

UNITED STATES DEPARTMENT OF AGRICULTURE  
AGRICULTURAL MARKETING SERVICE  
BEFORE THE ADMINISTRATOR

In re:  
Meriban S.A.  
El Oro, Ecuador

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**Administrator's Decision**  
**APL-068-19**

This Decision responds to an appeal (APL-068-19) of a Notice of Noncompliance and Proposed Suspension of National Organic Program (NOP) certification issued to Meriban S.A. (Meriban) of El Oro, Ecuador, by Control Union Peru SAC (Control Union). 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 such decision to the USDA Agricultural Marketing Service (AMS) pursuant to § 205.680

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

<sup>2</sup> 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 July 26, 2017, Meriban became certified for crops, specifically bananas.
2. On September 14, 2018, Control Union conducted an inspection of Meriban, specifically farm Colon 4, and collected banana leaf samples. The resulting September 26, 2018 laboratory results found prohibited substances on the banana leaf samples.
3. On October 9, 2018, Control Union issued a Notice of Proposed Suspension to Meriban, citing to the detection of prohibited substances found on banana leaf samples taken during the September 14, 2018 inspection and sampling, and other noncompliances.
4. On October 12, 2018, Meriban completed an Incident Report stating that the contamination of the banana leaves on its farms could be because its aerial fumigation contractor, [REDACTED] did not sufficiently clean its mixing systems and the supply plane, as [REDACTED] also conducts aerial fumigation for conventional farms. Meriban also suggested that the contamination could be due to aerial and ground spraying at two neighboring conventional farms. Meriban noted planned corrective actions, including proper cleaning of aerial fumigation equipment and planting trees as buffers to prevent drift from neighbors.
5. On October 17, 2018, Meriban requested mediation, proposing an agreement whereby Control Union would collect samples two or three times per year and would conduct two additional inspections per year, to corroborate Meriban's fulfillment of corrective measures.

6. On November 21, 2018, while Control Union was considering Meriban's mediation request, Meriban filed an Appeal to the October 9, 2018 Notice of Proposed Suspension with NOP.
7. On March 20, 2019, at the direction of NOP, Control Union rescinded the October 9, 2018 Notice of Proposed Suspension. This recession was necessary because Control Union hadn't issued a notice of noncompliance prior to issuing the proposed suspension notice, nor was the October 9, 2018 notice a combined notice of noncompliance and proposed suspension. The notice also had identified correctable noncompliances. Control Union was instructed to follow proper procedures in issuing adverse action notices.
8. On March 22, 2019, NOP dismissed the November 21, 2018 Appeal of Meriban as the Notice of Proposed Suspension had been rescinded.
9. On April 3, 2019, Control Union issued a Combined Notice of Noncompliance and Proposed Suspension citing to the September 14, 2018 banana leaf samples and the finding of prohibited substances.
10. On July 17, 2019, after having accepted Meriban's request for mediation, Control Union issued a Mediation Failure letter stating that Meriban didn't agree to the terms of the proposed mediation agreement.
11. On August 24, 2019, Meriban filed an Appeal to the April 3, 2019 Combined Notice of Noncompliance and Proposed Suspension. The appeal was accepted.
12. On October 9, 2019, Control Union issued a Notice of Noncompliance after the testing of banana leaf samples taken at the September 26, 2019 inspection of the Colon 4 farm again revealed prohibited substances.

13. On December 13, 2019, Control Union issued a Notice of Proposed Suspension based on the finding of prohibited substances on banana leaf samples taken at a September 26, 2019 inspection.

14. Meriban didn't file an Appeal to the December 13, 2019 notice and Control Union subsequently issued a Notice of Suspension on January 21, 2020. However, although Meriban has now been suspended, the Notice of Proposed Suspension is being addressed here because the adverse action was issued for the same violation, the finding of prohibited substances, when Control Union conducted a 'follow up' inspection, sampling, and testing.

### **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..." 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 §205.202, 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 §205.671, Exclusion from organic sale, state that, “When residue testing detects prohibited substances at levels that are greater than the 5 percent of the Environmental Protection Agency’s tolerance for the specific residue detected or unavoidable residual environmental contamination, the agricultural product must not be sold, labeled, or represented as organically produced.”

