

UNITED STATES DEPARTMENT OF AGRICULTURE

AGRICULTURAL MARKETING SERVICE

BEFORE THE ADMINISTRATOR

In re:)
Lakefront Brewery, Inc.) **Administrator's Decision**
Milwaukee, Wisconsin) **APL-041-18**
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This Decision responds to an appeal (APL-041-18) of a Notice of Noncompliance and Proposed Suspension of National Organic Program certification issued to Lakefront Brewery, Inc. of Milwaukee, Wisconsin by Oregon Tilth Certified Organic. 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. Lakefront Brewery, Inc. (Lakefront) was initially certified organic by Oregon Tilth Certified Organic (OTCO) on May 26, 2004.
2. On November 17, 2017, OTCO issued a Notice of Noncompliance and Proposed Suspension to Lakefront, citing several noncompliances found during the 2017 inspection.
3. On November 28, 2017, Lakefront entered into a Settlement Agreement with OTCO, addressing the noncompliances set forth in the November 17, 2017 Notice of Noncompliance and Proposed Suspension.
4. On April 25, 2018, OTCO conducted an annual inspection of Lakefront, after Lakefront submitted a renewal application for certification.
5. On August 1, 2018, OTCO issued a Notice of Noncompliance and Proposed Suspension to Lakefront, citing noncompliances found during the 2018 inspection that had already been identified in the 2017 inspection and which were the subject of the November 28, 2017 Settlement Agreement.
6. On August 10, 2018, OTCO denied Lakefront's August 1, 2018 Request for Mediation.
7. On September 4, 2018, Lakefront filed an Appeal to the Notice of Noncompliance and Proposed Suspension.

DISCUSSION

The USDA organic regulations at 7 C.F.R. 205.406(a), Continuation of certification, state that “To continue certification, a certified operation must annually pay the certification fees and submit the following information, as applicable, to the certifying agent:..(3) An update on the correction of minor noncompliances previously identified by the certifying agent as requiring correction for continued certification; and (4) Other information as deemed necessary by the certifying agent to determine compliance with the Act and the regulations in this part.”

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 groups(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; (3) Be maintained for not less than 5 years beyond their creation; and (4) Be sufficient to demonstrate compliance with the Act and the regulations in this part. (c) The certified operation must make such records available for inspection and copying during normal business hours by authorized representatives of the Secretary, the applicable State program’s governing State official, and the certifying agent.”

The organic regulations at §205.201, Organic production and handling system plan, state that, “(a) The producer or handler or a production or handling operation...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.” The requirements include a description of practices

and procedures to be performed and maintained; a list of each substance to be used as a production or handling input; a description of monitoring practices and procedures to be performed and maintained; a description of the recordkeeping system implemented by the operation; and any additional information deemed necessary by the certifying agent.

The organic regulations at §205.272, Commingling and contact with prohibited substance prevention practice standard, states that, “(a) The handler of an organic handling operation must implement measures necessary to prevent the commingling of organic and nonorganic products and protect organic products from contact with prohibited substances.”

OTCO proposed a suspension of Lakefront’s organic certification, which would prohibit the sale, labeling, or representation of its products as organic. Presenting the reasons for proposing a suspension, OTCO stated that Lakefront has displayed a repeated, systemic inability to comply with the organic regulations.

On November 17, 2017, OTCO issued a Notice of Noncompliance and Proposed Suspension to Lakefront, citing to the 2017 inspection’s findings of Lakefront’s use of a noncompliant input, implementing changes to the Organic System Plan (OSP) without prior approval, and insufficient recordkeeping affecting the ability to conduct a traceback audit. Additionally, Certifier stated there were incomplete records regarding the purge of equipment prior to organic production; the lack of a description of monitoring practices and procedures; and the lack of complete records and organic certificates for organic ingredients. OTCO also noted the same or similar noncompliances that had been found during the 2015 and 2016 inspections.

