

UNITED STATES DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE
BEFORE THE ADMINISTRATOR

In re:)	
Organic Food Development)	Administrator's Decision
and Certification Centre of China)	
Nanjing, China)	APL-045-19
)	

This Decision responds to an appeal (APL-045-19) of a Notice of Noncompliance and Proposed Suspension of Accreditation issued to the Organic Food Development and Certification Centre of China (OFDC) by the U.S. Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP). The certifier has been deemed not in compliance with the Organic Foods Production Act of 1990 (Act)¹ and the U.S. Department of Agriculture organic regulations.²

BACKGROUND

The Act authorizes the Secretary to accredit agents to certify crop, livestock, wild crop, and handling operations pursuant to the USDA organic regulations (7 C.F.R. Part 205). Accreditation of certifying agents is done by the NOP, which also initiates compliance actions to enforce program requirements. Noncompliance procedures for certifying agents are set forth in §205.665 of the USDA organic regulations. Persons subject to the Act who believe that they are adversely affected by a noncompliance decision of the NOP may appeal such decision to the

¹ 7 U.S.C. 6501-6522

² 7 C.F.R. Part 205

AMS Administrator, pursuant to §205.680 Adverse Action Appeals Process – General, and §205.681, Appeals of the USDA organic regulations.

FINDINGS OF FACT

1. On April 4, 2014, NOP accredited OFDC for crops, wild crops, livestock, and handling/processing. OFDC currently certifies 36 operations.
2. On June 11–15, 2018, NOP conducted a renewal audit/accreditation assessment of OFDC.
3. On March 7, 2019, NOP issued a Notice of Noncompliance and Proposed Suspension of Accreditation to OFDC based on the findings of the June 2018 audit.
4. On April 3, 2019, OFDC filed an Appeal.

DISCUSSION

The NOP proposed a suspension of OFDC’s accreditation, stating that OFDC is noncompliant with the USDA organic regulations at 7 CFR §205 as follows:

The organic regulations at 7 CFR §205.100(a) state, “Except for operations exempt or excluded in §205.101, each production or handling operation or specified portion of a production or handling operation that produces or handles crops, livestock, livestock products, or other agricultural products that are intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food groups(s))” must be certified according to the provisions of subpart E of this part and must meet all other applicable requirements of this part.”

The organic regulations at 7 CFR §205.201(a) state, “An organic production or handling system plan must include: (1) A description of practices and procedures to be performed and maintained, including the frequency with which they will be performed; (2) A list of each

substance to be used as a production or handling input, indicating its composition, source, location(s) where it will be used, and documentation of commercial availability, as applicable; (3) 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; (4) A description of the recordkeeping system implemented to comply with the requirements...; (5) A description of the management practices and physical barriers established to prevent commingling of organic and nonorganic products on a split operation and to prevent contact of organic production and handling operations and products with prohibited substances; and (6) Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations.”

The organic regulations at 7 CFR §205.403(c)(1) state, “The on-site inspection of an operation must verify: The operation’s compliance or capability to comply with the Act and the regulations in this part.”

The organic regulations at 7 CFR §205.403(e)(2) state, “A copy of the on-site inspection report and any test results will be sent to the inspected operation by the certifying agent.”

The organic regulations at 7 CFR §205.405(a) state, “When the certifying agent has reason to believe, based on a review of the information specified in §205.402 or §205.404, that an applicant for certification is not able to comply or is not in compliance with the requirements of this part, the certifying agent must provide a written notification of noncompliance to the applicant.” Additionally, §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...”

The organic regulations at 7 CFR §205.501(a)(3) state, “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.” Specifically, §205.404(b) states, “The certifying agent must issue a certificate of organic operation...”

The organic regulations at 7 CFR §§205.501(a)(5-6) state, “A private or governmental entity accredited as a certifying agent under this subpart must: 5) 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; 6) 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.”

The organic regulations at 7 CFR §205.501(a)(15)(i) state, “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...”