Control Union previously proposed a suspension of Meriban’s organic certification, which would prohibit the sale, labeling, or representation of its products as organic. Control Union detected prohibited substances on banana leaf samples from Meriban’s Colon 4 farm, collected during the September 14, 2018 inspection and again on banana leaf samples collected during the September 26, 2019 inspection. Although the initial October 9, 2018 Notice of Proposed Suspension, which was rescinded, cited to other noncompliances, the April 3, 2019 Combined Notice of Noncompliance and Proposed Suspension only cited to the finding of prohibited substances on banana leaf samples. Control Union previously attempted to mediate with Meriban, which wouldn’t accept the conditions of mediation. A second attempt at mediation was made after Control Union issued the April 3, 2019 Combined Notice of Noncompliance and Proposed Suspension, but Meriban again refused to accept the terms of the proposed mediation agreement. A second finding of prohibited substances on banana leaf samples taken at the September 26, 2019 inspection ultimately resulted in issuance of a Notice of Proposed Suspension on December 13, 2019, which Meriban didn’t appeal.

In its Appeal of the April 3, 2019 Combined Notice of Noncompliance and Proposed Suspension, Meriban contends that the prohibited substances on the banana leaves from the September 14, 2018 inspection are a result of improper cleaning of spraying equipment by its then-aerial fumigation contractor, [REDACTED] which also conducts aerial fumigation over conventional farms. Therefore, Meriban states it changed aerial fumigation contractors. Meriban also previously stated that drift from neighbors' conventional farms and their aerial fumigation is to blame and cites to the greater existence of prohibited substances in the buffer zone than on his crops. Meriban proposed that it extend the buffer zones for its farm Colon 4, plant trees as barriers to block drift, evaluate potential aerial spraying, and hire a technical manager to oversee aerial spraying. Meriban also proposed that Control Union conduct fruit sampling and testing 2 or 3 times a year, along with an additional 2 inspections per year, even though Meriban states that its vendor [REDACTED] regularly conducts tests on its bananas.

A review of the evidence shows that the sampling and testing of banana leaves obtained from Meriban's Colon 4 farm during the September 14, 2018 inspection revealed the existence of prohibited substances. Specifically, the laboratory analysis reports of September 26, 2018 from Eurofins found Difenoconazole at 0.012 mg/kg and Epoxiconazole at 0.017 mg/kg on 1 sample; and Epoxiconazole at 0.014 mg/kg on a second sample.

The sampling and testing of banana leaves taken during the subsequent inspection on September 26, 2019 again revealed prohibited substances. Specifically, the Eurofins laboratory analysis report of October 5, 2019 found DEET (N,N-Diethyl-meta-toluamide) at 0.050 mg/kg and Fenpropimorph at 0.038 mg/kg. A sampling sheet from the September 26, 2019 inspection and sampling of banana leaves from the Colon 4 farm contains information matching that on the lab report. This second finding is subsequent to the August 24, 2019 Appeal of the April 3, 2019

Notice of Noncompliance and Proposed Suspension, but is addressed here as Control Union had continued to monitor Meriban for the use of prohibited substances.

The Environmental Protection Agency (EPA) has established tolerance levels for different chemicals, setting limits on the amount of the chemical allowed on an agricultural product. The substances DEET and Difenoconazole do not have an established EPA tolerance level. Therefore, these substances at any level are prohibited.

Further, since DEET and Difenoconazole do not have EPA tolerance levels, the FDA (Food and Drug Administration) action levels must be reviewed. These 2 substances also do not have FDA action levels. The FDA website states that, "Action levels and tolerances represent limits at or above which FDA will take legal action to remove products from the market. Where no established action level or tolerance exists, FDA may take legal action against the product at the minimal detectable level of the contaminant." Therefore, the DEET and Difenoconazole are prohibited under FDA allowances.