Subsequently, OTCO and Lakefront entered into a Settlement Agreement on November 28, 2017. Lakefront agreed to submit proof of training of its production staff; confirm it ceased using certain substances identified by OTCO; and improve its recordkeeping and explain said

improvements in the OSP. Lakefront also agreed to ensure that organic purges of the grain mills can be verified, and that all ingredients from receiving through production to final sale can be tracked, allowing for mass balancing.

On April 25, 2018, OTCO conducted an inspection at Lakefront's facility and found continued inconsistent oversight and compliance with the organic regulations. Specifically, OTCO found required documentation was incomplete, there was a lack of follow up for employee training, and Lakefront didn't exercise document control, i.e. the use of old forms versus new forms. OTCO noted in the inspection report that Lakefront produces both organic and conventional beer, with only 15% of the production being organic. However, although sanitation procedures and materials are the same for both organic and conventional production, Lakefront didn't maintain sanitation logs. OTCO found that the dry grinder and grain delivery system were purged with 50 lbs. of organic malt at the end of the conventional beer production run prior to beginning organic production. However, for the organic Fuel Stout beer, the records did not show the previous batch made, and therefore, did not show that the purge had been completed.

OTCO also observed spray bottles of Alpet D2 with quaternary ammonia at various locations. Lakefront told the inspectors that this product was swapped out for (b) (4) prior to organic production; however, there was no record of the 'change-over.' OTCO also found that anticontamination measures were not adequately described in the Organic System Plan (OSP) or implemented in order to avoid cross contamination between organic and conventional products in all stages of receiving, processing, storing, and shipping. OTCO also noted a lack of invoices or Bills of Lading for the organic whiskey barrels, and that a receiving log was not maintained for incoming ingredients. Additionally, lot numbers were not included on invoices

from supplier (b) (4), and lot numbers were not on Bills of Lading from supplier (b) (4) both of which would affect trace back exercises. OTCO later confirmed that the issue with (b) (4) had been rectified. Many of the noncompliances found during the April 25, 2018 inspection had been found in prior inspections, were noted in the November 17, 2017 Notice of Noncompliance and Proposed Suspension, and were the subject of the November 28, 2017 settlement agreement.

Therefore, OTCO issued a Notice of Noncompliance and Proposed Suspension on August 1, 2018. OTCO again found that Lakefront's inputs are not traceable. Specifically, Lakefront is not recording the lot numbers for the whisky barrels used in organic production, and there were no invoices or records on the barrels available during the inspection. Incoming invoices for Lakefront's (b) (4) coffee supplier also do not contain lot information for verification. OTCO found that Lakefront changed the OSP again without prior approval, and used a restricted sanitizer containing quaternary ammonia without having procedures to prevent contamination with organic products. Lakefront still did not maintain receiving logs for trucks containing ingredients used in production, nor did it consistently record the purging of grain mills required in the OSP. Further, the inspector couldn't determine if Lakefront's current purging practices are sufficient to clear all conventional debris from equipment prior to organic production.

In its appeal, Lakefront states that it began brewing organic beer before the National Organic Program even began and applied on January 24, 2018 to continue their organic certification. Lakefront first states that their supplier of wooden barrels is no longer certified organic, and thus, Lakefront is withdrawing its request for organic certification of its Beerline Barleywine Ale. Lakefront then refuted each of the noncompliances cited by OTCO.

Lakefront states that the audit trail exercise done during the inspection shows that their inputs are traceable and cited to the inspector's tracing of Organic Fuel Coffee Stout, batch L1728, for which the inspector found no problems in the areas of shipping, bottling, or production. This is found on page 9 of the April 25, 2018 Inspection Report. Further, although the Bills of Lading did not note lot numbers at that time, Lakefront states their supplier (b) (4) (b) (4) agreed to list lot numbers on future Bills of Lading. (OTCO acknowledged this.)

Lakefront also states it utilizes OrchestratedBEER, a business management software program used by many breweries which allows the tracing of lot numbers. Lakefront further states that the mass balance exercise done by the inspector on organic Cascade hops resulted in all numbers balancing, and the inspector repeatedly noted in the inspection report that there were 'no issues.' This is on page 10 of the April 25, 2018 Inspection Report.

