

# **United States Department of Agriculture**

Agricultural Marketing Service National Organic Program

# OREGON DEPARTMENT OF AGRICULTURE

Capitol Street Northeast 635, Salem, Oregon, 97301, 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 <a href="http://www.ams.usda.gov">http://www.ams.usda.gov</a>

Certificate No: USDA-17-21 Effective Date: 8/11/2019

Renewal Date: 8/10/2024

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

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# NATIONAL ORGANIC PROGRAM: AUDIT & CORRECTIVE ACTION REPORT

#### **GENERAL INFORMATION**

Certifier Name Oregon Department of Agriculture, (ODA)

Physical Address Capitol Street Northeast 635, Salem, Oregon 97301, U.S.A.

Audit Type Mid-term Audit

Auditor(s) & Audit Dates Alison Howard, Stephen Nix, 07/27/2021 to 07/29/2021

Audit Identifier NOP-27-21

## **CERTIFIER OVERVIEW**

The Oregon Department of Agriculture (ODA) is a state government agency accredited September 28, 2009, to the USDA National Organic Program (NOP). ODA certifies 163 operations to the following certification scopes: Crops (103 and Handling (81). ODA's office is in Salem, Oregon and provides certification services in Oregon, California, and Washington.

No witness audits were conducted during this audit.

#### NOP DETERMINATION

NOP reviewed the audit results to determine whether ODA'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-2416-20 - Cleared.

AIA-2831-20 – Accepted. 7 C.F.R. §205.501(a)(6) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Conduct an annual performance evaluation of 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 implement measures to correct any deficiencies in certification services."

**Comments:** The NOP's review of ODA's 2020 Annual Report found that ODA did not conduct inspector field evaluations for all inspectors in 2019 and has not implemented an alternate proposal for inspector field evaluations per the requirements of NOP 2027 Personnel Performance Evaluations.

**2020 Corrective Action:** ODA cited multiple personnel changes, including the departure of an administrative specialist and the program manager, as the cause of the noncompliance. The interim program manager could not complete the field evaluations in addition to the position's other duties. ODA hired a new Organic Program Manager in September 2020 who will be working full-time in the organic program. ODA has also restructured their program to increase staff time working in the organic program. Additionally, ODA has completed all in-person field evaluations for inspectors for 2020.

**2021 Verification of Corrective Action:** The auditors reviewed personnel files and confirmed with certification staff that one inspector did not receive a field evaluation in 2020.

Corrective Action: ODA submitted an updated performance evaluation form (OCP.F.36, National Organic Program Employee Performance Evaluation) to be used for yearly performance evaluations. The form includes a line verifying that field evaluation was performed and for which operation; if field evaluation was not performed that year, there is a prompt to document the reason and the proposed remedy. ODA submitted a schedule of field evaluations to demonstrate that ODA's plan for compliance in 2024.

AIA-2832-20 – 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: The NOP's review of ODA's 2020 annual report found that ODA's procedure concerning the requirements for exporting products under the U.S. – Taiwan equivalence arrangement is outdated. The NOP issued an email notification to certifiers on August 19, 2020 advising of a change to the attestation statement required on TM-11s issued after September 1, 2020 for exports to Taiwan. The ODA procedure does not correctly describe the updated attestation statement.

**Corrective Action:** ODA updated its policy Requirements for export of US organic raw and processed agricultural products – Taiwan (OCP.DP.12) to include the correct attestation statement for exports to Taiwan. ODA notified staff of the change during a meeting on November 30, 2020.

**Verification of Corrective Action:** ODA has not issued a TM-11 since this corrective action was accepted. The auditors reviewed OCP.DP.12 in the Quality Manual and found that the policy was not updated.

**2023** Corrective Action: ODA updated OCP.DP.12 again to include the correct attestation statement and informed the two staff members who issue export certificates of the update. ODA has pre-filled the attestation statement on the TM-11 template in the Taiwan agreement folder. ODA submitted a copy of the updated policy and a sample TM-11 issued by ODA in April 2022.

**AIA-5703-21** – **Accepted.** (NOP-46-19.NC1) 7 C.F.R. §205.402(a)(1) states, "Upon acceptance of an application for certification, a certifying agent must: Review the application to ensure completeness pursuant to 205.401."

**Comments:** ODA does not consistently review applications for certification to ensure completeness. In three of six certification files reviewed, the organic system plans for handling operations did not include a description of the monitoring practices and procedures to be performed and maintained, including the frequencies at which they will be performed, to verify that the plan is effectively implemented. This is a requirement of §205.201(a)(3). ODA did not require the operations to provide the missing information.

Corrective Action: ODA updated the Initial Review Checklist for Crop and Handling operations (OCP.F.17 and OCP.F.18) to clearly state the need for follow up with the operations if material is missing. ODA also updated the Handling OSP Organic System Plan template (OCP.F.6) to require the description of monitoring practices and documentation for ensuring organic products are not contaminated during storage. Operations were provided the updated materials for 2020 and staff was trained on them at the annual internal refresher training on March 2, 2020; ODA provided a copy of the training agenda.