The organic regulations at 7 CFR §205.501(a)(21) state, “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 organic regulations at 7 CFR §205.504(a)(4) states, “A private or governmental entity seeking accreditation as a certifying agent must submit the following documents and information to demonstrate its expertise in organic production or handling techniques; its ability to fully comply with and implement the organic certification program established...and its ability to comply with the requirements for accreditation set forth in §205.501: A description of any training that the applicant has provided or intends to provide to personnel to ensure that they comply with and implement the requirements of the Act and the regulations in this part.”

The organic regulations at 7 CFR §205.642 state, “Fees charged by a certifying agent must be reasonable, and a certifying agent shall charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator. The certifying agent shall provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification.”

NOP stated in the March 7, 2019 Notice of Noncompliance and Proposed Suspension of Accreditation that the June 11-15, 2018 onsite renewal assessment of OFDC’s organic program revealed 13 noncompliances. The assessment covered OFDC’s certification services from July 2015 through June 2018. NOP found that 6 noncompliances remained outstanding from the prior audit in July 2015. Evidence showed that OFDC hadn’t fully implemented the corrective actions it previously presented to NOP for those 6 noncompliances and which NOP had approved to continue accreditation. NOP also found 7 new noncompliances during the June 2018 audit.

The Noncompliance Report from the June 2018 audit, dated October 17, 2018, describes all the noncompliances which occurred in the areas of OFDC inspection and certification services. These included OFDC personnel not properly reviewing and considering certification applications; deficiencies in the conducting of inspections; inadequate process for certification decisions; and improper issuance of and/or the failure to issue adverse action notices to operations. The June 2018 audit also revealed that OFDC 's personnel continue to lack the knowledge necessary to implement an organic certification program. Therefore, NOP recommended a suspension of OFDC's accreditation for 1 year.

OFDC stated in its Appeal that it is aware there are defects in some of its procedures and operations and that it hasn't fully met all the requirements for accreditation. However, OFDC contends it hasn't "seriously violated" any of the organic regulations or NOP procedures and policies. OFDC states it is making efforts to understand the standards and requirements of accreditation and is trying to resolve its noncompliances. OFDC stated it is "actively working" on resolving 8 of the 13 noncompliances cited in the March 7, 2019 Notice of Noncompliance and Proposed Suspension and plans on having all noncompliances resolved within 3 months (this would be July 2019, as the Appeal was filed April 3, 2019). OFDC also states it sent staff to the Biofach conference in Germany to meet with NOP staff, and had planned on attending the NOP training in Greenville, South Carolina on January 29, 2019, which was not held. OFDC states it will have in-depth training for personnel in the next few months. OFDC submitted a "Training Plan for Noncompliance Corrective Action to NOP 2019" addressing the noted noncompliances and stating that training in the deficient areas would be conducted in the "near future."

OFDC also submitted several new or revised documents with its Appeal which are titled:

Organic Certification Manual; Certification Staff Management Procedure; Guidance of Unannounced Inspection; Procedure of Staff Capability Assessment; Organic Contract Review Form Attachment; and Revised Certificate Template. The documents were drafted or revised April 1, 2019, and cover such topics as the hiring, training and evaluation of personnel; the duties of each position; the issuance of adverse action notices; and certification procedures including reviewing applications, conducting inspections, verifying information in Organic System Plans (OSP), conducting exit interviews, and providing inspection report copies to operations. The materials also cover OFDC's fees and residue testing.

However, the AMS review of this case finds voluminous evidence which substantiates OFDC's history of noncompliance with the Act and the organic regulations dating back to its application for accreditation. The noncompliances described in the Notice of Proposed Suspension of Accreditation are numerous and recurrent. OFDC has acknowledged defects in its procedures and operations, and that it hasn't met all the requirements for accreditation. OFDC failed to implement corrective actions for numerous noncompliances, despite previously having submitted corrective action plans to resolve the noncompliances and obtaining NOP's approval of the corrective actions. Further, in addition to not correcting previously noted noncompliances, the June 11–15, 2018 on-site renewal assessment revealed more noncompliances.