Regarding the matter of (b) (4) coffee invoices not containing lot numbers, Lakefront stated (b) (4) is a small, local, independent coffee roaster, for which no bills of lading are generated, as it is located a short distance from Lakefront and the coffee is either delivered by (b) (4) or picked up at (b) (4) by Lakefront. Despite their requests to (b) (4) to put lot numbers on the invoices, (b) (4) has yet to do so; and Lakefront merely emails (b) (4) for lot number information, which it then enters in the OrchestratedBEER program. Lakefront submitted several of their emails with (b) (4) in which Lakefront is requesting lot numbers for specific invoice numbers, and (b) (4) is promptly responding with the information. The emails also show Lakefront's requests to (b) (4) to include lot numbers on their invoices; however, (b) (4) states that since Lakefront is the only client making such a request, it 'falls through the cracks.'

Lakefront states that it has used Alpet D2 sanitizer with quaternary ammonia since 2008 for its conventional production, but this product is 'swapped out' for (b) (4) a sanitizer allowed in organic production, prior to producing the organic beverages. Lakefront states it has added this 'swap' procedure to the OSP, and two employees verified to the inspector that the sanitizer is swapped prior to organic production, even though the Transfer Sheet stating that all organic standard operating procedures (SOPs) were followed, isn't always initialed. Lakefront also stated that the Brewing Recipe Forms are initialed verifying that all organic SOPs were followed. Lakefront submitted a form for Organic White 50 barrels produced on April 17, 2018, as an example.

Regarding receiving logs, Lakefront states it does not have a receiving department or loading dock, and production staff unload the trucks as they arrive. Although there was a multi-entry receiving log on a hook by the 'receiving door,' the fast pace of unloading the trucks sometimes meant the log wasn't completed. However, to resolve this issue, Lakefront stated that since May 2018, it has utilized a single-sheet receiving log for each shipment, which is kept in a weather resistant plastic pouch clipped to the forklift and which provides for verification of all incoming shipments. A blank Receiving Log was submitted with Lakefront's appeal.

Lastly, Lakefront contends the purging of the grain mills and conveyances between organic and conventional production is sufficient. Lakefront refutes the contention that the inspector found their purging practices to be insufficient. Lakefront points to the inspection report wherein the inspector only states that she could not determine if the purging practices were effective at clearing conventional debris before organic production runs. Lakefront also cites to the organic regulations which state that inspections are to be conducted when activities can be observed. Lakefront states the April 25, 2018 inspection was not done at a 'representative

time,' because Lakefront was brewing non-organic products during the inspection. Lakefront states the Daily Production Activity Log covering the inspection date shows an organic batch had last been brewed eight days prior to inspection, and the Brewing Recipe Form for the prior organic product shows production staff verified that purging had been done. Lakefront claims that it consistently logs in the purging of the grain mill and conveyances prior to organic production.

The evidence shows that Lakefront has acted to rectify or implement compensating measures for several of the noncompliances found by OTCO. Lakefront withdrew its request for organic certification of a product which it stores in wood barrels due to the barrel supplier no longer being certified organic. This was confirmed by the inspector. Therefore, the matter of not recording lot numbers for whiskey barrels is now moot. Lakefront is utilizing the OrchestratedBEER software which, as stated by the inspector, can easily track lot numbers. Lakefront's supplier (b) (4) has agreed to list lot numbers on its invoices/bills of lading. Further, although supplier (b) (4) has failed to add lot numbers to its invoices, despite Lakefront's documented requests, Lakefront is still obtaining the information via email requests to (b) (4)

However, evidence also reveals that other noncompliances have remained unresolved, despite Lakefront having entered into a Settlement Agreement with OTCO, whereby Lakefront agreed to correct these noncompliances within thirty days of the Settlement Agreement's execution on November 28, 2017. Lakefront uses a sanitizer containing quaternary ammonia for conventional production and claims to swap this out for an allowed sanitizer for organic production. However, the inspector noted that while there was verbal confirmation of this, there was no documentation to verify this. Lakefront acknowledged that the 'transfer sheet' for the

sanitizer product isn't always initialed, but stated that the brewing recipe form, confirming that organic procedures were followed, is initialed. Further, Lakefront has not developed and implemented a SOP to address actions taken to prevent cross-contamination between organic and conventional production.

