UNITED STATES DEPARTMENT OF AGRICULTURE

AGRICULTURAL MARKETING SERVICE

BEFORE THE ADMINISTRATOR

In re:))	
K V Natural Ingredients Private Limited) Administrator's Decis	sion
Hyderabad, Telangana, India) APL-029-24	

This Decision responds to an Appeal (APL-029-24) of a Notice of Noncompliance and Proposed Suspension under the National Organic Program (NOP) issued to K V Natural Ingredients Private Limited (KV) of Hyderabad, Telangana, India by Ecocert S.A.S. (Ecocert), 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

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 October 20, 2022, KV was certified for handling by Ecocert.

2. On November 8, 2023, Ecocert conducted an inspection of KV, at which time several noncompliances were found.

3. On December 27, 2023, Ecocert issued a Notice of Noncompliance and Proposed Suspension to KV.

4. On February 5, 2024, Ecocert rejected KV's January 13, 2024 request for mediation.

5. On February 13, 2024, KV 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 §205.103, Recordkeeping by certified operations, state that, "(a) A certified operation must maintain records concerning the production, harvesting, and handling of agricultural products that are or that are intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s)). (b) Such records must: (1) Be adapted to the particular business that the certified operation is conducting; (2) Fully disclose all activities and transactions of the certified operation in sufficient detail as to be readily understood and audited; ... (4) Be sufficient to demonstrate compliance with the Act and the regulations in this part ..."

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 §205.271, Facility pest management practice standard, state that, "(a) The producer or handler of an organic facility must use management practices to prevent pests, including but not limited to: (1) Removal of pest habitat, food sources, and breeding areas; (2) Prevention of access to handling facilities; and (3) Management of environmental factors, such as temperature, light, humidity, atmosphere, and air circulation, to prevent pest reproduction. (b) Pests may be controlled through: (1) Mechanical or physical controls including but not limited to traps, light, or sound; or (2) Lures and repellents using nonsynthetic or synthetic substances consistent with the National List. (c) If the practices provided for in paragraphs (a) and (b) of this section are not effective to prevent or control pests, a nonsythetic or synthetic substance consistent with the National List may be applied... (e) The handler of an organic handling operation who applies a nonsynthetic or synthetic substance to prevent or control pests must update the operation's organic handling plan to reflect the use of such substances and methods of application. The updated organic plan must include a list of all measures taken to prevent contact of the organically produced products or ingredients with the substance used..."

The organic regulations at §205.300. Use of the term, "organic," state that, "(a) The term, "organic," may only be used on labels and in labeling of raw or processed agricultural products, including ingredients, that have been produced and handled in accordance with the regulations in this part..."

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 ... (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

KV was certified organic for handling by Ecocert on October 20, 2022. KV was previously certified by Lacon GmbH, but after Lacon surrendered its accreditation, KV obtained certification by Ecocert. KV handles/processes numerous products, including condiments and seasonings, medicinal and aromatic plants, plant products, and tea and coffee. KV activities include the receipt of raw materials, dedusting, testing, pulverization or milling, sifting, blending, packing, storage, and dispatch after 3rd party testing for organic finished products.

On November 8, 2023, Ecocert conducted the annual inspection of KV and found numerous noncompliances as cited to in the Audit Findings and Audit Results. Specifically, Ecocert stated that KV hasn't followed the practices and procedures it had described in its Organic System Plan (OSP). KV bought (b) (4) of whole Bacopa on August 16, 2023, and processed it on September 11, 2023 to produce Organic Bacopa Extract, Batch No. KVN/ORG/BAC/23/0901; however, per the processing records, KV used conventional ethanol as a processing aid, rather than organic ethanol as stated in the product recipe submitted to Ecocert. Ecocert also found drums of (b) (4) each in the conventional storage area, though the drums were labeled as Organic Turmeric Extract 95% Granular with batch numbers in the organic format. Further, KV didn't have specific records documenting the compliance of the incoming organic products, i.e. package integrity, delivery slips/receipt of products, labels, invoices, technical sheets, or supplier certificates.

Lastly, Ecocert stated that KV has used substances for pest control without having tried allowed preventative measures first. Ecocert notes that the prior inspection found that KV had sprayed chemical pesticides. A June 3, 2022 statement from the contractor previously submitted by KV states that it was spraying Azadirachtin 0.15% (Neem Baan) and (b) (4)

outside the handling facility. However, the pest control certificates provided by KV at the November 8, 2023 inspection mention the use of snake powder and other treatments for mosquitos and cockroaches among other pests. Ecocert stated that the use of prohibited treatments for pests was previously raised as a noncompliance at the last inspection and corrective actions haven't been implemented. Therefore, Ecocert issued a Notice of Noncompliance and Proposed Suspension to KV on December 27, 2023, reiterating the noncompliances cited in the Audit Findings of November 8, 2023. Ecocert states that KV labeled conventional products as organic, citing to the drums labeled as Organic Turmeric Extract 95% Granular and submitting pictures of some of the drums; failed to follow practices and procedures in its own OSP by using conventional ethanol as a processing aid for Organic Bacopa Extract; and used unapproved inputs as pest control without first trying approved methods for which it submitted Pest Control Certificates showing unapproved inputs.

