

UNITED STATES DEPARTMENT OF AGRICULTURE  
AGRICULTURAL MARKETING SERVICE  
BEFORE THE ADMINISTRATOR

In re:	)	
	)	
Hernan Rosendo Monsalve	)	
Aguilera	)	<b>Administrator’s Decision</b>
	)	<b>APL-053-22</b>
Pichincha, El Oro, Ecuador	)	
	)	

This Decision responds to an Appeal (APL-053-22) of a Notice of Proposed Suspension, and a combined Notice of Noncompliance and Proposed Suspension under the National Organic Program (NOP) issued to Hernan Rosendo Monsalve Aguilera (Hernan) of Pichincha, El Oro, Ecuador by Quality Certification Services (QCS), a USDA accredited certifying agent. The operation has been deemed not in compliance with the Organic Foods Production Act of 1990 (Act)<sup>1</sup> and the U.S. Department of Agriculture (USDA) organic regulations.<sup>2</sup>

**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

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<sup>1</sup> 7 U.S.C. 6501-6522

<sup>2</sup> 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 April 6, 2011, Hernan became certified for crops.
2. On October 6, 2021, QCS issued a Notice of Noncompliance to Hernan.
3. On January 17, 2022, QCS issued a Notice of Proposed Suspension to Hernan.
4. On January 17, 2022, QCS issued a combined Notice of Noncompliance and Proposed Suspension to Hernan citing to the same violations.
5. On February 25, 2022, QCS granted Hernan’s February 15, 2022 request for mediation.
6. On April 29, 2022, QCS issued a Notice of Mediation Failure to Hernan.
7. On May 27, 2022, Hernan filed an Appeal to both QCS notices.

### **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 (specified ingredients or food group(s))” must be: (a) Produced in accordance with the requirements specified in §205.101 or §§205.202 through 205.207 ... and all other applicable requirements of 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 §205.202, Land requirements, state that, “Any field or farm parcel from which harvested crops are intended to be sold, labeled, or represented as “organic,” must: ... (b) Have had no prohibited substances, as listed in §205.105, applied to it for a period of 3 years immediately preceding harvest of the crop ...”

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; ... (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 ...”

Hernan was certified organic for crops on April 6, 2011 and is comprised of 4 parcels/plots – El Pinco with (b) (4) acres; La Loayza with (b) (4) acres; La Playa with (b) (4) acres; and San Jose with (b) (4) acres. On September 29, 2021, a European Commission (EC) authorized inspection body notified QCS that an EC Organic Farm Information System (OFIS) alert had been issued due the finding of a prohibited substance on Hernan bananas exported to Germany. The alert, INTC-611/2021, lists Hernan as the processor/seller and (b) (4) as the producer. The alert further states that the bananas, identified as Lot WK30-2021, with grower code HM-002, and tested at the request of retailer/importer “real GmbH” revealed a finding of Cypermethrin at 0.059 mg/kg.

The September 22, 2021 laboratory report of Chemisches Labor Dr. Mang Food and Water Analyses, performed at the request of (b) (4), under whose tradename the bananas were

exported, showed the sampled and tested bananas from lot, EXP-HM002, from the El Pinco farm, with the cited Cypermethrin finding. Pictures of the banana shipment attached to the laboratory report show a box labeled as Lot EXP-HM002, referencing (b) (4) and Hernan (*Hernan Rosendo Monsalve Aguilera*), with the (b) (4) tradename. There is no EPA (Environmental Protection Agency) tolerance level for Cypermethrin in bananas; and therefore, its use is prohibited in organic banana production.