**Verification of Corrective Action:** The auditors reviewed certification files and determined ODA reviewers continue to fail to identify incomplete certification applications and annual updates to organic system plans. For example, sections of the organic system plan forms were not completed or were missing important information, such as cleaning/sanitation procedures and an up-to-date products list.

**2023** Corrective Action: ODA provided refresher training to staff on March 18, 2022 on how to verify files for completeness and when to ask for additional information. ODA provided a copy of the training agenda.

AIA-5704-21 – Accepted. (NOP-46-19.NC2) 7 CFR §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:** ODA did not conduct an annual inspection of all its certified operations in 2018. Of the 10 certification files reviewed, one handler operation did not receive an annual inspection for the 2018 certification year while ODA was working with the operation during the proposed suspension process.

Corrective Action: ODA determined that the cause of the noncompliance was misinterpretation of §205.403(a)(1) regarding operations that are undergoing a proposed suspension. ODA updated its Inspection Procedures (OCP.DP.5) to include operations that are undergoing a proposed suspension. ODA reviewed the policy and updated Inspection Procedures with organic staff during its March 2, 2020 internal refresher training; ODA provided a copy of the training agenda.

**Verification of Corrective Action:** The auditors reviewed ODA's inspection log and verified with certification staff that ODA did not conduct an annual on-site inspection of all its certified operations in 2019 and 2020.

**2023** Corrective Action: ODA updated its customer tracker for more real-time awareness of where operations are in the certification process and created an ARCGIS map of customer locations to assist with locating operations and grouping inspections. To ensure inspections are completed on all certified operations every year, in 2023, the Organic Program Manager began sending spreadsheets to the team that performs inspections and certification activities and discusses the numbers during the weekly Certification Meeting. For 2024, the Organic Program Manager will continue to send progress numbers each month (first Certification Meeting of each month) and has updated the 2024 internal timeline to complete all inspections by August 31, 2024. ODA submitted a timeline for 2024 to show how the inspection schedule fits in with other certification work.

## **Noncompliances Identified during the Current Assessment**

**AIA-7175-21** – **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:** ODA does not consistently demonstrate the ability to fully comply with the requirements for accreditation. ODA's policies, procedures, and work instructions for the review and approval of material inputs do not fully demonstrate the ability to fully comply with the requirements detailed in **NOP 3012 Interim Instruction Material Review**. The auditors found ODA does not maintain documentation to support its determinations about the status of a product's compliance with the regulations, including those products that are approved based on prior determination by another certifier, MRO, or the EPA.

**Corrective Action:** ODA reviewed input requirements with staff at several meetings; ODA provided records for the March 18, 2022 annual refresher training and March 29, 2022, April 5,

2022, and June 28, 2022 weekly meetings as evidence. ODA uses the Input Inventory form collect material information and records the source of each determination in a column named "Approved for Use in Organic Production By: (OMRI, WSDA, CDFA, NOP)."

AIA-1483-22 – 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:** ODA does not consistently demonstrate the ability to fully comply with the requirements for accreditation. The auditors reviewed ODA's Program Manual and Country Requirements document and found they contain incorrect or insufficient information. The Program Manual and Country Requirements documents incorrectly state the U.S.-Japan equivalence covers only plant-based products, incorrectly describes the scope and terms of the U.S.-Taiwan equivalence, and does not include the U.S.-U.K. equivalence requirements. This does not comply with NOP's organic equivalency trade requirements.

Corrective Action: ODA created or updated policy documents covering export requirements for Taiwan, Canada, the E.U., Korea, Switzerland, and the U.K. (OCP.DP.12, OCP.DP.15, OCP.DP.16, OCP.DP.17, OCP.DP.18, and OCP.DP.19, respectively), with direct links to online NOP resources about the trade arrangements. ODA updated its policy for Taiwan (OCP.DP.12) to include the correct attestation statement for exports to Taiwan. ODA also created a policy, "How to Support ODA Organic Program Customers Involved with Imports of Organic Products to the U.S." (OCP.DP.20) covering U.S. import requirements. ODA submitted a schedule of meetings during January 2024 in which these updates will be communicated to staff.

**AIA-1482-22** – **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:** The auditors' review of certification files found that ODA inspectors do not fully verify the accuracy and compliance of the organic system plan. The auditors reviewed three different inspection reports in which the inspector did not verify whether the export activities listed in the organic system plan were accurate and compliant with NOP international trade policies.

Corrective Action: ODA updated its Organic Handler Certification Inspection Report template to include specific questions about compliance with NOP trade arrangements. ODA provided refresher training to staff on March 18, 2022. The ODA organic program manager emailed ODA staff the NOP Exporting Organic Products Factsheet and NOP Importing Organic Products Factsheet on August 18, 2023.

