

UNITED STATES DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE
BEFORE THE ADMINISTRATOR

In re:)
Qufu Shengren)
Pharmaceutical Co., Ltd.) **Administrator’s Decision**
Shandong, China) **APL-68-20**

This Decision responds to an appeal (APL-068-20) of a Notice of Noncompliance and Proposed Suspension of National Organic Program (NOP) certification issued to Qufu Shengren Pharmaceutical Co., Ltd. (Qufu) of Shandong, China by Certification of Environmental Standards GmbH (CERES), 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 May 19, 2015, Qufu was certified organic for the scope of handling by USDA-accredited certifier Kiwa BCS Oko-Garantie GmbH (Kiwa).
2. On January 31, 2016, CERES certified Qufu organic for handling.
3. On February 28, 2017, CERES certified Qufu organic for crops for its Xingiang and Gansu locations.
4. On February 15, 2019, Qufu surrendered its CERES crop certification for both farms.
5. On March 5, 2019, USDA-accredited certifier Letis, S.A. certified Qufu organic for crops at the Gansu location.
6. On June 4, 2019, Letis, S.A. certified Qufu organic for crops at the Xingiang location.
7. On September 19, 2019, Qufu notified Letis, S.A. that it was surrendering the crop certification for the Gansu location. Letis S.A. processed this surrender on February 3, 2020. Letis, S.A. currently certifies only the Xingiang location for crops.
8. On April 16, 2020, USDA-accredited certifier NASAA Certified Organic (NCO) certified Qufu organic for crops at the Gansu location.
9. On May 20, 2020, CERES issued Qufu a Notice of Noncompliance and Proposed Suspension for its handling certification.
10. On May 27, 2020, Qufu requested mediation.
11. On June 2, 2020, CERES denied Qufu's mediation request.
12. On June 9, 2020, Qufu filed an Appeal.

DISCUSSION

The USDA organic regulations at 7 CFR §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: ... (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...” The specific synthetic substances on the National List which are allowed for use in organic crop production are identified at §205.601.

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 ... 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 production or handling system plan must include: (1) A description of practices and procedures to be performed and maintained...; (2) A list of each substance to be used as a production or handling input...(3) A description of the monitoring practices and procedures to be performed and maintained...(4) A description of the recordkeeping system implemented to comply with the requirements...(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...”

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)),” ... (1) Practices prohibited under paragraphs (e) and (f) of §205.105.”

The organic regulations at §205.272, Commingling and contact with prohibited substance prevention practice standard, state 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. (b) The following are prohibited for use in the handling of any organically produced agricultural product...(2) The use or reuse of any bag or container that has been in contact with any substance in such a manner as to compromise the organic integrity of any organically produced product or ingredient placed in those containers...”

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;

(b) Establish, implement, and update annually an organic production or handling system plan that is submitted to an accredited certifying agent... (d) Maintain all records applicable to the organic operation for not less than 5 years beyond their creation and allow authorized representatives of the ...certifying agent access to such records during normal business hours for review and copying to determine compliance with the Act and the regulations in this part...(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..."

CERES found numerous prohibited substances on organic stevia leaves sampled at a handling inspection of Qufu, as well as numerous noncompliances regarding recordkeeping, failure to follow their organic management plan (OMP), commingling of and failure to distinguish between organic and conventional stevia leaves, and not following proper intake procedures.

Qufu states that the contamination of organic stevia leaves with conventional stevia leaves was due to human error and it was explained at the inspection. Qufu states there are no noncompliances in its production line, facilities, and process, and that it has conducted additional training of staff on management procedures. Qufu also states it took samples of finished organic stevia leaves and no pesticides were found.