Specifically, the 2018 on-site assessment found that OFDC inspectors did not conduct inspections in accordance with the USDA organic regulations. OFDC inspectors didn't provide operations with a copy of the inspection report after unannounced inspections, and only provided a copy of test results when requested. Further, inspectors (1) couldn't consistently determine or weren't aware of labeling requirement differences for retail products versus nonretail containers; (2) didn't verify that OSPs accurately reflected practices of operations; (3) couldn't conduct

adequate traceability verifications; (4) didn't know to conduct exit interviews after inspections have concluded; (5) didn't review records such as sales invoices, shipping documents, and input material purchase invoices; (6) didn't review actual transactional documents and relied instead on logs generated by the operations; and (7) didn't reference the specific NOP organic regulations when identifying concerns to operations. Inspectors also addressed issues of concern which were not based on requirements in USDA organic regulations and inspectors issued Notices of Noncompliance, although they don't have the authority to do so. Additionally, OFDC improperly refers to China Food Safety Standards for pesticide tolerance levels instead of the Environmental Protection Agency tolerance levels and Food and Drug Administration action levels when pesticides are found. OFDC doesn't have a procedure for addressing pesticide residue test results.

Other noncompliances identified in the Noncompliance Report of October 17, 2018 include deficiencies in OFDC's template OSPs, which do not comply with the USDA organic regulations because they are incomplete and lack the detail needed for certification staff to effectively review and determine the compliance of operations. OFDC's certification staff also do not request sufficient documentation to review inputs according to NOP policies and procedures to determine whether the material may be used in organic production or handling; incorrectly identify certification anniversary dates; and issue improperly worded organic certificates. Overall, OFDC's certification personnel conducting certification reviews and making certification decisions don't demonstrate an adequate understanding of the USDA organic regulations and policies. This has resulted in notices of noncompliance not being issued when inspection reports identified issues of concerns; improperly granting certification to operations; improperly issuing adverse action notices to operations and not following procedures

for obtaining the operations' corrective actions; and not submitting Notices of Denial of Certification to the AMS Administrator after issuance. OFDC's fee schedule doesn't provide information on the potential refund of fees, and the schedule wasn't approved by NOP.

OFDC was also found deficient in the evaluation and training of its personnel. OFDC doesn't conduct annual field evaluations, including witness inspections, of its inspectors; and didn't provide NOP with a description of the training it intends to provide to its certification personnel to ensure they comply with and implement the NOP regulations. This has resulted in practices that are not consistent with the USDA organic regulations and NOP policies.

OFDC's noncompliance with the organic regulations date predates its accreditation by NOP. The Pre-Decisional Onsite Audit Report of the July 13–19, 2013 assessment revealed noncompliances in OFDC's planned certification services. OFDC's Combined Notice of Noncompliance and Denial of Certification template lacked information on an operation's right to reapply for certification, file an appeal, or request mediation. OFDC hadn't established procedures for selecting qualified mediators or procedures for notifying operations receiving adverse action notices on the right to appeal if mediation is unsuccessful. Additionally, OFDC was uncertain on who processes appeals to its adverse action notices, and the charging of fees for annual residue testing samples. NOP issued a Notice of Noncompliance to OFDC on January 2, 2014 for these noncompliances and OFDC submitted a response addressing the 4 noncompliances. NOP detailed OFDC's corrective actions in the Pre-Decisional Audit Report of March 11, 2014 and granted accreditation to OFDC on April 4, 2014. OFDC subsequently signed the Terms of Accreditation document on April 17, 2014 which required OFDC to resolve any deficiencies identified during desk audits and onsite evaluations by the date set by NOP, and to comply with the Act and NOP regulations, directives, and guidance. OFDC also agreed to

conduct an annual performance evaluation of all personnel who review certification applications; perform onsite inspections; review certification documents; evaluate qualifications for certification; make recommendations concerning certification or make certification decisions; and implement measures to correct any deficiencies in these areas.

