

UNITED STATES DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE
BEFORE THE ADMINISTRATOR

In re:)
Epigenetic Labs LLC,)
dba Organixx) **Administrator's Decision**
Stateline, Nevada) **APL-70-20**
)

This Decision responds to an appeal (APL-070-20) of a Notice of Denial of National Organic Program (NOP) certification issued to Epigenetic Labs LLC, dba Organixx (Organixx) of Stateline, Nevada, by Northeast Organic Farming Association of New York/NOFA-NY Certified Organic, LLC (NOFA-NY), an 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 June 11, 2020, NOFA-NY issued a Notice of Denial of Certification.
2. On June 25, 2020, Organixx filed an Appeal.

DISCUSSION

The USDA organic regulations at 7 CFR §205.100, What has to be certified, state that, “(a) 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 group(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 §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 §205.300, 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 of this part...”

NOFA-NY issued a Notice of Denial of Certification after finding that Organixx had falsified documentation submitted with its certification application; misrepresented that all product ingredients are certified organic; and used NOFA-NY’s seal on products when Organixx isn’t certified organic.

Organixx states that it didn’t intentionally falsify documentation or provide misleading information on its ingredients; and an oversight had resulted in a product with a NOFA-NY reference being left on its website.

A review of the evidence shows Organixx sells supplements and essential oils such as Organigreens Dehydrated Green Juice products, Nascent Liquid Iodine, Bone Broth Proteins, Ageless Brain, and 7M Immune supplements, which are manufactured by a copacker, Nutratech Labs (Nutratech). Organixx receives and stores the finished products; maintains a website to sell the products; and fulfills orders at its warehouse. On October 8, 2019, NOFA-NY had issued a Cease and Desist letter to Organixx stating that it had seen on Organixx’ website and other websites that Organixx had been labeling, advertising, and selling products identified as being certified organic by NOFA-NY. However, NOFA-NY stated that it hadn’t “been contacted by, granted certification to nor authorized the use of our agency name in any packaging, advertising or promotional materials for your products.” NOFA-NY instructed Organixx to immediately

remove “any and all reference to our agency from all labels, websites and promotional materials,” and asked that Organixx provide a written response confirming that it had taken those actions. Organixx’ products had been manufactured by Nutratch; however, Nutratch also wasn’t certified organic at the time. NOFA-NY subsequently certified Nutratch organic on February 12, 2020, and the certificate listed several products under Organixx’ name.

On or about April 22, 2020, Organixx applied to NOFA-NY for handling/processing certification after initially contacting NOFA-NY on October 9, 2019 about seeking certification. The Organic System Plan (OSP)/Application for Certification listed several products for which Organixx sought certification. However, NOFA-NY found that Organixx had altered the organic certificate of Nutratch, which is also certified organic by NOFA-NY. NOFA-NY submitted the organic certificate issued to Nutratch on February 12, 2020, as well as the altered Nutratch certificate which it found on Organixx’ website. The certificate was altered to remove products manufactured for an entity other than Organixx.

NOFA-NY issued another Cease and Desist letter to Organixx on April 29, 2020, stating that Organixx’ website was displaying an altered version of the Nutratch certificate addendum and that as the certificate is a legal and signed document, such altering of the certificate isn’t allowed. NOFA-NY also noted that Organixx’ website stated, “we’re proud to share our Organic Certificates below from the Northeast Organic Farming Association of New York...” NOFA-NY stated this statement is misleading as NOFA-NY doesn’t certify Organixx directly. NOFA-NY instructed Organixx to immediately remove the altered organic certificate from its website and revise the misleading statement, and then provide written confirmation of its actions.

Subsequently, on June 11, 2020, NOFA-NY issued a Notice of Denial of Certification to Organixx, stating that Organixx had continued to violate the organic regulations at 7 C.F.R.

§205.102, Use of the term, “organic.” Specifically, NOFA-NY stated that Organixx willfully falsified the organic certificate of Nutratch and its addendum dated April 22, 2020 which was submitted with Organixx’ application for certification; and that Organixx’ marketing materials found in numerous locations on Organixx’ website appeared to purposely mislead prospective customers that all ingredients in its products were certified organic. Further, as of June 11, 2020, Organixx’ website was found to contain a product, Restore Vitamin C Serum, with a statement of NOFA-NY certification on its packaging. NOFA-NY stated that Organixx hadn’t been granted certification; the Restore Vitamin C Serum product wasn’t submitted for approval; and it wasn’t listed in Organixx’ application. NOFA-NY also referenced the two previously issued Cease and Desist letters sent to Organixx. NOFA-NY didn’t conduct an inspection of Organixx’ handling facility as certification was denied at the initial review stage for reasons cited above.

NOP confirmed with NOFA-NY that it hadn’t issued a Notice of Noncompliance prior to issuance of the Denial of Certification. NOFA-NY stated that due to evidence of multiple willful violations of the regulations by Organixx, it didn’t first issue a Notice of Noncompliance. The regulations at 7 C.F.R. §205.405(g) state that, “if a certifying agent has reason to believe that an applicant for certification has willfully made a false statement or otherwise purposefully misrepresented the applicant’s operation or its compliance with the certification requirements pursuant to this part, the certifying agent may deny certification pursuant to paragraph (c)(1)(ii) of this section without first issuing a notification of noncompliance.” The prior violations of the organic regulations resulting in issuance of two Cease and Desist letters prior to Organixx’ application for certification and at the time Organixx applied for certification, justified a denial of certification without first issuing a noncompliance notice. Further, Organixx acknowledged in the Applicant Affirmation contained within the certification application that it must abide by

the organic regulations and that NOFA-NY's logo could only be used by Organixx with prior approval by NOFA-NY.