OTCO also found that receiving logs to document truck inspections for incoming ingredients were not maintained. Lakefront stated it does not have a separate receiving department or loading docks; and production staff must unload the trucks in addition to their regular proscribed duties. Lakefront acknowledges that the multi-entry receiving log was often misplaced which it attributed to production workers needing to quickly return to their regular duties because timing is crucial in the brewing of beer. Lakefront states it was unsure how to accurately verify incoming shipments to meet the terms of the Settlement Agreement, which required improvement in recordkeeping of ingredients from receipt through production to final sale. Although, Lakefront has begun utilizing a new single-sheet receiving log for each shipment, this was not done within 30 days of the Settlement Agreement's execution, but rather was not done until after the April 25, 2018 inspection. These new logs are reportedly kept affixed to the forklift so the receipt of shipments can easily be logged. However, since this was instituted after the inspection, OTCO has not been able to confirm this and that proper receiving records are maintained.

As to the purging of the grain mill prior to organic production, Lakefront produces organic beer approximately every other week as seen on Daily Production Activity Logs. Specifically, Lakefront submitted the Daily Production Activity Log for April 16 – 28, 2018, showing an organic batch produced on April 17, 2018, which is eight days prior to the inspection. A brewing recipe form for Organic White Ale produced on April 17, 2018, shows

brewer "RH" initialed the bottom of the form certifying that, "malt mill and transfer conveyors have been purged with organic malt prior to brewing" and "all organic standard operating procedures were followed." Brewing recipe forms for Riverwest Stein beer, which is non-organic, don't have the certification language at the bottom. Lakefront states that it doesn't purge equipment between non-organic production runs. However, even if the brewing recipe form is initialed to confirm compliance with purging procedures, the purging procedures and the materials used were not adequately described in the OSP, and purges were not appropriately documented for traceability. Further, the presentation of this documentation for one organic production run and covering only a single time frame is insufficient to show consistent compliance with all organic regulations and requirements. Additionally, Lakefront hasn't maintained records of the malt lot number used in the purging process.

During the April 25, 2018 inspection, the inspector noted continued concerns about inconsistent oversight of the organic program, including inconsistent completion of required documentation; lack of follow-up of employee training topics; problems with document control; and repeat noncompliances. All these noncompliances were addressed in the November 28, 2017 Settlement Agreement and were to have been resolved by the time of the April 25, 2018 inspection. The inspector noted that although required by the Settlement Agreement, the OSP still doesn't describe measures taken to avoid any contamination or commingling of organic products at all stages of receiving, processing, storing, and shipping. Further, the general receiving and shipping practices observed during the inspection were not consistent with what is written in the OSP. There was also not a monitoring system in place to ensure that policies and procedures in the OSP were effectively implemented on a day-to-day basis. The Settlement

Agreement clearly required Lakefront to improve these various recordkeeping systems and to fully explain the improvements and how they have resolved the noncompliances.

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. Lakefront violated the organic regulations at 7 C.F.R. §205.406, 7 C.F.R. §205.201, 7 C.F.R. §205.272 and 7 C.F.R. §205.103. Lakefront has shown systemic and repeated violations of the organic regulations. OTCO has worked to help Lakefront come into compliance, entering into a Settlement Agreement with Lakefront after having issued a prior Notice of Noncompliance and Proposed Suspension. However, despite the Settlement Agreement and Lakefront's agreement to resolve the noncompliances within thirty days of the Settlement Agreement's execution, and attempts to resolve noncompliances, some of the noncompliances remain unresolved.

DECISION

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

If Lakefront waives the hearing, the Agricultural Marketing Service will direct OTCO to issue a Notice of Suspension. At any time after suspension, Lakefront 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.”

Done at Washington, D.C., on this 11th
day of March, 2019.

A handwritten signature in black ink, appearing to read 'Bruce Summers', written over a horizontal line.

Bruce Summers
Administrator
Agricultural Marketing Service