**AIA-1484-22** – **Accepted.** 7 C.F.R. §205.501(a)(3) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670;"

**Comments:** *ODA* is not carrying out the provisions of the Act and regulations. The auditors reviewed a TM-11 Export Certificate ODA issued for a certified operation and found that ODA did not use the correct certifier abbreviation when creating the Unique Certificate Number on

the TM-11. This does not meet the requirements of NOP 2403 Certifying Agent Acronyms for TM-11 Export Certificates.

**Corrective Action:** ODA updated OCP.DP.12 to include the correct acronym and informed the two staff members who issue export certificates of the update. ODA submitted a copy of the updated policy and a sample TM-11 issued by ODA in April 2022.

**AIA-7176-21** – **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: The auditors reviewed certification files and found that ODA is not carrying out the provisions of the Act and regulations. ODA staff are not following a compliant adverse action process as outlined in their Quality Manual. The ODA Quality Manual states "If the customer fails to respond to a Notice of Denial, Proposed Suspension or Revocation of Certification within 30 days with a request for mediation or appeal, the ODA will inform the customer through written notification that its certification for organic production has been denied, suspended or revoked, as applicable and include a valid date of that action." The auditors reviewed four instances in which ODA staff issued Notices of Suspension five to ten months after the operations were issued a Notice of Proposed Suspension.

Corrective Action: ODA developed a timeline for 2024, which includes goal dates for specific activities throughout the certification cycle, including completing the adverse action process. ODA increased the number of "Reviewer/Certifiers" that can issue a notice of suspension, from one employee to three employees the organic program manager will be primarily for the complete noncompliance process while additional staff are being trained. ODA is tracking noncompliances in a spreadsheet to ensure timeliness. ODA submitted the timeline, the noncompliance tracker, and an updated copy of OCP.DP.03, Compliance and Appeal Procedures.

**AIA-7177-21** – **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:** *ODA did not meet the requirement to sample and test from 5% of its certified operations annually in 2020. The auditors reviewed ODA 's sample collection records and found that ODA sampled and tested from 3% of certified operations in 2020.* 

**Corrective Action:** ODA determined that the cause of the noncompliance was COVID-19 restrictions limiting onsite inspections and sampling opportunities. ODA has resumed onsite inspections, which will allow sampling to resume.

**AIA-1485-22** – **Accepted.** 7 C.F.R. §205.662(e) 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 or State organic program's governing State official shall send the certified operation a written notification of suspension or revocation."

**Comments:** The auditors reviewed a Notice of Proposed Suspension file and found that ODA incorrectly accepted corrective actions for a noncompliance after ODA had issued a Notice of Proposed Suspension to the certified operation.

**Corrective Action:** ODA updated OCP.DP.03, Compliance and Appeal Procedures, to include specific instructions for the noncompliance process. ODA also increased the number of "Reviewer/Certifiers" that can issue a notice of suspension from one employee to three employees; the organic program manager will be primarily for the complete noncompliance process while additional staff are being trained.

AIA-1486-22 – 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. Mediation shall be requested in writing to the applicable certifying agent. If the certifying agent rejects the request for mediation, the certifying agent shall provide written notification to the applicant for certification or certified operation. The written notification shall advise the applicant for certification or certified operation of the right to request an appeal, pursuant to §205.681, within 30 days of the date of the written notification of rejection of the request for mediation. If mediation is accepted by the certifying agent, such mediation shall be conducted by a qualified mediator mutually agreed upon by the parties to the mediation. If a State organic program is in effect, the mediation procedures established in the State organic program, as approved by the Secretary, will be followed. The parties to the mediation shall have no more than 30 days to reach an agreement following a mediation session. If mediation is unsuccessful, the applicant for certification or certified operation shall have 30 days from termination of mediation to appeal the certifying agent's decision pursuant to §205.681. Any agreement reached during or as a result of the mediation process shall be in compliance with the Act and the regulations in this part. The Secretary may review any mediated agreement for conformity to the Act and the regulations in this part and may reject any agreement or provision not in conformance with the Act or the regulations in this part."

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

- 1. One settlement agreement included non-finite terms that required ongoing compliance with a USDA organic regulation.
- 2. The terms of one settlement agreement were not compliant with **NOP 2609 Instruction Unannounced Inspections.** The settlement agreement terms allowed more than four hours notification prior to conducting an unannounced inspection.

Corrective Action: ODA updated OCP.DP.03, Compliance and Appeal Procedures, to include specific instructions for the mediation and settlement process, including the process for closing out settlements. ODA updated OCP.DP.05, Inspection Procedures, to state, "under no circumstances, including through noncompliance and mediation procedures, should a customer be given more than 4 hours' notice prior to an unannounced inspection."