However, the Onsite Assessment of July 14–17, 2015 revealed new noncompliances. The Corrective Action Report for the July 2015 assessment states that the 4 noncompliances previously noted during the July 2013 Pre-Decisional Onsite Audit Report and in the January 2, 2014 Notice of Noncompliance were corrected or cleared; however, 15 new noncompliances were found. The new noncompliances appeared in the areas of certification services; training; and maintaining personnel with the knowledge and expertise to administer the NOP organic certification program. NOP issued a Notice of Noncompliance on May 19, 2016 regarding the July 2015 onsite assessment, and asked OFDC to submit proposed corrective actions for all the noncompliances within 30 days of the notice's date. NOP instructed OFDC to indicate how the noncompliances will be corrected and how OFDC's management system will be modified to prevent future noncompliances. (A description of the corrective actions and NOP's acceptance is detailed in the Corrective Action Report for the July 2015 assessment.) NOP issued a Notice of Continued Accreditation on November 23, 2016 stating that corrective actions submitted in response to the 15 noncompliances from the July 2015 onsite assessment and prior noncompliances are accepted. NOP stated that the corrective actions would be verified during the next on-site assessment. However, as noted above, the June 11–15, 2018 onsite assessment revealed that 6 noncompliances from the July 2015 assessment remained outstanding as OFDC failed to properly and adequately implement the corrective actions. Further, the June 2018 onsite assessment revealed 7 new noncompliances.

CONCLUSION

The evidence substantiates that OFDC has violated the organic regulations at 7 CFR §205.100(a); 7 CFR §205.201(a); 7 CFR §403(c)(1); 7 CFR §205.403(e)(2); 7 CFR §205.405(a); 7 CFR §205.406(c); 7 CFR §205.501(a)(3); 7 CFR §§205.501(a)(5-6); 7 CFR §205.501(a)(15)(i); 7 CFR §205.501(a)(21); 7 CFR §205.504(a)(4); and 7 CFR §205.642. An accredited certifying agent must demonstrate the ability to fully comply with the requirements for accreditation set forth in the organic regulations. Specifically, an accredited certifying agent is required pursuant to 7 CFR 205.501, General requirements for accreditation, to “use a sufficient number of adequately trained personnel, including inspectors and certification review personnel...(and) 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.” Further, a certifying agent 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.”

OFDC has a history of noncompliance with the organic regulations regarding its certification services and oversight of its certification personnel. Despite being given opportunities to permanently resolve the noncompliances and submitting corrective actions which appear adequate, OFDC hasn't consistently implemented the corrective actions. While some noncompliances are resolved, others are not, and new noncompliances were subsequently found. OFDC doesn't contend that the noncompliance findings were in error and acknowledges there are 'defects' in its procedures and operations and that it hasn't fully met the requirements for accreditation.


In its appeal, OFDC submitted new or revised manuals/procedures regarding various aspects of its certification services; however, there is no evidence that these new or revised procedures have been implemented. Further, the procedures were only allegedly adopted effective April 1, 2019, and therefore, have not been reviewed by NOP's Accreditation and International Activities Division. OFDC is attempting to resolve noncompliances through the appeals process. However, these efforts are belated. Further, it is concerning that after 5 years of accreditation, OFDC states it is still making efforts to "understand the standards and requirements of accreditation," and NOP has found numerous noncompliances related to critical accreditation activities.

DECISION

The appeal is denied and OFDC's accreditation is to be suspended for 1 year. Attached to this formal Administrator's Decision is a Request for Hearing form. OFDC has thirty days to request an administrative hearing before an Administrative Law Judge. If OFDC does not request a hearing in that period, this Decision will be implemented and the suspension of OFDC's accreditation will become final.

In accordance with the organic regulations at 7 C.F.R. §205.665, OFDC may apply for reinstatement of its accreditation after the 1 year suspension has been served, in accordance with §205.502 of the organic regulations.

Done at Washington, D.C., on this 24th
day of June, 2019.



Bruce Summers
Administrator
Agricultural Marketing Service