The other substances, Epoxiconazole and Fenpropimorph, which were detected per laboratory reports of September 26, 2018 and October 5, 2019, respectively, have EPA tolerance levels for the fruit component of bananas. The EPA regulations at 40 C.F.R. §180.1(h)(1) state that, "The raw agricultural commodity bananas, when examined for pesticide residues, shall not include any crown tissue or stalk." However, because banana leaves were sampled, and not the fruit, there is no assessment of whether and at what levels those substances are present on the banana fruit. Of note, the levels of Epoxiconazole and Fenpropimorph detected on the banana leaf samples were within 5% of the applicable EPA tolerances. The EPA tolerance level for Epoxiconazole is 0.5 ppm, making the allowed 5% threshold for organic products 0.025. Therefore, the findings of Epoxiconazole at 0.014 mg/kg and 0.017mg/kg are both below the

allowed threshold. The substance Fenpropimorph has an EPA tolerance level for bananas of 2.0 ppm, and thus the allowed 5% threshold is 0.1. The finding of 0.038 mg/kg is also below the allowed threshold. Therefore, the findings of Epoxiconazole and Fenpropimorph are not prohibitive under EPA allowances. As these 2 substances have EPA tolerance levels, FDA action levels are not relevant.

Meriban submitted its Registry of Product Applications for 2018 which doesn't list any of the 4 substances. However, the absence of the substances on this list is not definitive evidence that the substances weren't used on Meriban's Colon 4 farm. The September 2018 sampling and testing of banana leaves showed the presence of Difenoconazole and Epoxiconazole, while the September 2019 sampling and testing of banana leaves showed the presence of DEET and Fenpropimorph. Meriban submitted a laboratory report of August 30, 2017, from testing performed on samples taken from Colon 4, and tested for [REDACTED], Meriban's vendor. Epoxiconazole wasn't detected, but the laboratory didn't test for the other 3 substances. Further, the sampling and testing for the August 30, 2017 report pre-date the sampling and testing by Control Union by a year and 2 years respectively for the September 2018 and September 2019 reports and does not negate Control Union's subsequent findings.

Meriban also submitted laboratory analysis reports from the AGQ Labs, dated October 23, 2019, for testing done on banana leaf samples and banana fruit samples. On both reports, all 4 substances tested at <0.010 mg/kg on the leaves and the fruit. However, these tests were performed over a year after Control Union's initial sampling and testing which revealed Difenoconazole and Epoxiconazole and only a month after Control Union's September 2019 sampling and testing which revealed DEET and Fenpropimorph. Further, although the levels of Epoxiconazole and Fenpropimorph found by Control Union are below the allowed EPA



threshold, there is no EPA tolerance level for DEET or Difenoconazole and any finding of those substances is prohibitive. Further, the DEET and Difenoconazole are prohibited under FDA allowances. Therefore, Meriban's results do not negate the findings by Control Union.

Meriban suggested that its aerial fumigation company, [REDACTED] is to blame due to inefficient cleaning of plane tanks since [REDACTED] does aerial fumigation on conventional and organic farms. However, although Control Union acknowledged that Meriban has changed aerial fumigation contractors, this does not negate the finding of prohibited substances on Meriban's crops. Further, Meriban is responsible for the actions or inactions of its contractor, [REDACTED]. Meriban submitted invoices from its new fumigation service, [REDACTED], for services performed on August 31, 2018; September 22, 2018; and September 28, 2018. Two of those dates are after an inspection and sampling of banana leaves, while one date is prior to an inspection and sampling. However, even if these fumigation sprayings didn't contain prohibited substances, this does not negate the impact of prior sprayings containing prohibited substances. Meriban also submitted numerous statements and certifications from [REDACTED] regarding its inspection, calibration, and cleaning of its equipment. These documents include a Commitment Letter of Aircraft Spray Calibration; a Certificate stating that [REDACTED] will triple wash its containers; and a Certificate of Procedures. All the documents are on [REDACTED]'s letterhead and are dated August 9, 2019. However, while the change in companies and [REDACTED]'s commitment would be "good going forward," they don't negate the prior findings of prohibited substances. Further, subsequent to, and despite, the change in fumigation services, the banana leaf samples taken at the September 26, 2019 inspection again revealed the presence of prohibited substances.

Meriban also suggested that cross contamination of its land was caused by drift from two neighboring conventional farms but didn't provide any information on the neighboring farms or substances they use. Meriban states that the finding of prohibited substances in the buffer zones at a higher concentration compared to the organic crops, supports the contention that drift is to blame. However, the laboratory reports noted above resulted from the sampling and testing of banana leaf samples from the Colon 4 farm, and there is no indication that the banana leaves were from buffer zones. The inspector also noted in the September 14, 2018 inspection report that there was cross-contamination from two conventional neighbors. Control Union alluded in its October 9, 2018 letter to Meriban's buffer zones being a 'critical' noncompliance, inferring the buffer zones were not adequate. However, even if one assumes that the contamination was a result of drift from conventional neighbors, it is Meriban's responsibility as an organic operation to have adequate buffer zones to prevent drift contamination. Meriban re-submitted the map of the Colon 4 farm with buffer zones marked. However, again, while an increased buffer zone is advantageous going forward, it doesn't negate the prior findings. Further, the sampling and testing of banana leaves taken at the September 26, 2019 inspection against revealed prohibited substances.

