

UNITED STATES DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE
BEFORE THE ADMINISTRATOR

In re:)
)
)
Eco Gold Nutri and Organics LLP) **Administrator’s Decision**
)
) **APL-050-24**
Indore, Madhya Pradesh,)
India)

This Decision responds to an Appeal (APL-050-24) of a Notice of Proposed Suspension under the National Organic Program (NOP) issued to Eco Gold Nutri and Organics LLP (EGNO) of Indore, Madhya Pradesh, India by OneCert International Private Limited (OCI), a USDA accredited certifying agent. The operation has been deemed not in compliance with the Organic Foods Production Act of 1990 (Act)¹ and the U.S. Department of Agriculture (USDA) organic regulations.²

BACKGROUND

The Act authorizes the Secretary to accredit agents to certify crop, livestock, wild crop, and/or handling operations to the USDA organic regulations (7 C.F.R. Part 205). Certifying agents also initiate compliance actions to enforce program requirements, as described in section 205.662, Noncompliance procedure for certified operations. Persons subject to the Act who believe they are adversely affected by a noncompliance decision of a certifying agent may appeal

¹ 7 U.S.C. 6501-6522

² 7 C.F.R. Part 205

such decision to the USDA Agricultural Marketing Service (AMS) pursuant to § 205.680 Adverse Action Appeals Process – General, and § 205.681, Appeals of the USDA organic regulations.

FINDINGS OF FACT

1. On January 10, 2019, EGNO was certified for handling by OCI.
2. On June 8, 2022, OCI issued a Notice of Noncompliance after finding a prohibited substance on sampled and tested product.
3. On July 14, 2022, OCI issued a Notice of Noncompliance Status letter stating that the prior noncompliance notice remains unresolved.
4. On August 10, 2022, OCI issued a Notice of Noncompliance Resolution after confirming that the affected produce would be sold as conventional.
5. On June 8, 2023, NOP issued an Investigative Request to OCI, requesting that OCI investigate a report of several prohibited substances being found on EGNO product imported into the United States.
6. On June 26, 2023, OCI issued a Notice of Noncompliance based on an importer of EGNO reporting a finding of several prohibited substances on EGNO product.
7. On July 20, 2023, OCI issued a Notice of Noncompliance Resolution, imposing corrective actions to be taken by EGNO, which OCI stated would be verified at the next inspection.
8. On November 2, 2023, OCI issued a Notice of Noncompliance after a NOP Accreditation Auditor was denied access to EGNO's facility.
9. On December 5, 2023, OCI issued a Notice of Noncompliance after a tested sample from EGNO revealed the presence of several prohibited substances.

10. On March 28, 2024, OCI issued a Notice of Proposed Suspension after finding that EGNO's reply to the December 5, 2023 noncompliance notice was insufficient.
11. On April 22, 2024, EGNO requested mediation of the proposed suspension.
12. On April 24, 2024, OCI issued a Notice of Mediation Rejection.
13. On May 11, 2024, EGNO filed an Appeal.

REGULATORY CITATIONS

The USDA organic regulations at 7 C.F.R. §205.102, Use of the term, “organic,” state that, “Any agricultural product that is sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” must be: ... (b) Handled in accordance with the requirements specified in §205.101 or §§205.270 through 205.272 and all other applicable requirements of this part 205.”

The organic regulations at §205.105, Allowed and prohibited substances, methods, and ingredients in organic production and handling, state that, “To be sold or labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” the product must be produced and handled without the use of: (a) Synthetic substances and ingredients, except as provided in §205.601 or §205.603; (b) Nonsynthetic substances prohibited in §205.602 or §205.604 ...”

The organic regulations at §205.201, Organic production and handling system plan, state that, “(a) The producer or handler of a production or handling operation ... intending to sell, label, or represent agricultural products as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” 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: (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; ... (4) A description of the recordkeeping system implemented to comply with the requirements established in §205.103; (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 §205.270, Organic handling requirements, state that, “(c) The handler of an organic handling operation must not use in or on agricultural products intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” or in or on any ingredients labeled as organic: (1) Practices prohibited under paragraphs (e) and (f) of §205.105.”

