendered, suspended or revoked" is not included on any certificates being issued by LACON. Corrective Action: LACON updated its certificate template to include the statement "Certified organic under the US National Organic Program 7 CFR Part 205," and the statement "Once certified, a production or handling operation's organic certification continues in effect until surrendered, suspended or revoked." The term "Certificate renewal date," instead of "anniversary date," was added to the template because LACON decided the phrase "anniversary date" is confusing when translated. LACON stated that the new template has been used for all certificates issued since January 2013 and submitted five example certificates issued since December, 2012 through March, 2013 demonstrating the changed format. LACON highlighted the changed template for its staff in a training slide that it sent to its staff in July, 2013, and that will be presented again during the next annual training week where all inspectors are present in-person in January 2014.



NP2281EEA.NC2 – Accepted - §205.642 states, "... 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 estimate of certification costs provided by LACON is for inspection days only and for the issuance of transfer certificates and does not cover any of the other costs associated with certification such as travel expenses, which affect the total cost considerably. In one file, the estimate was not itemized by day or part of day for inspection and day or part of day for travel as per the LACON template for estimates. The expenses are collective under "announced audit", Travel and accommodation costs are not listed. For the file, the actual cost was €1000 more than the original estimate.

Corrective Action: LACON noted that the non-compliance was discussed with the USDA Auditor during the closing meeting and concerned only the operations certified in third countries; German operations receive a different fee estimate. To correct the issue concerning renewing operations outside of Germany, LACON began providing an estimate of travel expenses to its renewing clients based upon the previously issued invoice for the operation. LACON stated that it instituted this practice in January, 2013. LACON submitted five recently issued fee estimates, issued from January, 2013 to February, 2013, demonstrating the presence of "traveling days" and "travel expenses," which can include a flight, taxi, rental car, and hotel cost, in the fee estimate. LACON also submitted the invoices for these operations showing the actual expenses charged to the operations. LACON also revised its fee schedule for foreign applicants to explain that these various costs would be included in the renewing operation's estimate.

Regarding new applicants, LACON stated that it requests a completed OSP and issues an estimate based upon the estimated inspection days. LACON has not received any new clients in 2013. Estimates are provided by phone or by email. LACON stated that it does not have a template or instruction in regard to these estimates, only the fee schedule. Each inspector is responsible for their own estimate, and the Quality Manager checks all estimates and invoices that are issued to NOP clients. LACON updated its Quality Manual to state that the travel and accommodation costs would be included in the estimate to new applicants.

LACON submitted a copy of a training slide that stated that the cost of travel expenses must now be estimated for foreign clients. The training slide was sent to LACON's staff in July, 2013, and will be presented again during the next annual training week where all inspectors are physically present in January 2014.

NP2281EEA.NC3– Accepted - §205.662(a) states, "Notification. When an inspection, review, or investigation of a certified operation by a certifying agent or a State organic program's governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation. Such notification shall provide: (1) A description of each noncompliance; (2) The facts upon which the notification of noncompliance is based; and (3) The date by which the certified operation must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible." Eight of the ten files reviewed included 2 to 14 "Measures" with no non-compliances issued. Examples of "measures" included: 1.) No documents available to verify organic seedling, sale of untreated seed, delivery notices, etc.; 2.) No traceability of product from delivery to the field of origin – records of dates of harvesting, cutting, bagging ,etc., and cleaning records for dual purpose equipment; 3.) No documentation to show the 3 year previous history of fields included in the OSP; and 4.) No clean out verifications concerning cleanliness



of containers used for delivery. Measures from the previous year are still open regarding record keeping. There is no record of a non-compliance being issued to any certified operation since the previous assessment.

Corrective Action: LACON explained that it previously used the term "measure" instead of the term "noncompliance" and that the inspector notified the operation of the measure (now called deficiency/noncompliance) and proposed a deadline for resolution. This information was then confirmed by the reviewer and the reviewer conducted follow-up. The NOP determined that this procedure was not compliant with 7 CFR §205.501(a)(11)(vi). In response, LACON changed its exit interview form (called a Non-Compliance Report, form Y037) to state that the noncompliance is *proposed* by the inspector, that the reviewer must review the noncompliance, and that the notice of noncompliance created by the reviewer must be sent to the operator and the USDA. LACON also changed its "Review of evaluation report Project inspection" (form Y009) to state that measures *proposed* during the inspection by the auditor must be confirmed by the staff reviewer as noncompliances in report Y037.

