

UNITED STATES DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE
BEFORE THE ADMINISTRATOR

In re:)
APAX USA, Inc.) **Administrator's Decision**
Castle Rock, Colorado) **APL-047-19**
)

This Decision responds to an appeal (APL-047-19) of a Notice of Proposed Suspension of National Organic Program certification issued to APAX USA, Inc. (APAX) of Castle Rock, Colorado by Oregon Tilth Certified Oregon (OTCO). 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 such decision to the USDA Agricultural Marketing Service (AMS) pursuant to § 205.680

¹ 7 U.S.C. 6501-6522

² 7 C.F.R. Part 205

Adverse Action Appeals Process – General, and § 205.681, Appeals of the USDA organic regulations.

FINDINGS OF FACT

1. On December 12, 2018, OTCO issued a Notice of Noncompliance.
2. On March 8, 2019, OTCO issued a Notice of Proposed Suspension.
3. On April 8, 2019, APAX filed an Appeal to NOP.

DISCUSSION

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 (specific ingredients or food group(s))” must be: (a) Produced in accordance with the requirements specified in §205.101 or §§205.202 through 205.207 or §§205.236 through 205.240 and all other applicable requirements of part 205; and (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 §205.300, 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 §205.301, Product composition, state that, “(b) Products sold, labeled, or represented as “organic.” A raw or processed agricultural product sold, labeled, or represented as “organic” must contain not less than 95 percent organically produced raw or processed agricultural products. Any remaining product ingredients must be organically produced, unless not commercially available in organic form, or must be nonagricultural substances or nonorganically produced agricultural products produced consistent with the National List in subpart G of this part. If labeled as organically produced, such product must be labeled pursuant to §205.303.”

OTCO proposed a suspension of APAX’s organic certification, which would prohibit the sale, labeling, or representation of its products as organic. OTCO stated in the March 8, 2019 Notice of Proposed Suspension that pursuant to the organic regulations at 7 CFR 205.301, only non-organic ingredients included on the NOP National List may be used in finished products making an organic claim. Further, said ingredients must not comprise more than 5% of the finished product. OTCO stated that APAX’s Turmeric, Ginger, Omega 3-6-9, and Garlic capsules sold under the brand name of Feel Good Superfoods do not use an organic capsule, specifically the capsule ‘shell.’ OTCO further stated that these four products, along with the Echinacea product and Vita-Fruit-Veggie product were not produced by a NOP-compliant co-manufacturer, and therefore, all are non-compliant with NOP standards. OTCO acknowledged that it had previously approved these products, but said the approval was in error. OTCO stated

that APAX must no longer sell, label, or represent the identified encapsulated products as organic.

In its appeal, APAX stated that each of the products in the identified capsules is 100% organic and only the capsule itself is at issue. APAX stated it permanently ceased using the capsule 'shells' in question when it received the December 12, 2018 Notice of Noncompliance and will start using a new organic-certified capsule on August 31, 2019 at the latest. APAX states it has obtained a new manufacturer for the capsules and presented the Ecocert Attestation for the EU for Natural Capsules Ltd. which manufactures empty hard cellulose capsules. APAX asked OTCO if it can use the remaining inventory of Feel Good Superfoods products with the capsule shell in question. APAX contends that OTCO erred in reversing its prior certification of the capsules, because they are subject to the 2012 US-EU Organic Equivalency Agreement since the capsules are certified organic by Ecocert to EU standards.

Further, APAX states the capsules were already in 'the stream of commerce' when OTCO reversed its prior approval. APAX explained that after OTCO re-affirmed the certification of the products subsequent to the September 2018 inspection, APAX negotiated with its customers for 2019 to have its products in the customers' planograms for retail space. APAX states it made firm commitments to its retail customers to provide sufficient quantities of the products on demand and failure to do so is a breach of contract. APAX contended that these products are in existing inventory and are already committed to specific customers.

APAX was initially certified organic for handling on December 20, 2017. A review of all the evidence shows that OTCO had already approved for organic certification APAX's Feel Good Superfoods products of Turmeric, Ginger, Omega 3-6-9, Garlic, Echinacea and Vita-Fruits-Veggie, but then rescinded that approval in the December 12, 2018 Notice of

Noncompliance. That Notice states that the capsule ‘shell’ used in the first four products wasn’t certified organic. Additionally, all the products weren’t produced by a NOP-compliant co-manufacturer.