After receipt of the OFIS alert, QCS issued a Notice of Noncompliance to Hernan on October 6, 2021, informing Hernan of the notification of the Cypermethrin finding, and giving Hernan until November 6, 2021 to provide a response to the findings. Subsequently, on October 11, 2021, QCS conducted an inspection of Hernan's operation and took a sample of water residue from Hernan's fumigation equipment. The resulting Groen Agro Control laboratory analysis report of October 25, 2021 revealed the presence of 9 prohibited substances. One of these detections was Cypermethrin at 7.3 mg/kg; the detection in the equipment residue was even higher than that found on the previously tested bananas. Clorpirifos, Difenconazol, Propiconazol, and Tridemorf were also detected, and like Cypermethrin, don't have an EPA tolerance level. Therefore, their use is prohibited. Fenpropidin, Spinosad, Tebuconazole, and Triadimenol, also detected, have EPA tolerance levels for bananas, those substances were found at rates significantly exceeding the 5% of the EPA level allowed in organic banana production. The QCS Inspection Report also stated that numerous lots lacked buffer zones, and there also hadn't been any risk analysis regarding neighboring operations.

At the same time, (b) (4), whose tradename was used for the shipment, had USDA-accredited certifier CERES (Certification of Environmental Standards GmbH) conduct the OFIS follow-up inspection of Hernan's operation over the course of October 20-22, 2021. CERES

took several samples which were analyzed by the Eurofins laboratory resulting in 3 reports on November 19, 2021. The Eurofins analysis report for a mixed sample of banana fruit and leaves from the El Pinco farm revealed some of the same prohibited substances as found by QCS as well as additional substances: Propiconazole, Tebuconazole, Difenoconazole, Epoxiconazole, Fenpropridin, Fenpropimorph, Pyrimethanil, and Spiroxamine. The Eurofins analysis report for a mixed sample of banana fruit and leaves from the La Loayza farm revealed several of the same substances: Triadimenol, Difenoconazole, Fenpropidin, Fenpropimorph, Spiroxamine, and Tebuconazole. Lastly, the Eurofins analysis report for a mixed sample of banana fruit and leaves from the La Playa farm revealed several of the same substances and a new substance: Chlorpyrifos, Propiconazole, Triadimenol, Difenoconazole, Epoxiconazole, Fenpropridin, Fenpropimorph, Flutriafol, Pyrimethanil, Spiroxamine, and Tebuconazole. Sample forms/labels are attached to each laboratory report.

QCS stated that it went to Hernan's operation again on November 10, 2021, after Hernan stated that the prior positive pesticide residue tests were due to contaminated water sources. QCS collected 4 more samples, testing both water and leave samples, which all were positive for pesticide residues. The Groen Agro Control lab report of November 17, 2021 showed the tested banana leaves from the El Pinco farm contained Fenpropridin, Fenpropimorf, and Spiroxamina. The Groen Agro Control report of the same date for banana leaves from the La Playa farm showed Fenpropimorf. The Groen Agro Control report of November 22, 2021 for water sampled from the El Pinco farm showed Azoxistrobina, Clorpirifos, Miclobutanil, Propiconazol, Pirimetanil, and Tebuconazole – some of the same substances found on banana fruit and leaves, along with some new substances. The Groen Agro Control report of November 22, 2021 for water sampled from the La Playa farm showed Propiconazol, Tebuconazole, and Triadimenol.

QCS submitted a chart showing the various samples by date, and the various substances. As QCS stated, there were substances found in the bananas and banana leaves, as well as the fumigation equipment, that weren't found in the irrigation water, negating Hernan's statement that the contamination is due to the irrigation water. Further, there were substances found at higher levels in the fumigation equipment than in the irrigation water, with 2 substances found at levels 10 times higher. These findings point to the application of prohibited substances via the fumigation sprayers.

Hernan provided a response to the October 6, 2021 Notice of Noncompliance, however, QCS found the response didn't resolve or rebut the numerous findings of prohibited substances. Hernan had submitted several laboratory analysis reports from the second half of 2021, showing no prohibited substances had been found on Hernan products; however, the tested samples weren't taken by the laboratory or a USDA-accredited certifier and the results don't negate the findings of QCS and CERES. Therefore, QCS issued a Notice of Proposed Suspension on January 17, 2022, as well as a combined Notice of Noncompliance and Proposed Suspension. Both notices cite the findings that resulted in the OFIS alert; the findings from samples taken by QCS on October 11, 2021 and November 10, 2021; and the findings from samples taken by CERES for (b) (4) on October 20-22, 2021. QCS stated that the finding of 16 different prohibited substances during the course of 1 month points to a systemic failure of Hernan's organic system plan. Additionally, the evidence doesn't support Hernan's claim that external sources caused the contamination.