A review of the evidence shows that CERES conducted an inspection of Qufu's handling operation on April 23 and 24, 2020, at which samples were taken of packaged organic stevia leaves in Qufu's warehouse from Batch YJCP-20181009-XG-1. Qufu produces and handles its own organic and conventional stevia leaves. The '2018' in the batch number represents the 2018 crop, while the XG represents Qufu's Gansu Farm in Xiagou Village as the source of the stevia

leaves. The laboratory analysis report of May 14, 2020 from Eurofins' testing of the sample revealed the presence of the following prohibited substances: Acetamiprid, Azoxystrobin, Chlorantraniliprole, Clothianidin, Difenoconazole, Imidacloprid, Metalaxyl, Metalaxy11//Metalaxyl-M, Methoxyfenozide, Metolachlor, Pyraclostrobin, Thiamethaxam, Bifenthrin, Chlorfenapyr, Cyfluthrin, Cyfluthrin/lambda, Indoxacarb, Procymidone, Folpet/PI, and Phthalimide. None of the substances have an EPA (Environmental Protection Agency) tolerance level for stevia leaves except s-Metolachlor, and none of the synthetic substances are listed as allowed on the National List. An EPA tolerance sets a maximum limit for a specific pesticide residue on specific agricultural commodities.

CERES' Inspection Report for the April 2020 inspection, as well as the final Inspection Findings sheet also state that Qufu's OMP is incomplete, Qufu hasn't implemented corrective actions, there is no proper reception/intake procedure, there is insufficient risk management or oversight of suppliers and supplier information, and records are incomplete or missing, including declarations for non-agricultural ingredients and purchase documents. CERES also noted there was contamination of the organic stevia leaves by conventional materials; organic and conventional stevia leaves are stored in the same warehouse in close proximity to each other; and incoming records don't reflect whether the suppliers are organically certified and if package labels reflect organic status of the materials, batch number, or quantity. CERES also noted there was a lack of knowledge of organic processes by Qufu's employees.

Qufu requested mediation arguing several points, which CERES responded to individually in its Notice of Mediation Denial. Qufu made the same arguments in its Appeal. Qufu acknowledged the contamination of organic stevia leaves by non-organic stevia leaves, but states it was due to human error, and all the contaminated stevia leaves in the warehouse were

destroyed. Qufu also stated during the inspection that there was no inventory of organic stevia leaves from 2019 to demonstrate organic processing to the inspector; and therefore, leaves from 2018 were used. However, while Qufu identified the 2018 Batch as YJYL-20180928-DW-1, from Qufu's Gansu Farm in Dongwant Village, the May 14, 2020 Eurofins lab report cited above shows the sample tested by CERES was from Batch YJCP-20181009-XG-1 which is from the Gansu Farm in Xiagou Village. The batch numbers also don't match. Qufu also contends it told the inspector that conventional stevia leaves had been mixed with organic stevia leaves, and the finished product would be sold as conventional. However, Qufu then identified the Batch as YJCP-20200423-RA-60, which is from a 2020 crop, and doesn't identify the source; whereas CERES had sampled and tested a 2018 batch. The inspector found Qufu doesn't have any outside sources and produces all of its own organic stevia leaves. CERES confirms that Qufu told the inspector about the alleged commingling error but states that Qufu didn't include this information in its OMP of April 2020 as it was required to do, didn't otherwise report the incident, and didn't remove the organic labels from the contaminated bags of stevia leaves.

Qufu stated that the mixing of organic and conventional stevia leaves occurred when it was transporting loose conventional stevia leaves, specifically (b) (4) tons/ (b) (4) bags on April 3, 2020 from the warehouse. Qufu states the truck scraped a stack of bagged organic stevia leaves and the organic packages fell onto the transport vehicle and broke open. The mixed leaves were repacked and marked with the original organic outer bag noting Batch YJYL-20181008-XG-1 and put in the organic area of the warehouse. However, this is not the same batch number that was sampled by CERES during the inspection, and also doesn't match the batch number for 2018 identified by Qufu as being used during the inspection or the batch number identified by Qufu as

the finished product that would be sold as conventional due to contamination. It appears that more than 1 batch was contaminated, as Qufu has identified different batch numbers.

Further, CERES states that pictures taken at the inspection show closed and labeled bags, not loose leaves in warehouse, and that Qufu stated in its OMP that it separates and labels the organic and conventional stevia leaves at all points in the processing and handling steps. Therefore, CERES contends that if Qufu had implemented its own procedures, the accident described by Qufu should not have been possible. Pictures submitted by CERES show the bags of organic and conventional stevia leaves stacked in the warehouse and there are no loose leaves seen. Lastly, while Qufu stated the conventional stevia leaves being transported were loose, it then identified them as (b) (4) bags.