Specifically, OTCO found that APAX was using capsule shells from an unknown supplier which, therefore, couldn’t be confirmed as being certified organic. Further, APAX’s contractor, Stiriti Ayur Therapies Pvt. Ltd. (Stiriti), which ‘filled’ the capsule shells, didn’t have its then-certifier OneCert review and approve the final product, which would have required the review of the capsule shells. Therefore, Stiriti’s prior certification is irrelevant. Research shows that Stiriti of Hyderabad, India does private-label production and contract manufacturing of dietary and nutraceutical supplements, specifically ‘capsule filling,’ for its customers. Stiriti’s website shows that it is GMP – Good Manufacturing Practices – compliant but isn’t certified organic to US/NOP or EU standards. Stiriti also doesn’t appear in NOP’s Organic Integrity database. APAX stated that Stiriti was the only manufacturer of their encapsulated products. Therefore, the Feel Good Superfoods products listed above are non-compliant with the USDA organic regulations.

OTCO explained that a former employee erroneously approved Stiriti as a co-manufacturer based on Stirit’s organic certification by India’s National Programme for Organic Production (NPOP) which is under India’s Ministry of Commerce and Industry. However, India’s NPOP doesn’t have an equivalency agreement with NOP, and therefore, it was an error to approve Stiriti, which resulted in the December 12, 2018 Notice of Noncompliance reversing the prior approval of the above products.

Subsequent to the December 12, 2018 notice, APAX states it obtained a new manufacturer for the capsules, Natural Capsules Ltd., and presented an Ecocert Attestation for

the 'empty hard cellulose capsules' of Natural Capsules Ltd., which Appellant purports to be organic certification. Natural Capsules Ltd. of Bangalore, India is a manufacturer of hard gelatin and hard cellulose capsule shells. However, Ecocert stated that the Attestation is not any guarantee of the capsule shell's compliance with NOP regulations. The Attestation states that it was issued to the entity for "inputs suitable for use in Organic Farming." Ecocert explained that 'inputs' includes those used on fields and also food additives that can be used during the processing of products. As hydroxypropyl methyl cellulose is a food additive listed in the EC organic regulations as being allowed for use as encapsulation materials for capsules if made from plant or animal origin. However, Ecocert further stated that the Attestation doesn't mean that the capsule shell is certified organic to EU standards, because cellulose capsules can't be certified according to EU organic regulations because it is not an agricultural substance.

Further, while APAX stated that its new supplier of the capsule shells is Natural Capsules Ltd., OTCO states that APAX submitted a 'largely incomplete' request to add a hydroxypropyl methyl cellulose shell to its certification. OTCO states that the composition sheet submitted for the new capsule shell shows the material is not NOP-compliant for use. Therefore, although APAX stated that it would start using organically certified capsule shells by August 31, 2019 at the latest, there is no evidence that APAX has done so. Further, APAX stated that it took action upon receipt of the December 12, 2018 Notice of Noncompliance and ceased further production of the Feel Good Superfoods products of Turmeric, Ginger, Omega 3-6-9, and Garlic, using the non-organic capsule shell, as well as production of the Echinacea and Vita-Fruits-Veggie products, which along with the other four products were manufactured by an uncertified manufacturer. However, APAX also offered no evidence of this.

OTCO also stated that APAX hasn't identified any new manufacturer to 'fill' the capsule shells which were previously filled by Stiriti. APAX was asked to provide information on any new manufacturer, but APAX failed to respond to NOP requests for information on this and other matters.

Research shows that APAX is a wholesale supplier of various nutritional supplements to numerous retailers in the United States and around the world. APAX states it relied on OTCO's initial certification of the above-listed products when negotiating with its retail customers for 2019 sales and made contractual commitments to the customers to provide sufficient amounts of products, which it then produced and either delivered to its customers or put in inventory, and that the customers already 'granted' APAX's products shelf space in their planograms. A planogram is a diagram or model that indicates the placement of retail products on shelves in order to maximize sales. APAX states it negotiated with retailers for shelf space for its products and that failure to then provide the necessary products per the planogram can result in not only the loss of sales but also the loss of reputation and future contracts with that retailer.