**AIA-1487-22** – **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. Mediation shall be requested in writing to the applicable

certifying agent... If mediation is unsuccessful, the applicant for certification or certified operation shall have 30 days from termination of mediation to appeal the certifying agent's decision pursuant to § 205.681..."

**Comments:** *ODA* does not consistently require its operations to request mediation in writing. The auditor's review of mediation requests accepted by *ODA* and interviews with certification staff found that *ODA* had accepted a verbal request for mediation.

Corrective Action: ODA updated OCP.DP.03, Compliance and Appeal Procedures, to include specific language describing ODA's noncompliance process, including the statement that mediation requests must be in writing. ODA increased the number of "Reviewer/Certifiers" that can issue a notice of suspension from one employee to three employees; the organic program manager will be primarily for the complete noncompliance process while additional staff are being trained.

AIA-1488-22 – 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:** ODA does not ensure that its employees with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques prior to performing the duties assigned. The auditor's review of certification files and interviews with certification staff found the following:

- 1. The auditors reviewed one file in which the inspector did not verify whether an operation used another form of pest control prior to using a restricted pest input as is required by §205.271(a-d).
- 2. The auditors' review of an operation's certification files found that the inspector had failed to verify the cleaning and sanitation procedures described in the handling operation's organic system plan.

Corrective Action: ODA created Input Inventory forms to document certifier-approved inputs in organic system plans (OSPs). ODA updated its Organic System Plan (OCP.F.6) for Handling to include areas for inspectors to review sanitation practice documentation. ODA assigned all staff courses on handling, processing, and input requirements in the Organic Integrity Learning Center, to be completed by January 17, 2024. ODA submitted the inventory forms, updated OSP, and emails assigning the training to staff. ODA submitted a schedule of meetings during January 2024 in which these updates will be communicated to staff.



# NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

## AUDIT AND REVIEW PROCESS

An onsite Renewal assessment of the Oregon State Department of Agriculture (ODA) organic program was conducted on October 29 - 31, 2019. The National Organic Program (NOP) reviewed the auditor's report to assess ODA's compliance to the USDA organic regulations. This report provides the results of NOP's review of the certifier's corrective actions and assessment of the certifier's capability to operate as a USDA accredited certifier.

## **GENERAL INFORMATION**

Applicant Name	Oregon State Department of Agriculture
Physical Address	635 Capitol Street NE
Mailing Address	Salem, OR 97301
Contact & Title	Susanna L. Pearlstein, Ph.D. Interim Certification Program
	Manager and Produce Safety Program Manager;
	Larissa Dean, Certification Specialist & Auditor
E-mail Address	spearlstein@oda.state.or.us
Phone Number	503-986-4620
Reviewer & Auditors	Alison Howard, NOP Reviewer;
	Miguel A. Caceres, On-site auditor
Program	USDA National Organic Program (NOP)
Review & Audit Dates	Corrective Action Review: August 7, 2020 – February 3, 2021
	NOP Review: June 29, 2020
	Onsite audit: October 29 – 31, 2019
Audit Identifier	NOP-46-19
Action Required	No
Audit & Review Type	Renewal Assessment
A di4 Ob i 4i	To evaluate the conformance to the audit criteria; and to verify the
Audit Objective	implementation and effectiveness of ODA's certification
Audit & Determination	7 CFR Part 205, National Organic Program as amended
Criteria	
Audit & Review Scope	ODA's certification services in carrying out the audit criteria
	during the period: April 28, 2018 through October 31, 2019

ODA is a state government agency that was accredited on August 10, 2009. ODA is accredited for the scopes of Crops and Handling. ODA's certified operations at the time of the assessment included 153 operations: 96 Crops and 73 Handling (45 processors; 3 distributors; and 27 retailers). ODA does not certify grower groups. ODA's certified operations are located in the states of Oregon and California.

ODA's main office is in Salem, Oregon; however, certification staff also work out of offices in Medford and Gales Creek, Oregon. ODA's certification staff consist of the Certification Program Manager/Produce Safety Program Manager (CPM) and four Certification Specialists (CS). All CS's conduct certification reviews and inspections. Certification decisions are made by the CPM and one CS. Certification activities at the Medford and Gales Greek offices are limited to initial application review; inspection planning; inspection report review; materials review; and product label review. All certification activities, including certification decisions, are conducted out of the Salem office.

As part of the renewal assessment, two witness audits were conducted. The first witness audit was an observation of a Crops operation inspection and the second was an observation of handling operation inspection.

#### NOP DETERMINATION

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

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

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

# **Noncompliances from Prior Assessments**

NP6290LCA.NC5 – Cleared.

NOP.2.18.NC1 - Cleared.

NOP.2.18.NC2 - Cleared.

NOP.2.18.NC3 - Cleared.

NOP.2.18.NC4 - Cleared.

NOP.2.18.NC5 - Cleared.

NOP.2.18.NC6 - Cleared.

