

UNITED STATES DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE
BEFORE THE ADMINISTRATOR

In re:)	
Alejandro Marquez Mendez)	Administrator's Decision
Descafeinadores Mexicanos,)	APL-008-15
S.A. de C.V. (dba Descamex))	

This Decision is in response to an appeal (APL-008-15) of a Combined Notice of Noncompliance and Proposed Revocation issued by the U.S. Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP) to Descafeinadores Mexicanos, S.A. de C.V. (dba Descamex), located in Cordoba, Veracruz, Mexico. The operation was deemed not in compliance with the Organic Foods Production Act of 1990 (OFPA)¹ and the 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 §205.662. The Act authorizes the NOP to enforce the USDA organic regulations. Persons subject to the Act who believe they are adversely affected by a noncompliance decision, such as a Combined Notice of Noncompliance and Proposed Revocation, may appeal such decision to the AMS Administrator pursuant to §205.680 of the USDA organic regulations.

¹ 7 U.S.C. 6501-6522

² 7 C.F.R. Part 205

FINDINGS OF FACT

1. Descafeinadores Mexicanos, S.A. de C.V. is a certified organic operation located in Cordoba, Veracruz, Mexico.
2. On December 30, 2014, the NOP issued Descamex a Combined Notice of Noncompliance and Proposed Revocation. The adverse action was based on laboratory samples showing the presence of a prohibited substance, methylene chloride, in coffee decaffeinated by Descamex and then labeled for sale as organic.
3. On January 21, 2015, Descamex appealed the Notice; the appeal was accepted and was acknowledged on January 28, 2015.

DISCUSSION

The NOP issued Descamex a combined Notice of Noncompliance and Proposed Revocation. The Proposed Revocation was issued because laboratory samples showed the presence of a prohibited substance, methylene chloride, in coffee decaffeinated by Descamex and labeled for sale as organic. The NOP had received a complaint alleging that Descamex was using methylene chloride to decaffeinate organic coffee, in violation of the USDA organic regulations. During the complaint investigation, the NOP collected four samples of organic coffee decaffeinated by Descamex from (b) (4), (b) (7)(E) Testing found residues of methylene chloride, which is prohibited for use in organic agriculture under the USDA organic regulations.

The Descamex appeal contains four key points. First, Descamex argued that the combined Notice of Noncompliance and Proposed Revocation was inappropriately cited, as Descamex does not use methylene chloride in the production of organic coffee. To support this point, Descamex contended that the OFPA and USDA instructions to certifiers do not prohibit

the *de minimis* presence of prohibited substances in organic agricultural products, especially if such substances are ubiquitous in the environment, as is methylene chloride. Descamex noted that the methylene chloride levels detected were very low, and below Food and Drug Administration (FDA) Action Levels for methylene chloride in coffee. As such, Descamex claims that the laboratory results did not warrant a proposed revocation of organic certification, but instead only notification about the residues.

In response to this first point, AMS notes the OFPA and the USDA organic regulations do prohibit the sale or labeling of agricultural products as organic if the products contain residues of prohibited substances. The USDA organic regulations at §205.671 state that an agricultural product containing prohibited substances at levels greater than 5 percent of the Environmental Protection Agency (EPA) tolerance may not be sold as organic. The NOP further clarifies the requirement in an Instruction to certifiers, stating that if a substance has no EPA tolerance, but is present at a level above the FDA Action Level in an agricultural product, that product cannot be sold as organic.

The EPA has not established a tolerance for methylene chloride in coffee. The FDA has not set an Action Level for methylene chloride in coffee, although it allows it to be used as a secondary direct additive in conventional coffee. Because methylene chloride is a substance prohibited for use in organic production and handling, and because there is no EPA tolerance and no FDA Action level for methylene chloride in coffee, its presence renders coffee ineligible for sale as organic.

The second point in Descamex's appeal noted that two previous sampling events of its decaffeinated organic coffee tested negative for the substance. The first samples were collected in July 2013 at the Descamex production facilities during an unannounced inspection by the

operation's certifier, the Organic Crop Improvement Association (OCIA). The second samples were collected in April 2014 at the Descamex production facilities, (b) (4)

(b) (4) Testing of both sample sets did not find residue of methylene chloride.

In response to this second point, AMS notes that the two negative test results Descamex described (from samples collected in July 2013 and April 2014) are irrelevant to whether the NOP acted appropriately in issuing the combined Notice of Noncompliance and Proposed Revocation. The NOP issued the adverse action based on USDA laboratory testing of samples taken during an NOP October 2014 visit to (b) (4), (b) (7)(E) Government staff collected the samples as part of its investigation of a complaint alleging that Descamex used methylene chloride to decaffeinate organic coffee. Any other test results asserted by Descamex do not successfully rebut the violation cited in the Notice.

Further, AMS considers the July 2013 OCIA test results cited by Descamex in its appeal to be invalid, due to procedural issues at the time of sample collection. As part of the complaint investigation and at the NOP's request, OCIA conducted an unannounced inspection of Descamex production facilities on July 5, 2013. Descamex initially denied the OCIA inspector access to all of its facilities, violating the USDA organic regulations. Further, after the OCIA inspector was allowed full access to Descamex facilities, he personally collected only one of the seven coffee samples taken during the inspection. Six of the samples were taken by Descamex' in-house laboratory and provided to the inspector, violating the USDA organic regulations.

For the third point in its appeal, Descamex argues that the USDA laboratory testing that found residue of methylene chloride in Descamex decaffeinated organic coffee was flawed, due to chain of custody issues, and because, again, the amount of methylene chloride detected was *de minimis* and below the level triggering adverse action. Descamex claims that methylene chloride

is ubiquitous in the environment and, given the amount of time the sampled coffee was out of Descamex' control, it could have been contaminated. Descamex also noted that one of the NOP samples labeled "Blank" was, in fact, not a field blank sample measuring possible environmental contamination, but a product sample, and therefore, the lab results are unreliable.