Therefore, APAX asked OTCO if it could use up the inventory of the encapsulated products in question. However, OTCO states that APAX never addressed how much inventory it had or where the inventory was held. OTCO states it was only told by APAX that the inventory was still in APAX's control.

NOP asked APAX to identify and substantiate how much inventory it still held of the products with the non-organic capsule shell and manufactured by the uncertified co-manufacturer. NOP also asked APAX where this inventory was held. However, APAX did not provide any information or documentation on the alleged inventory to NOP. NOP also asked APAX to provide information and evidence substantiating the retail contracts for its products and

proof of APAX's placement on retailers' planograms. APAX also did not provide any information or documentation, including sales orders, on alleged contractual commitments to retailers.

APAX also states the subject capsules committed to retailer customers were already in 'the stream of commerce' when OTCO reversed its prior approval of them. The Preamble of the Final Rule at 65 Fed. Reg. 80627, Dec. 21, 2000, provides that the "USDA will not, unless the noncompliance involves a food safety issue under FSIS [the USDA Food Safety and Inspection Service], require the recall or relabeling of product in the channels of commerce prior to the issuance of a suspension or revocation order." In January 15, 2013, NOP stated that products in the stream of commerce are those that are already manufactured, in storage, or on retail shelves. However, as stated above, despite requests to APAX, APAX hasn't provided any information or documentation to substantiate the retail contracts and alleged commitments to retailers. Therefore, there is no evidence to support its claim that the products were already in the stream of commerce.

Further, APAX contends that the products are subject to the US-EU Organic Equivalency Agreement of 2012. The agreement states that the EU recognizes the NOP as equivalent to the EU Organic Program and allows U.S. organic products to be marketed as 'organic' in the EU using the EU organic logo. Conversely, the U.S. allows European products produced and handled under the EU Organic Program to be marketed as 'organic' in the U.S. using the USDA organic logo. However, as discussed above, APAX hasn't provided any information to OTCO on its alleged new manufacturer of the encapsulated products previously produced by Striti. Further, the capsules of Natural Capsules Ltd. aren't certified organic to NOP or EU standards.

Finally, a review of APAX's website shows that the above-listed Feel Good Superfoods products are still being sold with the USDA organic seal on the packaging. A review of the ingredient list of the products shows as 'other ingredients' the 'vegetable cellulose (capsule).'

In conclusion, APAX used uncertified capsule shells in the production of its Feel Good Superfoods products of Turmeric, Ginger, Omega 3-6-9, and Garlic capsules, and had these products, along with its Echinacea and Vita-Fruits-Veggie products manufactured by an uncertified manufacturer. APAX contends it has obtained a new supplier of capsule shells, Natural Capsules, Ltd., however, this entity is not certified organic under NOP or EU standards. APAX has not provided any information on a new co-manufacturer. Further, although APAX requested to use its remaining inventory of the above products, citing to contractual commitments to retailers, APAX has not responded to NOP and provided any information or documentation to substantiate the contractual commitments or amount of inventory on hand, and has not substantiated that the products in this alleged inventory are already in 'the stream of commerce.' APAX has also continued to label and represent the products in question as organic on its website, using the NOP organic seal.

CONCLUSION

The USDA organic regulations assure consumers that products with the USDA organic seal meet consistent, uniform standards. Key to these standards is that products with the USDA organic seal are produced and handled in accordance with the organic regulations. However, APAX violated the organic regulations at 7 C.F.R. §205.102; 7 C.F.R. §205.105; 7 C.F.R. §205.300; and 7 C.F.R. §205.301. These noncompliances do not allow for continued certification at this time.

DECISION

The appeal is denied and APAX's organic certification is to be suspended. Attached to this formal Administrator's Decision denying APAX's appeal is a Request for Hearing form. APAX has thirty (30) days to request an administrative hearing before an Administrative Law Judge.

If APAX waives the hearing, the Agricultural Marketing Service will direct OTCO to issue a Notice of Suspension. At any time after suspension, APAX may, "...submit a request to the Secretary for reinstatement of its certification. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part." APAX may work with any certifier to complete a request for reinstatement.

Done at Washington, D.C., on this 2nd
day of November, 2019.



Bruce Summers
Administrator
Agricultural Marketing Service