In the adverse action notice, Ecocert also stated that after learning that KV had used conventional ethanol in processing Organic Bacopa Extract, it took a sample from the specific batch processed on September 11, 2023. The November 17, 2023 lab report from Eureka Lab shows that Tricyclazole at 0.050 mg/kg and Anthraquinone at 0.175 mg/kg were detected on the sample, with both levels being above the level allowed in organic production and handling. Ecocert stated, therefore, that the batch of Organic Bacopa Extract couldn't be sold as organic. The Environmental Protection Agency (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. However, there is no EPA tolerance level for Anthraquinone. Therefore, it may not be used at all. Tricyclazole only has a tolerance level for rice and grains, and therefore isn't allowed in other agricultural products.

As the tested sample of Bacopa Extract revealed the presence of prohibited substances, Ecocert issued a combined Notice of Noncompliance and Proposed Suspension. The finding of prohibited substances isn't correctable, and therefore, AMS finds the issuance of the combined notice is in accordance with the organic regulations at 7 C.F.R. §205.662(c). On January 13, 2024, KV requested mediation, which Ecocert rejected on February 5, 2024.

KV filed an Appeal on February 13, 2024. In it, KY addressed the use of conventional ethanol in the processing of Organic Bacopa Extract and stated that it had encountered problems in sourcing organic ethanol but has now located an organically certified supplier for organic ethanol. KV stated it is selling the batch of Organic Bacopa Extract for which a tested sample revealed the presence of prohibited substances, as conventional; and will provide the appropriate documentation after the sale of the entire batch. KV stated that it has removed the 'Organic Turmeric Extract 95% Granular' labels from all drums and replaced them with labels identifying the product as 'Turmeric Extract 95% (Pesticide Free).' KV submitted a picture of a newly labeled drum. KV also stated that it will verify pest control services for compliance with the organic regulations and maintain monitoring records; and submitted a Pest Control Monitoring Record showing the spraying of Azadirachtin 0.15% at various locations in the operation on numerous dates from November 2023 through February 2024. Per 40 C.F.R. §180.1119, Azadirachtin is exempted from the requirement of an EPA tolerance if specific use directions are followed. Ecocert was aware of the use of Azadirachtin and hasn't cited any noncompliance in regard to its use. Lastly, KV stated it has provided training to personnel on document verification, labeling, vendor management, and contamination of organic product by conventional inputs. KV provided Training Attendance Records for the various training sessions.

Although KV states it is taking corrective measures and will sell the drums of Turmeric Extract 95% as conventional, the fact remains that KV labeled conventional product as organic, and but for the finding of this noncompliance at the November 8, 2023 inspection, the mislabeled product could have been sold as organic. KV also deviated from its own procedures which it had identified to Ecocert, by processing Bacopa Extract with conventional ethanol, to which it admitted doing. Difficulty in sourcing organic ethanol doesn't excuse the use of conventional ethanol in a product labeled as organic. KV could have delayed production until the required organic ethanol was sourced. The lab report of the testing done on sampled Bacopa Extract processed with conventional ethanol showed there were prohibited substances in the Bacopa Extract. KV also used substances for pest control without having tried allowed preventative measures, and then used inputs other than those identified previously to Ecocert. If practices provided for in the regulations aren't effective to prevent or control pests, a nonsynthetic or synthetic substance consistent with the National List may be applied, if the operation and the certifier agree on the substance and its use. However, KV used inputs which hadn't been submitted to, or approved by, its certifier. Lastly, as noted by Ecocert, though not addressed by KV in its Appeal, KV failed to maintain records that fully document the compliance and organic integrity of incoming products. Although KV's recent training sessions for its personnel is acknowledged, KV's prior failure to ensure its personnel were fully cognizant of the organic regulations and their requirements under the regulations, contributed to the cited noncompliances.

CONCLUSION

AMS finds the evidence substances that KV has violated the organic regulations at 7 C.F.R. §205.102, Use of the term, "organic;" 7 C.F.R. §205.103, Recordkeeping by certified operations; 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. §205.271, Facility pest management practice standard; 7 C.F.R. §205.300, Use of the term "organic;" 7 C.F.R. §205.400, General requirements for certification; and 7 C.F.R. §205.406, Continuation of certification. AMS finds that KV labeled conventional product as organic and failed to follow its own recipes/OSP when it used conventional ethanol instead of organic ethanol as a processing aid for organic product. Further, a sample of the Organic Bacopa Extract, for which conventional ethanol was used, tested positive for prohibited substances. Additionally, KV failed to maintain numerous records documenting the compliance of organic products including organic certificates for suppliers of products to KV. KV also used unapproved inputs for pest control contrary to KV's prior statement of the inputs being used. These noncompliances threaten the integrity of the handling/processing of organic product. Further, KV's certifier needs to be able to rely on KV's OSP and other documentation to accurately reflect the actual activities of the operation. Although KV has allegedly begun conducting training of its personnel on these matters, KV must be able to demonstrate it has come into full compliance and can remain in compliance with the organic regulations. Therefore, KV may not remain certified at this time.

DECISION

KV's February 13, 2024 Appeal of the December 27, 2023 Notice of Noncompliance and Proposed Suspension is denied. KV's certification is to be suspended. However, pursuant to the organic regulations at 7 C.F.R. §205.662, KV may apply for reinstatement of certification at any time, with any certifier, upon providing verifiable documentation that it has taken needed corrective measures and resolved all noncompliances cited by Ecocert. Additionally, attached to this formal Administrator's Decision denying KV's Appeal is a Request for Hearing form. Should it wish to further appeal this decision, KV has thirty (30) days to request an administrative hearing before an Administrative Law Judge.

Done at Washington, D.C., on this <u>26th</u> day of <u>March</u>, 2024.

BRUCE SUMMERS Date: 2024.03.26 16:22:00 -04'00' Bruce Summers

Administrator Agricultural Marketing Service