NOP.2.18.NC7 - Cleared.

## **Noncompliances Identified during the Current Assessment**

**AIA-5703-21 (NOP-46-19.NC1)** – **Accepted.** 7 C.F.R. §205.402(a)(1) states, "Upon acceptance of an application for certification, a certifying agent must: Review the application to ensure completeness pursuant to 205.401."

**Comments:** ODA does not consistently review applications for certification to ensure completeness. In three of six certification files reviewed, the organic system plans for handling operations did not include a description of the monitoring practices and procedures to be performed and maintained, including the frequencies at which they will be performed, to verify that the plan is effectively implemented. This is a requirement of §205.201(a)(3). ODA did not require the operations to provide the missing information.

Corrective Action: ODA updated the Initial Review Checklist for Crop and Handling operations (OCP.F.17 and OCP.F.18) to clearly state the need for follow up with the operations if material is missing. ODA also updated the Handling OSP Organic System Plan template (OCP.F.6) to require the description of monitoring practices and documentation for ensuring organic products are not contaminated during storage. Operations were provided the updated materials for 2020 and staff was trained on them at the annual internal refresher training on March 2, 2020; ODA provided a copy of the training agenda.

**AIA-5704-21 (NOP-46-19.NC2)** – **Accepted.** 7 CFR §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:** ODA did not conduct an annual inspection of all its certified operations in 2018. Of the 10 certification files reviewed, one handler operation did not receive an annual inspection for the 2018 certification year while ODA was working with the operation during the proposed suspension process.

**Corrective Action:** ODA determined that the cause of the noncompliance was misinterpretation of §205.403(a)(1) regarding operations that are undergoing a proposed suspension. ODA updated its Inspection Procedures (OCP.DP.5) to include operations that are undergoing a proposed suspension. ODA reviewed the policy and updated Inspection Procedures with organic staff during its March 2, 2020 internal refresher training; ODA provided a copy of the training agenda.



## NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

#### AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a mid-term and a Livestock scope extension assessment of Oregon Department of Agriculture (ODA). An onsite audit was conducted, and the audit report reviewed to determine ODA's capability to continue operating as a USDA accredited certifier.

## **GENERAL INFORMATION**

Applicant Name	Oregon Department of Agriculture (ODA)
Physical Address	635 Capital Street NE, Room 247
	Salem, OR 97301-2532
Mailing Address	635 Capital Street NE, Room 247
	Salem, OR 97301-2532
Contact & Title	Ms. Lindsay Eng, Program Manager
E-mail Address	leng@oda.state.or.us
Phone Number	541-386-2040
Reviewer(s) &	Graham Davis, NOP Reviewer; Lars Crail and Rebecca Claypool, On-site
Auditor(s)	Auditors.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	Corrective action review: February 22, 2017
	NOP assessment review: November 17, 2016
	Onsite audit: October 17 - 20, 2016
Audit Identifier	NP6290LCA
Action Required	None
Audit & Review Type	Mid-Term and Livestock Scope Extension Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the
	implementation and effectiveness of ODA's certification program.
Audit & Determination	7 CFR Part 205, National Organic Program as amended
Criteria	
Audit & Review Scope	ODA's certification services in carrying out the audit criteria during the
	period: August 22, 2014 through October 17, 2016. ODA's ability to offer
	livestock certification services.

ODA is a government agency accredited on August 10, 2009 and is accredited for the scopes of crops and handling. ODA requested to add a livestock scope to their accreditation. ODA's list of USDA organic certification operations at the time of the assessment includes 144 operations: Crops (76) and Handler/Processor/Exporter (68). There are no grower groups certified by ODA. Certified operations are located in Oregon and California.

ODA's administration office is located in Salem, Oregon; however, certification staff are located at district offices throughout the State and are State employees. ODA's staff consists of six individuals: Certification Programs Manager, two Certification Specialists, Administrative Support, Area Representative, and a Shipping Point Inspector. All ODA staff may conduct certification review; and, all may conduct inspections with the exception of the Programs Manager and the Administrative Support. Certification decisions are made by the Certification Programs Manager.

## SUMMARY OF WITNESS INSPECTIONS AND REVIEW AUDITS CONDUCTED

As part of the mid-term onsite assessment activities, five witness audits (observation of initial, annual, and unannounced inspections) were conducted on a crops (pears) operation; handler/processor operations (salsa, fruit, coffee roaster); and a handler/warehousing operation.

## **NOP DETERMINATION:**

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

# NP4230AKA.NC1- 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.

**NP6290LCA.NC1** – **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 3.1, describes the elements of an organic certificate that should be included.

**Comments:** The following organic certificate elements are incorrect or missing on the certificates issued by ODA:

- 1. The "Anniversary date" is defined by ODA as the date of when the next certificate should be issued and not the date of the operation's annual update is due.
- 2. The certification scope for crops is listed as "Organic Grower" and not as "Crops."