Hernan requested mediation on February 15, 2022, which QCS accepted on February 25, 2022. QCS attempted to resolve the noncompliances by offering Hernan a settlement agreement on March 30, 2022. In addition to other terms, the agreement would have required Hernan to

surrender its organic certification and place the farms in transition for 3 years from the last detection of prohibited substances. Hernan rejected this offer, and QCS issued a Notice of Mediation Failure on April 29, 2022.

Hernan filed an Appeal on May 27, 2022, appealing the Notice of Proposed Suspension, and the combined notice. Hernan stated that it had informed QCS and (b) (4) that the contamination was from irrigation water sources and acknowledged that QCS returned to the operation to collect additional samples of irrigation water and banana leaves. Hernan disputes that there is insufficient evidence to support the contention that external sources are the cause of the contamination. Hernan states it is certified under the standards of NOP, the EC, Ecuador, and Japan, and is also certified to (b) (4) and has been evaluated by the numerous certification bodies. Hernan's Appeal letter contains a chart of all the 'schemes' under which it is certified, the dates of certification, and the number of inspections it has undergone by each certifying body. Hernan states that in the last 20 years, it has undergone 149 different analyses at great expense, with 115 pesticide residue tests of multiple media, with 80% of the tests being done since 2019. Hernan contends that despite this history of 'clean' tests, QCS's proposed suspension only considers tests taken in a 2 month period.

Hernan further states that since its product is bananas, only bananas should be tested. However, the organic regulations at 7 C.F.R. §205.670 state that, "(b) The Administrator, applicable State organic program's governing State official, or the certifying agent may require preharvest or postharvest testing of any agricultural input used or agricultural product to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance ..." Further, the provision states that,

“Samples may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed product samples.” Therefore, QCS was allowed and was justified in taking whatever samples it deemed necessary to assess the compliance status of the operation.

(b) (4) also was within its right to engage CERES to conduct an inspection and take samples on its behalf since (b) (4) brand name was used, and it had received the OFIS alert requiring it to make an investigation into the matter.

Hernan also states that the sample of the exported bananas which revealed Cypermethrin was taken in the ‘destination market’ and its traceability and chain of custody can’t guarantee that the contaminated fruit was theirs. However, the OFIS alert clearly identifies Hernan as the seller of the bananas, and the box from which the sample was taken shows the Lot as EXP-HM002, referencing the producer of Exprobiologico and Hernan Rosendo Monsalve Aguilera. The box also has a sticker on it showing “HM 02” and the same green stickers starting with “HM” and followed by a number are seen in pictures from CERES’ October 2021 inspection of Hernan. CERES also obtained dozens of documents during its inspection showing Hernan as a supplier of bananas to Exprobiologica. The documents include invoices to Exprobiologico, transport documents, and inspection forms showing the specific bananas for Lot EXP-HM002. Therefore, it has been clearly established that the bananas tested by (b) (4), and resulting in the OFIS alert, were from Hernan.

Hernan also questions the competence of CERES in conducting the sampling for (b) (4). However, CERES is a USDA-accredited certifier, and its accreditation covers the sampling of agricultural products. Hernan also states that QCS received the (b) (4)-initiated lab reports and assumed they were valid. (b) (4) used a laboratory used in many organic cases, and Hernan has presented no specific reason or evidence that the laboratory wasn’t competent to



conduct the testing of the samples. Hernan also disputes the mixing of fruit and leaves for CERES samples; however, QCS subsequently returned to Hernan's operation and took samples of banana leaves and irrigation water from the El Pinco farm and the La Playa farm which were tested separately, and still resulted in the finding of numerous prohibited substances. Hernan also questioned the right of CERES to conduct sampling for (b) (4). However, QCS stated that (b) (4) has engaged certifiers to conduct their inspections, and that QCS has also conducted inspections for (b) (4). In this case, (b) (4) engaged CERES to conduct the inspection and sampling in question due to receiving the OFIS alert regarding (b) (4) brand name bananas. (b) (4) confirmed this to NOP, and also provided its authorization for CERES to conduct the inspection and sampling/testing on its behalf. Further, QCS stated that it didn't issue the proposed suspension based on CERES' sampling and testing alone, as QCS returned to Hernan's operation after the CERES inspection, and took additional samples, which also revealed prohibited substances.