Organixx stated in its Appeal that it worked with NOFA-NY and thought all deficiencies had been corrected. Specifically, Organixx stated that it had redacted products from the organic certificate of Nutratch which that entity produced for another customer because Organixx doesn't sell those products. Organixx stated it has since removed the redacted Nutratch certificate from its website. Regarding NOFA-NY's allegation that Organixx appeared to be making purposely misleading statements by claiming that all ingredients in their products are certified organic, Organixx stated that it has complied with the organic regulations and discussed these allegations with NOFA-NY. Lastly, Organixx stated that it had done an 'overhaul' of its website and the Restore Vitamin C Serum product which was labeled as being certified by NOFA-NY was mistakenly left on their website. Organixx states it has removed non-compliant language from its website and trained staff on the organic regulations.

However, while one can argue that leaving the Restore Vitamin C Serum on the website was an oversight, and that removing products from Nutratch's organic certificate which weren't produced for Organixx was done in an effort to avoid confusion, Organixx' noncompliant actions are more far-reaching than these incidences. Organixx labeled and represented products as being certified organic by NOFA-NY prior to even applying for certification, and prior to its co-packer Nutratch applying for certification. NOFA-NY stated that Nutratch submitted a partial application on October 16, 2019, for Bee Friendly products but didn't identify any Organixx products for which it sought certification. Nutratch wasn't certified organic until February 12, 2020, after asking NOFA-NY to expedite its application, though by that time Organixx products had been added to its request for certification. However, NOFA-NY had already issued a Cease

and Desist notice to Organixx on October 8, 2019, requesting that it remove organic claims and NOFA-NY's name from its products which hadn't been approved for organic certification. A second Cease and Desist letter was subsequently issued on April 29, 2020, regarding the unauthorized revisions to Nutratech's organic certificate. Further, NOFA-NY issued a third Cease and Desist letter on July 17, 2020, when it found that Organixx' website still displayed an unauthorized NOFA-NY certification statement on the Vitamin C Serum labels within the Radiant Skin Classic Kit and the Radiant Skin Deluxe Kit, when NOFA-NY doesn't certify the Vitamin C Serum. NOFA-NY again told Organixx to immediately revise/remove reference to NOFA-NY on any products not certified by NOFA-NY and to provide written confirmation of the actions.

As further evidence that NOFA-NY was justified in its issuance of the Notice of Denial of Certification, NOP's Compliance and Enforcement Division received complaints about Organixx' website using the USDA/NOP organic seal on products and making organic claims on the labels. NOP issued a Warning Letter to Organixx on December 20, 2019, stating that "an initial review of your labeling and marketing material shows that you may be labeling products as organic in violation of the U.S. Department of Agriculture (USDA) organic regulations." Organixx was instructed to immediately correct the violation as well as any other violations that are the same or similar. However, despite the Cease and Desist letters from NOFA-NY, the Warning Letter from NOP, and the Notice of Denial of Certification, Organixx has continued to represent and label products as organic although it has not been granted organic certification. Specifically, a review of Organixx' website on November 24, 2020, revealed it is marketing numerous products with packaging showing the USDA NOP organic seal and/or stating that the

products are certified organic by NOFA-NY, i.e. 7M Immune Support, Ageless Brain, and Organigreens.

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, the evidence substantiates that Organixx violated the organic regulations at 7 C.F.R. §205.100, What has to be certified; 7 C.F.R. §205.102, Use of the term, “organic;” 7 C.F.R. §205.300, Use of the term, “organic;” and 7 C.F.R. §205.400, General requirements for certification. Specifically, the evidence substantiates that Organixx represented and labeled its products as organic, making claims that it and its products are certified organic. Additionally, the continued use by Organixx of the USDA organic seal on its product labeling and website, as well as stating that products are certified organic by NOFA-NY, despite numerous prior directives to cease and desist such activity, constitutes a willful violation of the organic regulations and an aggravating factor to the violation. In fact, Organixx used the USDA NOP organic seal and NOFA-NY’s logo before it even contacted NOFA-NY to inquire about seeking certification and before even Nutratech applied for certification. Therefore, Organixx is not eligible for organic certification.

DECISION

The June 25, 2020 Appeal is denied, and the June 11, 2020 Notice of Denial of Certification is affirmed. Organixx is denied organic certification. However, pursuant to 7 C.F.R. §205.405(e), Organixx may apply for certification again at any time with any certifying

agent, though any such application must include a copy of the June 11, 2020 Notice of Denial of Certification.

Attached to this formal Administrator's Decision denying Organixx' Appeal is a Request for Hearing form. Organixx has thirty (30) days to request an administrative hearing before an Administrative Law Judge. If Organixx waives the hearing, this Administrator's Decision denying Organixx certification will become final. Organixx remains uncertified during this period.

Done at Washington, D.C., on this 12th
day of January, 2021.

**BRUCE
SUMMERS**

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Bruce Summers
Administrator
Agricultural Marketing Service