**2016 Corrective Action:** Since the mid-term audit, ODA has issued certificates with the date listed as "April 1st", which is the date when renewals are due each year. ODA changed the anniversary date to "April 1st" on their organic certificate template. ODA also changed "Grower" to "Crops" on their organic certificate template. ODA submitted its organic certificate template (Attachment A).

**NP6290LCA.NC2** – **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 2027, Personnel Performance Evaluations, Section 3.2(b) states "Field Evaluation (Inspectors only) Inspectors should be evaluated during an onsite inspection by a supervisor or peer (another inspector) at least annually."

**Comments:** Inspector field evaluations were not conducted for all inspectors in 2015. One inspector was not evaluated. ODA is planning to conduct field evaluations for all inspectors in 2016.

**2016 Corrective Action:** ODA conducted field evaluations for all four of its inspectors in 2016. Two of ODA's four inspectors have received field evaluations for 2017. The remaining two inspectors will be evaluated between April and June of 2017).

**NP6290LCA.NC3** – **Accepted.** 7 C.F.R. §205.403(c)(2) states, "The on-site inspection of an operation must verify: That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation;..."

**Comments:** During the witnessing of crop and handler inspections, the following issues were identified by the auditors:

- A seed inoculant was used by the operator that was not listed in the organic systems plan (OSP) and the inspector did not update the OSP with the operator, nor identify the omission as an issue of concern.
- During the witness audits, inspectors did not consistently use flow charts or facility/field maps to confirm and verify activities and locations of organic production and handling.
- An inspector did not verify the operation's use of an additional mixed-use packing line/equipment which was not identified in the OSP and was in operation during the inspection. Prior to the discovery of the additional packing line/equipment, the inspector did identify an unapproved wholesale label on product rolling off the packing line, but did not inspect and verify the additional packing line/equipment.
- During the inspection of a handler operation, the inspector did not adequately verify the storage and handling of products that are purchased from vendors other than the operation's subsidiary. For example, the inspector did not request to inspect any existing inventory or storage areas where these products are handled or kept.

- During the inspection of a crop operation, no maps were used by the inspector to identify, confirm, and record boundaries, buffer zones, and neighboring fields.
- ODA's system of requiring operations to complete an OSP upon initial application and then an annual update form during subsequent years does not facilitate the verification process. The current system of maintaining an accurate OSP is unmanageable due to the multiple documents and potential changes to the OSP during multiple years. After several years of providing annual OSP updates, there is no single document that clearly describes and records the operation's OSP. The existing system of maintaining OSP information is cumbersome to verify and subject to error.
- Inspectors use an inspection checklist as a reference and basis to conduct inspection activities rather than using the operation's current OSP and/or Annual Updates

2016 Corrective Action: ODA has created new inspection reporting forms that tie directly to review of the Organic System Plan. ODA's Organic Handler Certification Inspection Report requires verification of an operation's existing inventory and storage areas where products are handled. The organic handler inspection report also requires verification of implemented measures to prevent the comingling of organic and nonorganic products during processing and packaging of product. ODA has a new input inventory form that will be used by the customer to verify their inputs each year and will also be required during inspection verification. The new crop OSP form (OCP.F.5) requires that all buffers be listed and indicated on a farm map, the new inspection form (OCP.F.22) specifically asks inspectors if the crop OSP (including the farm map) is accurate. An annual update form is no long being used; the new OSP is now filled out once, and will be sent back to customers at the beginning of each calendar year for customers to update their current OSP and submit before the application deadline on April 1st. ODA will provide training on the new forms in March 2017.

**NP6290LCA.NC4** – **Accepted.** 7 C.F.R. §205.501(a)(4) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part;..."

**Comments:** During the witnessing of crop and handler inspections, the following issues were identified by the auditors:

- *ODA does not require inspectors to conduct and record mass-balance and trace-back verification activities during inspections.*
- When ODA inspectors do conduct mass-balance and trace-back verification activities to demonstrate compliance, they are insufficient.
  - During one inspection of a handler, a mass-balance verification was conducted; however, the inspector did not review or include actual sales figures, inventory, and consideration of parallel product handling. The mass-balance activity did not

- adequately test the operation's recorded information to assess the operation's organic sales during a specific time period.
- Ouring one inspection the inspector did not conduct a thorough trace-back of the operations records from sales to purchase of ingredients which would demonstrate compliant product handling and recording activities by the operation.

**2016 Corrective Action:** ODA submitted a revised inspection procedure requiring inspectors to conduct and document both a trace back exercise and a mass-balance audit for each operation during the onsite inspection. ODA created an audit trace back form to be used during inspections. ODA created and submitted audit trail worksheets for crops, livestock, and handling. ODA will provide training on trace back and mass balance exercises and the new forms in March 2017.