The organic regulations at §205.400, General requirements for certification, state that, “A person seeking to receive or maintain organic certification under the regulations in this part must: (a) Comply with the Act and applicable organic production and handling regulations in this part; (b) Establish, implement, and update annually an organic production or handling system plan ... (c) Permit on-site inspections with complete access to the production or handling operation, including noncertified production and handling areas, structures, and offices by the certifying agent ... (f) Immediately notify the certifying agent concerning any: (1) Application, including

drift, of a prohibited substance to any field, production unit, site, facility, livestock, or product that is part of an operation ...”

The regulations at §205.406, Continuation of certification, states, that “(a) To continue certification, a certified operation must annually pay the certification fees and submit the following information, as applicable, to the certifying agent: (1) An updated organic production or handling system plan ... (4) Other information as deemed necessary by the certifying agent to determine compliance with the Act and the regulations in this part.”

DISCUSSION

EGNO was certified organic for handling by OCI on January 10, 2019. EGNO handles/processes soybean meal, soybean seeds, soybean meal expeller, soybean crude oil, cracked corn, and corn. Specifically, the term soybean or soybean seed refers to the whole yellow seeds, while soybean meal or soybean cake refers to product derived from soybean seeds via a pressure extrusion process that extracts the soybean oil. Per OCI, soybean meal powder is soybean meal that goes through the hammer mill and is converted to powder form. OCI explained that this last product is sometimes referred to as “soybean meal powder (waste).” However, it is not ‘waste’ as one normally defines it.

OCI conducted a container inspection of EGNO on May 26, 2022, taking a sample of organic soybean meal, specifically organic oil cake and oil cake meal of soybean expeller from Lot OSBM/06/22-23. The sample was tested by NAWaL Analytical Laboratories and the May 30, 2022 report shows that Chloropyrifos was detected at 0.105 mg/kg. Therefore, on June 8, 2022, OCI issued a Notice of Noncompliance to EGNO citing to the finding. OCI stated that

EGNO must submit all related records, investigate the possible origin of the contamination, and must explain their corrective and preventive action plan to prevent future contamination.

After EGNO failed to address and resolve the noncompliance notice, OCI issued a Notice of Noncompliance Status with Adverse Action and Conditions on July 14, 2022. OCI reiterated the prior findings and stated that at EGNO's request, it had retested the available sample, which again revealed prohibited substance Chloropyrifos, at 0.130 mg/kg. The level was even higher than the first tested sample. These levels of Chloropyrifos, found on both tested samples, also exceed the 5% of the EPA (Environmental Protection Agency) tolerance level for this substance allowed in organic production or handling. The EPA sets limits on the amount of a chemical allowed on agricultural products, and there is a 5% threshold allowed for use on organic agricultural products. If the EPA hasn't established a tolerance level for a substance, it is banned from organic production and handling.

Subsequently, on July 30, 2022, OCI issued an Additional Inspection Authorization to EGNO, stating that due to the prior finding of a prohibited substance on EGNO product, it is subject to an additional inspection at which stock would be verified, and product would be sampled. The inspection was conducted August 1, 2022, and the inspector noted in the report that samples were collected from two other lots, which didn't reveal the presence of prohibited substances. EGNO also agreed to downgrade Lot OSBM/06/22-23, in which Chloropyrifos was detected, to conventional. Therefore, OCI issued a Notice of Noncompliance Resolution on August 10, 2022.

Subsequently, USDA accredited certifier CCOF conducted sampling and testing of EGNO product which one of CCOF's certified operations had imported into the United States. Sales, shipping, and customs documents, including the NOP Import Certificate, show the

“organic oil – cake and oil cake meal of soybean, expeller variety” product originated with EGNO, as Lot OSBM/21/22-23, and entered the United States on April 6, 2023. The EGNO organic soybean meal was sampled April 19, 2023 by CCOF, and the AGQ Lab Analytical Report of April 21, 2023 revealed the presence of several prohibited substances. Specifically, the report shows the following: Azoxystrobin at 0.012 mg/kg; Chlorpyrifos at 0.020 mg/kg; Isoprothiolane at 0.022 mg/kg; Pyrimethanil at 0.016 mg/kg; Tebuconazole at 0.022 mg/kg; Thiamethoxam at 0.018 mg/kg; and Tricyclazole at 0.050 mg/kg. The Azoxystrobin level is below the 5% threshold allowed in organic production and handling. However, the Chlorpyrifos and Tebuconazole are at levels above the 5% organic allowance; and there is no EPA tolerance level for Isoprothiolane, Pyrimethanil, Thiamethoxam, or Tricyclazole. Therefore, they are not allowed at any level in organic production and handling.