Hernan also alleges that it was in competition for the (b) (4) fruit market with the entity that prompted the September 2021 sampling and testing which lead to the OFIS alert and loss of (b) (4) certification. Hernan has also alleged collusion between QCS and CERES leading to issuance of the adverse action notice. However, no evidence of market interference has been presented or substantiated.

Lastly, Hernan states it has conducted an in-depth analysis to determine the possible cause of contamination found by QCS and CERES sampling/testing and has taken corrective actions to address this. Specifically, Hernan states that to address possible pesticides in water sources, the source of water for the El Pinco farm has been changed from the Barbones River to the Motuche River and wells, requiring Hernan to extract ground water and invest in canals and

pipes from the new water source. Hernan suspended the use of water from the ‘provincial council irrigation canal due to fumigation waste being dumped in the canal. Hernan is washing backpack pumps with water bottled for human consumption; requiring double deep washing of fumigation equipment in planes; will stop using aerial sprayings for 5 months; ‘installed’ up to 100 meter wide buffer barriers to mitigate any drift; and has continued to train personnel on the avoidance of contamination. Hernan concludes by stating that it has decided to separate the certification of the farms to be able to more closely monitor the farms for possible contamination. QCS informed NOP that Hernan submitted a renewal certification application to QCS for the La Loayza and La Playa plots but is seeking new certification for the San Jose plot under the name (b) (6), and for the El Pinco plot under the name (b) (6). These matters are pending before QCS.

## CONCLUSION

Evidence substantiates that Hernan has violated the organic regulations at 7 C.F.R. §205.102, Use of the term, “organic;” 7 C.F.R. §205.105, Allowed and prohibited substances, methods, and ingredients in organic production and handling; 7 C.F.R. §205.202, Land requirements; and 7 C.F.R. §205.400, General requirements for certification. The laboratory analysis of samples taken at inspections of Hernan’s operation on October 11, 2021 and November 10, 2021 revealed the presence of numerous different prohibited substances on bananas, banana leaves, irrigation water, and water residue on equipment. Although Hernan has undergone many inspections and sampling and testing by various certification entities which didn’t reveal the presence of prohibited substances, this doesn’t negate the findings of certifier QCS. QCS had initiated an inspection with sampling and testing after receipt of an OFIS alert

which cited to a September 22, 2021 laboratory analysis report showing a finding of a prohibited substance on Hernan's product sampled at its destination point. Further, while QCS' findings stand alone, they were corroborated by the findings of CERES, which conducted an inspection along with sampling and testing on behalf of (b) (4) on October 20, 2021. Hernan has proposed several correction actions to address any possible contamination of its product; however, this also doesn't negate the prohibited substance findings. Therefore, Hernan may not remain certified for crops at this time.

### DECISION

Hernan's May 27, 2022 Appeal of the January 17, 2022 Notice of Proposed Suspension, and January 17, 2022 combined Notice of Noncompliance and Proposed Suspension is denied. Hernan's crop certification is to be suspended for a period of 3 years from the last sampling date which resulted in the prohibited substance findings, November 10, 2021. Pursuant to the organic regulations at 7 C.F.R. §205.662(f), Hernan may apply for reinstatement of its crop certification after November 9, 2024, with proof that all needed corrective actions have been taken.

Additionally, attached to this formal Administrator's Decision denying Hernan's Appeal is a Request for Hearing form. Hernan has thirty (30) days to request an administrative hearing before an Administrative Law Judge.

Done at Washington, D.C., on this 30th  
day of November, 2022.

**BRUCE SUMMERS** Digitally signed by BRUCE  
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Date: 2022.11.30 23:00:29 -05'00'

Bruce Summers  
Administrator  
Agricultural Marketing Service