Qufu stated that since the organic stevia leaves couldn't be distinguished from the conventional stevia leaves, when the warehouse found that commingling had occurred, it was reported to quality control that the (b) (4) tons of mixed leaves couldn't be used in organic production. However, Qufu states that one of their employees left and the new employee wasn't familiar with procedures and failed to downgrade the leaves pursuant to procedure and the organic stevia leaves were still listed in the organic ledger. CERES replied that if Qufu's procedures to ensure organic integrity of its products are so weak that a change in an employee results in a breakdown of procedures, Qufu isn't 'certifiable.' The alleged accident that caused the commingling should have resulted in Qufu taking measures to ensure that the mixed contaminated leaves weren't used in organic production, labeled as organic, or listed in any documentation/ledger as organic. Qufu should have ensured that any employee handling organic stevia leaves or involved in the organic process/handling, was aware of the procedures and capable of complying with them. Instead, Qufu rebagged the contaminated leaves in an organic

labelled bag. This also contrasts with Qufu's statement that all contaminated organic stevia leaves had been destroyed.

Qufu also stated that Batch YJYL-20181008-XG-1 of (b) (4) tons, which was contaminated, was put in storage on June 28, 2019, and hasn't been sold or used for organic production. This is the same batch number identified above as being rebagged, marked and labeled as organic after the alleged accident despite the mixture of organic and conventional stevia leaves. However, this is not the batch from which CERES took and tested a sample. Qufu states other batches of organic stevia leaves that had been put in the same stack with mixed leaves were also downgraded as non-organic. However, CERES stated that at the inspection in April 2020, the downgrading of the contaminated leaves hadn't yet been done. Further, Qufu said that only organic lots had lot numbers on the bags. Therefore, the bags used for sampling, as they were allegedly contaminated, shouldn't have had lot numbers on them. As CERES concluded, Qufu hadn't downgraded the contaminated leaves and only stated it would do so after the prohibited substances were found on the samples.

Qufu stated that it plans on building a separate warehouse for its organic stevia leaves and organic materials to avoid contamination by conventional stevia leaves. However, while CERES replied that it is a 'good plan for the future,' Qufu's current processes are inadequate and unreliable. Further, any plan to provide for separation of organic and conventional stevia leaves in the future doesn't negate Qufu's prior and current noncompliances which by Qufu's own admission allowed the mixing of organic and conventional stevia leaves. Qufu also stated in its Appeal that it would re-purchase new raw organic materials and make sure that its warehouse is thoroughly cleaned and that its staff are re-trained. However, again this doesn't negate the

noncompliances and commingling of organic and conventional stevia leaves, nor the finding of multiple prohibited substances on the sampled organically-labeled stevia leaves.

Qufu also stated in its Appeal as well as its July 8, 2020 statement to NOP, that it has re-trained its warehouse teams on organic procedures, required information on intake documentation, and management procedures after realizing there were deficiencies. Qufu submitted a Training Record from a May 16, 2020 training on storage and labeling procedures, as well as a Training Record from a May 16 – 17, 2020 training on processing regulations, cleaning, and sanitation, with both being signed by attending employees, along with pictures of the training sessions. However, the recent training of staff on organic processing and related matters doesn't negate the finding of numerous prohibited substances on organic stevia leaves. Further, Qufu's OMP already identified its processes, and the alleged accident shows that Qufu hadn't complied with its own processes.

Qufu also stated in its additional July 8, 2020 statement that it took samples from the products with the contaminated organic leaves and lab analysis confirmed the presence of pesticide residues on the leaves, and therefore, those products will be sold as conventional products. Qufu submitted a Eurofins lab report of June 22, 2020 for Batch YB20200612 which shows a finding of Procymidone at 0.34 mg/kg; Difenoconazole at 0.012 mg/kg; and Metalaxyl at 0.028 mg/kg. Since Qufu states the sample for this test was taken from the contaminated organic stevia leaves, a finding of prohibited substances is expected. However, this sample was taken from a 2020 batch, whereas CERES took samples from a 2018 batch at the inspection and also found prohibited substances. It appears that more than just one 2018 batch was contaminated. Further, there are no identifiers on this sampled batch as to where the stevia leaves originated.