After being informed of the finding of several prohibited substances on EGNO product, NOP wrote OCI on June 8, 2023, requesting that OCI conduct an investigation. NOP identified the EGNO Lot number, importer, and laboratory findings, also stating that the inspector had witnessed the arrival and receipt of sealed containers with the EGNO product. NOP requested numerous documents from EGNO, including inspection reports, a supplier list, purchase records for ingredients used to make Lot OSBM/21/22-23, production records, export records; and asked OCI to report its investigative findings to NOP.

Having been informed of the prohibited substance findings in EGNO product, OCI issued a Notice of Noncompliance on June 26, 2023, which was updated July 8, 2023, to include NOP’s Compliance and Enforcement Division’s case number. The specific findings were detailed, and EGNO was asked to submit various records for identified lots, investigate the possible source of the contamination, and present its corrective and preventive action plan to prevent future

contamination. It is noted that a prior Notice of Noncompliance issued on June 8, 2022, imposed the same requirements after a finding of prohibited substance residue.

On June 30, 2023, EGNO submitted a Reply to the June 26, 2023 noncompliance notice. EGNO stated that it investigated the matter, and no other customers receiving product from that lot have complained about prohibited substance residue. EGNO stated that pesticides weren't found in their processing facility, and presented actions it would take to prevent future findings of prohibited substance. However, EGNO also questioned how sampling was done overseas (meaning the United States); suggested that perhaps the individual conducting sampling mishandled or contaminated the sample; and also stated that contamination may occur during the unloading of containers. However, as stated above, the CCOF inspector witnessed the arrival of the sealed container with the EGNO product; and therefore, contamination did not appear to occur at the port. Further, it was a CCOF inspector who is trained in doing such sampling who collected the EGNO sample.

However, on July 20, 2023, OCI issued a Notice of Noncompliance Resolution, setting forth numerous corrective actions that ENGNO must take to prevent any future occurrences of contamination, and stating that the implementation of these actions would be verified at the next EGNO inspection. OCI then sent a Reply to Investigation Request to NOP on July 22, 2023, confirming the product sampled by CCOF for its certified operation originated with EGNO. OCI detailed its investigation, including the issuance of a noncompliance notice to EGNO on June 26, 2023; EGNO's response; and the fact that an unannounced inspection of EGNO was conducted June 30, 2023, and a tested sample taken at that time didn't reveal prohibited substances. OCI stated that their investigation didn't find any prohibited substances being used at the EGNO

facility; and that the lot found to be contaminated by the CCOF sampling and testing would be downgraded to conventional. Therefore, OCI issued a resolution notice.

However, on November 2, 2023, OCI issued a Notice of Noncompliance to EGNO after it denied access to an NOP Accreditation Division auditor on October 30, 2023. The Accreditation Division auditor was conducting a review audit of another operation, certified by another certifier. The EGNO processing facility is at the same location as that operation; therefore, the NOP auditor decided to visit EGNO, but was denied access. Further, OCI cited to EGNO's statement that only waste materials were present at the facility at that time. However, the NOP auditor observed through a window that there were also soybeans present. OCI again asked EGNO to present a corrective and preventive action plan to ensure the noncompliance wouldn't occur again. EGNO stated in its November 16, 2023 Reply to the November 2, 2023 Notice of Noncompliance, that their facility was closed on October 30, 2023 due to a local labor holiday.