**NP6290LCA.NC5** – 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." The NOP website provides instructions and the terms of international trade arrangements. The 2016 Certifier Training Presentation, International Trade Arrangements, pp 31-33, instructs certifiers what must be verified.

**Comments:** During the witnessing of crop and handler inspections, the following issues were identified by the auditors:

- Inspectors are not verifying compliance of imported products or ingredients purchase through organic trade arrangements. OSPs are not designed to request this information from operations.
- During an inspection, the inspector accepted proof of an organic product with a transaction certificate instead of an organic certificate.

**2016 Corrective Action:** ODA revised and submitted their OSP template. The template now requires ODA's client to list the types of documentation they receive with imported products. ODA has created new inspection reporting forms that to ensure that adequate documentation is supplied for verification during inspection. ODA created and submitted inspection preparation forms which include a checkbox for collecting import certificates when applicable. ODA will provide training on import/export requirements, document verification, and the new forms in March of 2017.

**NP6290LCA.NC6** – **Accepted.** 7 C.F.R. §205.403(d) states, "*Exit interview*... The inspector must also address the need for any additional information as well as any issues of concern."

**Comments:** Operations are provided an "Exit Interview" report at the conclusion of the inspection. This document records Issues of Concern, Requested Items, and general inspector comments. When issues of concern are identified and recorded on this document, inspectors do not reference and list the organic regulations.

**2016 Corrective Action:** ODA submitted a revised exit interview form. The form requires that the inspector list citations with each issue of concern. ODA will provide training on the use of this form in March of 2017.

**NP6290LCA.NC7** – **Accepted.** 7 C.F.R. §205.402(a)(1)(2) states, "Upon acceptance of an application for certification, a certifying agent must: Review the application to ensure completeness pursuant to §205.401.... 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."

**Comments:** ODA is accepting initial Organic System Plans and Annual Updates that are incomplete and do not fully demonstrate how operations comply or plan to comply with USDA organic regulations and NOP policies:

- The use and of lot numbers are not fully disclosure and described.
- The nature of the business and the business activities conducted are not fully described.
- Incomplete maps
- *Incomplete flow charts*
- Labels are missing or missing approval marks.
- *Incomplete description of record keeping documents and evidence of trace-ability.*
- Missing or incomplete vendor lists.

**2016 Corrective Action:** ODA has revised and submitted its inspection preparation form (Attachment H). The revised form ensures that anything that was not originally on file is reviewed and/or collected during the onsite inspection. ODA revised its OSP template so that operations are required to clearly detail their recordkeeping and traceability programs. ODA is in the process of hiring a new Administrative Specialist (the position announcement closed on January 8, 2017). One of the roles of this new position will be to review every customer file for missing documents (labels, maps, process flow charts). ODA will provide training on the initial review process in March 2017.

**NP6290LCA.NC8** – **Accepted.** 7 C.F.R. §205.501(a)(1)(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:** ODA must modify the Livestock OSP and Inspection Report templates to include references to the USDA organic regulations and the NOP Handbook as similarly displayed on existing ODA Crops and Handling OSPs and Inspection Report templates.

**2016 Corrective Action:** ODA submitted updated livestock OSP and inspection reports to the NOP. The documents now reference the USDA organic regulations and the NOP Handbook. ODA plans to provide training on the livestock scope and the livestock OSP in March 2017



## NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

#### AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a renewal assessment of the Oregon Department of Agriculture (ODA). An onsite audit was conducted and the audit report reviewed to determine ODA's capability to continue operating as a USDA accredited certifying agent. This report provides the results of the renewal assessment and review of ODA's corrective actions.

## **GENERAL INFORMATION**

Applicant Name	Oregon Department of Agriculture (ODA)
Physical Address	635 Capital Street NE, Room 247, Salem, OR 97301
Mailing Address	635 Capital Street NE, Room 247, Salem, OR 97301
Contact & Title	Kate Allen, Certification Development and Programs Manager
E-mail Address	kallen@oda.state.or.us
Phone Number	(503) 576-9176
Reviewer(s) & Auditor(s)	Robert Yang, NOP Reviewer; Mike Lopez, Onsite Auditor
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	Review of corrective actions date: January 16, 2015 Onsite assessment date: August 18 – 22, 2014
Audit Identifier	NP4230AKA
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 ODA's certification system.
Audit & Determination	7 CFR Part 205, National Organic Program as amended
Criteria	
Audit & Review Scope	Review of corrective actions submitted on December 23, 2014 for noncompliance resulting from the renewal assessment.

The Oregon Department of Agriculture (ODA) is a state government entity which was initially accredited on August 10, 2009 for the scopes of crops and processing/handling. ODA currently certifies a total of 89 operations (43 crops, 46 processors), all of which are located in Oregon. All key activities are performed in ODA's office in Salem, Oregon.

#### NOP DETERMINATION:

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

NP0306OOA.NC1 – Cleared NP0306OOA.NC2 – 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.