Finally, in a prior case, Control Union accepted Meriban's request for mediation, and Meriban proposed additional inspections and samplings of banana fruit and banana leaves, as well as extending the buffer zone, evaluating its fumigation service, and hiring a technician. However, Meriban filed an Appeal while Control Union was still considering the mediation agreement terms.

After issuing the April 3, 2019 Combined Notice of Noncompliance and Proposed Suspension, Control Union again accepted Meriban's request for mediation and again offered a

mediation agreement whereby Meriban would agree to remove the Colon 4 farm from organic production for 3 years due to the finding of prohibited substances. Further, the agreement would require Meriban to undergo 2 inspections per year with sampling; inform Control Union of any changes to its Organic System Plan; meet the deadlines for responding to any future notices of noncompliance; and not use any prohibited substances on its fields. However, Meriban rejected Control Union's terms for an agreement resulting in Control Union issuing the July 17, 2019 Mediation Failure notice. Meriban had previously agreed and again stated in its subsequent August 24, 2019 Appeal that Control Union could take samples from the farm multiple times each year and it would create additional buffers. However, Meriban wouldn't agree to the 3-year ban on the farm required under 7 C.F.R. 205.202 when prohibited substances are found. Subsequent testing on banana leaf samples from September 26, 2019 again revealed the presence of prohibited substances.

In conclusion, banana leaf samplings from Meriban's Colon 4 farm have revealed prohibited substances on two occasions in the last 15 months. There is no EPA tolerance level nor FDA action level for DEET or Difenconazole for bananas and therefore, these substances are prohibited in the edible portion of the crop in any amount. Further, pursuant to the organic regulations at 7 C.F.R. §205.671, the crop may not be sold, labeled, or represented as organically produced.

The organic regulations at 7 C.F.R. §205.202, specifically require that land from which harvested organic crops are sold, labeled, or represented as organic must not have had prohibited substances applied to it for a period of 3 years immediately preceding the harvest. Also, the organic regulations at 7 C.F.R. §205.105 state that synthetic substances and ingredients may not be used in organic crop production unless they are allowed per the National List. However, none

of these substances detected are an allowed substance per the organic regulations and Meriban was not able to offer an alternative explanation for the apparent application of prohibited substances. Additionally, although Meriban has obtained a new aerial fumigation service which has equipment cleaning procedures in place, this doesn't negate the prior findings of prohibited substances. Further, sampling and testing after the change in fumigation services again revealed the presence of prohibited substances.

### **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, Meriban violated the organic regulations at 7 C.F.R. §205.102; 7 C.F.R. §205.105; 7 C.F.R. §205.202; and 7 C.F.R. §205.671. These noncompliances do not allow for continued certification.

### **DECISION**

The appeal is denied and the suspension of Meriban's organic certification is affirmed. Meriban is not eligible for organic certification for 3 years from the date of the last sampling for which prohibited substances were found on Meriban's farm, Colon 4, specifically September 26, 2019. Barring the interim use of prohibited substances on the land or crops, the farm will be eligible for organic certification on September 25, 2022, when Meriban may apply for reinstatement of its organic certification pursuant to 7 C.F.R. §205.662(f). Until Meriban's certification has been reinstated, it may not sell, label, or represent a product as organic.

Attached to this formal Administrator's Decision denying Meriban's appeal is a Request for Hearing form. Meriban has thirty (30) days to request an administrative hearing before an Administrative Law Judge.

If Meriban waives the hearing, the Agricultural Marketing Service will direct Control Union to issue a Notice of Suspension. At any time after suspension, Meriban 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." Meriban may work with any certifier to complete a request for reinstatement.

Done at Washington, D.C., on this 7<sup>th</sup>  
day of February, 2020.



Bruce Summers  
Administrator  
Agricultural Marketing Service