However, after the NOP Auditor was denied access on October 30, 2023, he asked OCI to conduct an unannounced inspection and collected a sample of soybean meal powder (waste). The OCI inspector gained access on October 31, 2023 and collected the requested samples. The sample was sent to Eureka Analytical Services by the USDA, and the resulting November 14, 2023 lab report found prohibited substances as follows: Azoxystrobin at 0.029 mg/kg; Chlorpyrifos at 0.027 mg/kg; Clothianidin at 0.018 mg/kg; Isoprothiolane at 0.092 mg/kg; Tebuconazole at 0.054 mg/kg; Thiamethoxam at 0.042 mg/kg; and Tricyclazole at 0.063 mg/kg. The Azoxystrobin, Chlorpyrifos, Clothianidin, and Tebuconazole are all at levels above the allowed 5% in organic production and handling. The other substances do not have an EPA tolerance level and therefore, are prohibited at any level.

Therefore, on December 5, 2023, OCI issued another Notice of Noncompliance citing to the November 14, 2023 Eureka lab report and the finding of prohibited substances. Again, OCI stated that EGNO needed to investigate the possible source of the contamination and present a corrective and preventive action plan to prevent future contamination. EGNO submitted a Reply to the noncompliance notice on December 18, 2023, stating that the sample taken was of waste material that was a cumulation of previous production batches, added with other daily waste and maintenance waste. EGNO explained that the material wasn't useable during the start of production due to inconsistency in the oil content until the production reaches stability. EGNO stated that it would immediately start removing such waste material from the production/plant area within 48 hours of completing each production batch. However, it is noted that the USDA's NOP Accreditation Division Auditor directed the taking of the sample on October 31, 2023, and OCI stated that the sample was soybean meal powder. It was not 'waste' such as sludge, floor waste, dust, and machinery waste as claimed by EGNO.

OCI issued a Notice of Proposed Suspension to EGNO on March 28, 2024, stating that EGNO's response to the noncompliance notice didn't address the potential source of the contamination or establish a preventive action plan for pesticide residue contamination. OCI noted that it had issued noncompliance notices to EGNO in the past for the same violation; and noted the specific notices issued and the prohibited substance findings upon which the notices were based. OCI stated that past corrective actions, such as not spraying pesticides around the handling facility and proposed corrective actions have not been successful; and EGNO hasn't addressed how pesticide residues have been repeatedly found in their product. OCI also noted that the most lab report from Eureka revealed the presence of Clothianidin which wasn't previously found, indicating additional contamination.

EGNO requested mediation on April 22, 2024, stating that the contamination may be from the port/warehouse. However, OCI denied EGNO's request in a Notice of Mediation Rejection issued April 24, 2024. OCI stated that in considering the mediation request, they noted that due to the repeated noncompliance, and the significant breakdown of EGNO's Organic System Plan (OSP) which is to include monitoring practices, mediation is not likely to result in finding or eliminating the source of the prohibited substance contamination. EGNO then filed an Appeal on May 11, 2024, in which it again stated that the most recent sample in which prohibited substance residues were found was from waste material; and that its organic soybean seed doesn't have any pesticide contamination.

AMS finds that the evidence substantiates that EGNO violated the organic regulations, as shown by several findings of prohibited substances in EGNO product, whether organic soybean meal or specifically organic oil cake and oil cake meal of soybean expeller, or soybean meal powder (waste). Despite OCI issuing several noncompliance notices setting forth findings of prohibited substance residue on EGNO product; asking EGNO to investigate the source of the contamination; and asking EGNO to submit corrective action and preventive plans to address the continued findings of prohibited substances on its products; EGNO has been unable to identify the source of contamination or prevent contamination of its product by prohibited substances. Although EGNO states that the most recent finding of prohibited substances occurred in waste material, the soybean meal powder (waste) sample was taken at the direction of the NOP Auditor who had been denied access to the EGNO facility the prior day. The sample was not 'waste' such as machinery refuse, sludge, or floor dust as EGNO claims.

Further, the organic regulations at 7 C.F.R. §205.670 specifically state that samples taken for testing for the presence of prohibited substance residue can include soil, water, plant tissue,

seed, waste, and processed products whether from plants or animals. Therefore, it is irrelevant that the most recent tested sample was from soybean meal powder (waste), and not plant tissue, seed, soil, or water. Further, samples of organic soybean meal also have tested positive for prohibited substance residue. The cited lab reports from AGQ and Eureka show the presence of several different prohibited substances; and while Pyrimethanil found in the April 21, 2023 AGQ lab report doesn't appear in the November 14, 2023 Eureka lab report, a new substance, Clothianidin appears in the Eureka lab report. As OCI stated, this points to yet another prohibited substance being introduced into EGNO's handling operation.