Qufu also submitted Eurofins lab reports of April 25, 2020 for an April 15, 2020 sample from Batch YJCP-20200309; April 25, 2020 for an April 15, 2020 sample from Batch YJCP-20200324; and June 16, 2020, for a June 14, 2020 sample from Batch YJCP-20200321. These 3 lab reports do not show the detection of any pesticides. However, these samples were taken from different batches than the sample taken by CERES during the inspection; were taken after the inspection; have no identifiers as to where these batches were grown; and Qufu took the samples itself with no oversight by CERES.

Several of the substances detected on the organic stevia leaves, as seen in the above referenced Eurofins lab report of May 14, 2020 are pesticides, while Qufu states in its OMP that it doesn't use pesticides. However, while the substances were found on the organic stevia leaves at Qufu's warehouse, CERES didn't sample and test organic stevia leaves in the crops grown by Qufu at the Gansu and Xingiang farms since CERES no longer certifies Qufu for crops. However, Qufu's explanation of an accident resulting in commingling is implausible. The organic and conventional stevia leaves are already packaged in bags when placed in the warehouse and aren't transported or stored as loose leaves. Therefore, the alleged scraping of bags of organic stevia leaves with a truck carrying loose conventional stevia leaves, resulting in commingling, wouldn't have been possible. Rather, the finding of prohibited substances on the CERES-sampled 2018 batch of organic stevia leaves; Qufu's reference to other 2018 batches being contaminated other than that sampled and tested by CERES; and Qufu's own sampling and testing of 2020 batches on which prohibited substances were found, points to the use of prohibited substances on the organic stevia crops prior to harvest, transport, and packaging. Further, while admitting to a commingling accident, Qufu states it rebagged the contaminated organic stevia leaves in a bag labelled organic, and CERES found Qufu didn't remove the

contaminated organic stevia leaves from the organic ledger. The finding of prohibited substances and Qufu's actions justified CERES' issuance of a combined Notice of Noncompliance and Proposed Suspension.

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 Qufu 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. §205.272, Commingling and contact with prohibited substance prevention practice standard; 7 C.F.R. §205.300, Use of the term, "organic;" and 7 C.F.R. §205.400, General requirements for certification. Specifically, evidence substantiates that prohibited substances were found on organically-labeled stevia leaves from both the 2018 and 2020 crops of Qufu. Evidence substantiates that Qufu commingled organic stevia leaves with conventional stevia leaves; failed to take appropriate measures to prevent the contamination of organic stevia leaves by conventional stevia leaves; failed to segregate contaminated organic stevia leaves and then record/downgrade and properly label the contaminated stevia leaves; and failed to report the commingling to CERES. Qufu also failed to comply with its own OMP; failed to follow proper reception/intake procedures and obtain all required information on raw materials/ingredients; failed to follow proper processing/handling

procedures; failed to ensure risk management/oversight of its suppliers; failed to maintain adequate records, including purchase documents; and failed to ensure that its staff were properly and adequately trained on organic processes. Therefore, Qufu may not remain certified.

DECISION

The June 9, 2020 Appeal is denied, and the May 20, 2020 Notice of Noncompliance and Proposed Suspension as to Qufu's handling certification is affirmed. Both the CERES-issued handling certification as well as the Kiwi-issued handling certification are suspended. While its handling certification is suspended, Qufu may not represent, sell, or label stevia leaves from the handling operation as organic. However, pursuant to 7 C.F.R. §205.662(f)(1), Qufu may apply for reinstatement of its handling certification at any time, though it must correct all noncompliances and provide evidence of such before reinstatement will be granted.

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

Done at Washington, D.C., on this 29th
day of December, 2020.

BRUCE SUMMERS

Digitally signed by BRUCE
SUMMERS
Date: 2020.12.29 20:16:40 -05'00'

Bruce Summers
Administrator
Agricultural Marketing Service