**NP4230AKA.NC1- Accepted.** 7CFR §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." Furthermore, 7CFR §205.304(a)(1)(iii) states, "Agricultural products in packages described in §205.301(c) may display on the principal display panel, information panel, and any other panel ... the statement: "Made with organic ..." which appears in letters that do not exceed one-half the size of the largest type size on the panel...."

**Comments:** The "Made with Organic" statement on a label approved by ODA was the largest type size on the panel.

**Corrective Action:** ODA issued a notice of noncompliance to the operation for the noncompliant label. The operation submitted a revised label, which was verified by ODA to be compliant. ODA also updated its Label Review Procedures (revision 2.3) and Organic Product and Label Review checklist (revision 2.0) to include verification of the type size of a "Made with Organic" statement. Certification review staff has been trained on the updated procedure and checklist.

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## **AUDIT INFORMATION**

ACA Name:	Oregon Department of Agriculture (ODA)
Est. Number:	N/A
Physical Address:	635 Capital Street NE, Room 247, Salem, OR 97301
Mailing Address:	635 Capital Street NE, Room 247, Salem, OR 97301
Contact & Title:	Lindsay Eng, Program Manager
E-mail Address:	leng@oda.state.or.us
Phone Number:	503-872-6600
Auditor(s):	Lars Crail, NOP Regional Accreditation Manager (RAM)
Program:	USDA National Organic Program (NOP)
Audit Date(s):	NOP Review: December 7, 2010 through March 14, 2011.
Audit Identifier:	NP0306OOA
Action Required:	No
Audit Type:	Corrective Action Review
Audit Objective:	To verify continuing compliance to the requirements of the audit criteria.
Audit Criteria:	7 CFR Part 205, National Organic Program, Final Rule, December 21, 2000, amended August 24, 2010. Program Handbook: Guidance and Instructions For Accredited Certifying Agents & Certified Operations, Winter Edition, January 31, 2011.
Audit Scope:	The company's quality manual including personnel, processes, procedures, facilities, and related records.
<b>Location(s) Audited:</b>	Desk

On December 7, 2010, NOP staff received and reviewed the Accreditation, Review, and Compliance Branch (ARC) audit report of ODA's Initial On-site audit. Prior to NOP issuing a Notice of Noncompliance to ODA, they submitted corrective materials addressing NC1:

- ODA's Annual Report.
- ODA's Program Manual procedure update, CID.OCP.DP.8.

On December 15, 2010, NOP issued a Notice of Noncompliance to ODA requesting submission of corrective actions addressing NC2.

ODA staff submitted the following materials on January 12, 2011 and March 16, 2011:

- A copy of the Notice of Noncompliance issued to the operation found noncompliant during ARC's review of client files.
- ODA's Program Manual update regarding certification procedures: CID.OCP.DP.11.



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#### **FINDINGS**

Corrective actions and supporting documentation submitted by Oregon Department of Agriculture staff adequately addressed the two noncompliances.

NP0306OOA.NC1 – Adequately Addressed. NOP §205.510(a) states, "Annual report and fees. An accredited certifying agent must submit annually to the Administrator, on or before the anniversary date of the issuance of the notification of accreditation, the following reports and fees: (1) A complete and accurate update of information submitted pursuant to §§205.503 and 205.504; (2) Information supporting any changes being requested in the areas of accreditation described in §205.500; (3) A description of the measures implemented in the previous year and any measures to be implemented in the coming year to satisfy any terms and conditions determined by the Administrator to be necessary, as specified in the most recent notification of accreditation or notice of renewal of accreditation; (4) The results of the most recent performance evaluations and annual program review and a description of adjustments to the certifying agent's operation and procedures implemented or to be implemented in response to the performance evaluations and program review." Interviews with the Program Manager indicated that an annual report had not been submitted to the Administrator in 2010. Corrective Action: On November 15, 2010, prior to completion of the ARC Audit Report NO0306OOA NC, ODA staff submitted their annual report to NOP. On December 8, 2010, ODA staff submitted an updated program manual procedure (CID.OCP.DP.8) covering the annual report and fee submission requirements. All documents were reviewed for compliance and found to adequately address the noncompliance.

NP0306OOA.NC2 – Adequately Addressed. NOP § 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." The decision letter of one of the files reviewed had items that were identified as recommendations which were non compliant to the NOP Rule. Any issues found that are non compliant to the NOP Rule must be identified as a non-compliance. Corrective Action: On January 12, 2011 and March 14, 2011 ODA staff submitted materials to address the noncompliance. ODA staff issued a Notice of Noncompliance to the operator on November 17, 2010. On January 12 and March 16, 2011, ODA staff submitted an updated program manual procedure (CID.OCP.DP.11) addressing and clarifying procedures for the issuance of noncompliances. All documents were reviewed for compliance and found to adequately address the noncompliance.