Further, except for one substance seen on the April 21, 2023 AGQ lab report, all detected residues were found in levels exceeding the 5% of the allowed EPA tolerance level, or are totally prohibited from any organic production or handling. The tolerance levels found for some of the substances are for soybean seed, not soybean meal or soybean meal powder. However, as soybean meal and soybean meal powder are derived from soybean seed, the seed tolerance levels were used. Further, with the exception of one substance (the same one substance referenced above), the substances found on the Eureka lab tested sample as seen on the November 14, 2023 lab report were at higher levels than those same substances found on the AGQ lab tested sample as seen on the April 21, 2023 lab report. Therefore, the contamination increased, instead of being eliminated. As OCI cited, the Eureka lab report even shows a new substance not found in prior samples. Additionally, the substance detected on the sample of organic soybean meal tested by the NAWaL Analytical Lab was also at a level above the 5% organic allowance.

As discussed above, each time OCI issued a Notice of Noncompliance, and when issuing the Notice of Proposed Suspension, OCI asked EGNO to conduct an investigation to determine the source of contamination, and also present a corrective and preventive action plan. However,

EGNO has been unable to determine the source; and corrective/preventive actions either haven't been implemented, implemented correctly, or are not sufficient to address and prevent the contamination risk. Even though OCI issued resolution notices to EGNO on two occasions, after EGNO agreed to downgrade the affected lots to conventional, and not sell them as organic, the continued findings of prohibited substances on EGNO product points to a severe, significant, systemic noncompliance by EGNO.

CONCLUSION

AMS finds the evidence substantiates that EGNO has violated the organic regulations at 7 C.F.R. §205.102, Use of the term, “organic;” 7 C.F.R. §205.105, Allowed and prohibited substances, methods, and ingredients in organic production and handling; 7 C.F.R. §205.201, Organic production and handling system plan; 7 C.F.R. §205.270, Organic handling requirements; 7 C.F.R. §205.400, General requirements for certification; and 7 C.F.R. §205.406, Continuation of certification. AMS finds that prohibited substance residue has been found on EGNO product several times as evidenced by the tested samples taken by OCI and at the direction of the USDA’s NOP Auditor most recently as October 31, 2023. OCI has also issued several noncompliance notices to EGNO regarding these findings and asked EGNO each time to investigate the source of the contamination and present its corrective/preventive actions to avoid such contamination in the future. Such actions should be part of EGNO’s OSP, and its monitoring of its products for contamination should be fully explained. However, despite these numerous opportunities, tested samples from EGNO product continued to reveal the presence of prohibited substances in levels exceeding the 5% allowance for organic products and handling, and substances for which no EPA tolerance exists, and are therefore, prohibited at any level.

AMS finds EGNO's noncompliance is continuing, severe and systemic. Therefore, EGNO may not remain certified at this time.

DECISION

EGNO's May 11, 2024 Appeal of the March 28, 2024 Notice of Proposed Suspension is denied. EGNO's certification is to be suspended. However, pursuant to the organic regulations at 7 C.F.R. §205.662(f)(1), EGNO may apply for reinstatement at any time, with any certifier, upon providing verifiable documentation that it has fully investigated and determined the cause of the prohibited substance contamination incidents discussed above; and fully implemented needed corrective measures to prevent future contamination of its product by prohibited substances.

Additionally, attached to this formal Administrator's Decision denying EGNO's Appeal is a Request for Hearing form. Should it wish to further appeal this decision, EGNO has thirty (30) days to request an administrative hearing before an Administrative Law Judge.

Done at Washington, D.C., on this 25th
day of September, 2024.

BRUCE SUMMERS Digitally signed by BRUCE
SUMMERS
Date: 2024.09.25 20:08:05 -04'00'
Bruce Summers
Administrator
Agricultural Marketing Service