In response to this third point, AMS finds that the USDA laboratory testing of organic coffee decaffeinated by Descamex was valid. In October 2014, NOP staff visited the (b) (4), (b) (7)(E) (b) (4), (b) (7)(E) and collected samples of Descamex decaffeinated coffee product. Staff took the samples from bulk shipments sent from the Descamex production facilities in Veracruz, Mexico to (b) (4), (b) (7)(E) sampled decaffeinated organic coffee from intact bags shipped from Descamex to (b) (4), (b) (7)(E) and collected documents demonstrating the chain of custody for the sampled bags of coffee. There is no evidence that the bags were opened and contaminated while in shipment between Descamex (b) (4), (b) (7)(E) Further, NOP staff collected samples in a way that avoided cross-contamination.

Maintaining proper chain of custody and other collection protocols, NOP staff submitted the samples for testing to an accredited laboratory. The laboratory found the presence of methylene chloride in the samples of Descamex decaffeinated organic coffee. Given sampling conditions, there is no mechanism by which methylene chloride would contaminate the coffee.

AMS does acknowledge that one of the samples of Descamex coffee was mislabeled "Blank" on the chain of custody form. The sample was not a blank, but rather, a product sample to be tested for methylene chloride. A mislabeled sample on the chain of custody form does not invalidate the positive test results for the four coffee samples. Further, the laboratory did use a soil sample as a "method blank" to rule out contamination in the laboratory and this "method blank" tested negative for methylene chloride.

Further, as the investigation that led to the appealed Notice of Noncompliance and Proposed Revocation continued, NOP subsequently collected nine additional samples of organic coffee decaffeinated by Descamex and shipped to (b) (4), (b) (7)(E). Again, the samples were taken from intact bags of coffee and the chain of custody was documented. All nine samples were found positive for methylene chloride. Staff collected a field blank as a part of this sampling event, a sample of organic coffee (b) (4), (b) (7)(E) decaffeinated by a different company. The field blank had no detectable methylene chloride. As with the testing cited in the Notice of Noncompliance and Proposed Revocation, for these samples, the laboratory also used a soil sample as a "method blank" to rule out contamination in the laboratory and the sample tested negative for methylene chloride.

Finally, AMS reiterates that, contrary to Descamex's argument, there is no FDA Action Level for methylene chloride in coffee. Instead, under its regulations at 21 CFR 173.255, FDA has established a tolerance for methylene chloride as a secondary direct food additive in decaffeinated coffee (10 ppm). A secondary direct food additive is used for a technical effect in food during processing and is ordinarily removed from the final product (e.g., a processing aid). FDA establishes Action Levels for poisonous or deleterious substances that unavoidably contaminate food. FDA has not established an action level for methylene chloride.

As the fourth and final point in its appeal, Descamex argues that the combined Notice of Noncompliance and Proposed Revocation violated Descamex' procedural and substantive due process rights, as well as the USDA organic regulations, because NOP did not demonstrate that the alleged violation was uncorrectable or willful, which are thresholds for proposing revocation under the USDA organic regulations at §205.662. Descamex also noted that the Notice of Noncompliance and Proposed Revocation did not reference mediation rights.

In response to this final point in the appeal, the Combined Notice of Noncompliance and Proposed Revocation violated neither Descamex' due process rights, nor the USDA organic regulations. The USDA organic regulations at §205.660(b) state that the NOP may: "...initiate suspension or revocation proceedings against a certified operation when the Program Manager has reason to believe that a certified operation has violated or is not in compliance with the Act or regulations in this part. The NOP is not bound by the USDA organic regulations at §205.662 (they apply only to certifying agents and State organic programs), but often uses the criteria set forth there in in determining what type of response is appropriate to identified noncompliance. Using the criteria at §205.662(c), the NOP determined that a Combined Notice of Noncompliance and Revocation was appropriate, as correction in response to the presence of a prohibited substance in an organic product would not be possible.

In proposing revocation, the NOP also took into account the complainant's allegation of willful violation and the coffee industry's use of methylene chloride to decaffeinate conventional coffee, as willful violation would warrant proposed revocation under the USDA organic regulations at §205.662(d). As the violation was an uncorrectable noncompliance, and possibly a willful noncompliance, the proposed revocation was appropriate. Descamex was provided the opportunity to appeal the adverse action, and the appeal was timely allowed.

Finally, the NOP does not offer mediation when proposing adverse actions against certified operations. The regulations at §205.662, which addresses mediation rights, govern only certifiers and State organic programs. Thus, the NOP did not violate the USDA organic regulations by not providing the right to request mediation in its Notice.

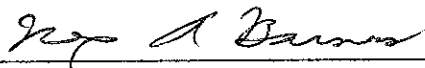
CONCLUSION

The evidence indicates that the NOP's December 30, 2014, Notice of Noncompliance and Proposed Revocation to Descamex was appropriate due to the nature of the violations.

DECISION

The appeal is denied. Descamex's organic certification is to be revoked. Attached to this formal Administrator's Decision is a Request for Hearing form. Descamex has thirty (30) days to request an administrative hearing before an Administrative Law Judge. If Descamex does not request a hearing in that period, this Decision will be implemented and the NOP will revoke Descamex's organic certification. In accordance with §205.662(f)(2) of the USDA organic regulations, "A certified operation or a person responsibly connected with an operation whose certification has been revoked will be ineligible to receive certification for a period of 5 years following the date of such revocation."

Done at Washington, D.C., on this 7
day of DECEMBER, 2015.



Rex A. Barnes

Associate Administrator