As evidence of corrective actions, LACON submitted documents showing that it had issued a notice of noncompliance to one of its operations; the noncompliance was also submitted to the proper email address of the USDA for submission of adverse actions. LACON will present training on this topic to its inspectors at the next in-person training in January 2014.

**NP2881EEA.NC4** – **Accepted** - §205.402(a)(1) states, "Upon acceptance of an application for certification, a certifying agent must: (1) Review the application to ensure completeness pursuant to §205.401; (2) Determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part." A review of 10 certification files indicated that the OSP's submitted for groups and wild harvest operations are deficient in the amount of information necessary to determine a group or a wild harvest operations' ability to comply. If maps are included they are not descriptive of the area and do not contain specific information about collections, buffers or other information required to verify compliance.

Per NOP 5022, dated July 22, 2011, Section 5.2 Organic System Plan states, "A wild-crop harvesting Organic System Plan (OSP) includes: 1. A full map of the area(s) to be harvested defining boundaries, borders, adequate buffer zones, point and non-point sources of contaminants and prohibited materials, and wild crops to be harvested. 2. Documentation that no prohibited materials have been applied to or have contaminated the land or aquatic area within the last three years. 3. A description of the natural environment of the harvest area (e.g. scrub steppe, oak-chaparral woodland, deciduous hardwood forest). 4. A description of the proposed ecosystem management and harvesting practices, the impact of their proposed harvesting on the long-term viability of the wild species and on the area's ecosystem, and information on any equipment planned for use or being used to harvest and manage the wildcrop and ecosystem. a. This should include a description of the monitoring system that will be used to ensure that the crop is harvested in a sustainable manner that does not damage the environment, including soil and water quality. 5. A list of any rare, threatened, or endangered terrestrial or aquatic plants or animals that occur in the harvest area. a. The presence of rare, threatened, or endangered species in a wild harvest area does not automatically disqualify an operation from organic certification, but any potential or actual impacts need to be described and addressed." The wild harvest files reviewed during the assessment included some of the above requirements, but mapping, approvals from public and private landowners,



descriptions of buffers and surrounding land use were not provided. One file reviewed concluded that the maps of the wild harvest area were non-descriptive. Some areas were blackened through duplication and the poor quality did not provide the intended mapping to show the designated collection areas. Additionally, there was no description and no buffers described.

• The same file showed the list of collectors is 19. The list included berries and plants of every description. For the de-hydration of the apples and berries, there is no description or process in the OSP or accompanying information. The only process described is at the distillery for making essential oils and waters. Almost all of the herbs, plants and berries are described as dried. There is no process for drying described in the OSP. In general, the required information for wild harvesting and subsequent processing is not being submitted for initial review to determine the ability to comply.

Corrective Action: LACON decoupled its OSP for crops and wild crops, creating two separate OSP templates. LACON submitted its new, draft OSP form for wild crops (form Y134e Rev. No. 00); the form incorporates the requirements of NOP Wild Crop Harvesting Guidance (NOP 5022). For example, the form requires the submission of a full map that defines boundaries, borders, adequate buffer zones, point and non-point sources of contaminants and prohibited materials for each plot/field. The draft OSP form also includes questions prompting the operator to describe post-harvest handling procedures. LACON also submitted an updated Inspection Form for Wild Crops (Doc.No. Y 074) that prompts the inspector to verify the information in the OSP.

Regarding the poor map quality and inadequate description of buffer zones, LACON indicated that it collects maps annually from its operators in association with the inspection, and some of its auditors use GPS to update the maps made available by the operator. LACON plans to collect this information at the upcoming inspections.

LACON will present training on this topic to its inspectors at the next in-person training in January 2014.