



Marketing and
Regulatory
Programs

October 7, 2022

Washington, DC
20250

The Honorable Mark Warner
United States Senate
703 Hart Senate Office Building
Washington, DC 20510

Dear Senator Warner:

Thank you for your letter of March 31, 2022, cosigned by Senator Kaine, urging our Agency of the U.S. Department of Agriculture (USDA) to pursue aggressive Animal Welfare Act (AWA) enforcement action against Envigo RMS, LLC (Envigo). We regret the delay in responding. I understand our Agency's Legislative Director, Mr. Christopher Needham, was in touch with your staff in the interim.

We appreciate you sharing your concerns and assure you we are deeply committed to enforcing the AWA. USDA works with the U.S. Department of Justice's (DOJ) Environment & Natural Resources division, along with the U.S. Attorneys offices, to pursue enforcement actions that achieve the goals of the AWA and other humane protection statutes. On July 15, 2022, in a consent decree entered by the U.S. District Court for the Western District of Virginia, Envigo agreed to a permanent prohibition from engaging in any AWA-regulated activity at its facilities in Cumberland, Virginia. Envigo also agreed to relinquish thousands of beagles remaining at the facility to the Humane Society of the United States (HSUS).

This result arose from the United States filing suit against Envigo in May 2022, alleging the company was failing to meet the AWA minimum standards for handling, housing, feeding, water, sanitation, and adequate veterinary care, among other requirements. The complaint included over 60 citations for AWA noncompliances, many of which were critical in nature. It followed the execution of a Federal search warrant, during which the United States seized numerous dogs and puppies determined by veterinarians to be in acute distress. Additional dogs and puppies were later seized. On May 21, 2022, the Federal court granted a temporary restraining order requiring Envigo to take action to address the AWA noncompliances identified in the complaint. After the court issued a preliminary injunction on June 17, 2022, DOJ and Envigo jointly submitted a plan—which was approved on July 5, 2022—to transfer the remaining beagles to HSUS and make them available for adoption by September 5, 2022.

Prior to taking these actions, and despite challenges arising from the COVID-19 pandemic, our Agency's Animal Care program worked diligently to improve animal welfare at Envigo by conducting inspections at a greater frequency and identifying, documenting, and requiring that the facility correct noncompliances. We also understand the importance of making AWA inspection reports available to the public in a timely manner. When inspections are complex—as was the case with Envigo—that can delay our ability to make the findings public. However, our Agency does not impose a second 21-day hold following an appeal and report modification.

Licensees have 21 days from the date they receive an inspection report to appeal its findings and are only allowed one appeal per inspection report. Periodically, a licensee may request an extension to the 21-day deadline to review the report more thoroughly. If they do so in advance of the deadline, we may allow a few days of additional time. However, our officials review the appeal upon receipt and make every effort to respond within 30 days. The final inspection report—whether modified or not—is posted on our public search tool as soon as the licensee receives the appeal reply. While the complexity of the situation with Envigo resulted in some delays, we are committed to promptly publishing inspection reports.

We have answered your additional questions below.

1. Has APHIS taken any enforcement actions against the Cumberland, Virginia Envigo facilities (breeding facility: Certificate 32-A-0774, site 005 and research facility: Certificate 23-R-0187, site 002), or does it plan to do so?

Please refer to the previous information about AWA enforcement actions against Envigo.

2. What number and type of AWA violations would typically be sufficient to warrant various types of enforcement actions, including regulatory correspondence, stipulated penalties, license suspension or revocation, confiscation of animals, and formal administrative proceedings?

We may pursue enforcement action for even one alleged violation. However, the law requires that we consider several factors when pursuing enforcement actions. These include the size of the facility, the nature and severity of the noncompliances, the facility's efforts to correct noncompliances, and any prior history of violations. Enforcement actions can include letters of warning, monetary penalties, or license suspension or revocation. We may refer cases involving the most serious violations to DOJ for civil or criminal action.

3. Over the last three years, has APHIS cited any single facility for more violations of the AWA in a nine-month span than Envigo has received (73 violations)?

Two licensees have more documented noncompliances: Mr. Daniel Gingerich, a class A breeder, and Mr. Daniel and Ms. Bobbi Pradon, class B dealers. Mr. Gingerich accrued

more than 100 AWA noncompliances in 6 months. In a consent decree entered in November 2021, Mr. Gingerich agreed to surrender all his dogs and puppies, and his USDA license was permanently revoked.

Mr. and Ms. Pradon accrued 77 noncompliances in 5 months. On December 6, 2021, our Agency suspended the Pradon's license for 21 days. On December 20, 2021, the Pradons requested that our Agency cancel their license, and they are no longer conducting AWA-regulated activity. Our Agency is in the process of determining if further enforcement action is warranted.

4. APHIS outlines in its Animal Care Inspection Guide that "inspection reports are to be finalized... within 5 business days of the date of the inspection." Was that the case in the inspections at Envigo's Cumberland facilities in July, October, and November 2021?

a. If so, did the appeals process account for the remainder of the delay before reports were posted or were there other causes for delay?

As we mentioned previously, we work diligently to finalize inspection reports and make them available to the public in a timely fashion. We are unable to specify which portion of the drafting, review, and appeals process accounted for the delays because the timeline for each inspection report was different and was affected by several factors. These included the complexity and volume of the noncompliances, the time required for AC supervisory review, and the appeals process itself.

When AC officials requested records to document noncompliances, we allowed Envigo additional time to make appropriate redactions. Due to these factors, the reports took longer than normal to finalize and deliver to the facility.

5. What is the median time between the date of an APHIS inspection and the publication of the inspection report in instances where licensed facilities appeal the inspection report?

In fiscal year (FY) 2020, it took on average 46 days between when an inspection was completed and when the appealed inspection report was posted to our website. In FY 2021, that timeframe was reduced to 40 days. Complex appeals can take longer to evaluate for the reasons we described previously.

6. Given that APHIS' most recent inspection of the Envigo facility on March 8, 2022, uncovered five repeat AWA violations, will APHIS inspectors return to the facility for a fifth time to monitor progress on corrective actions?

AC officials continued to conduct inspections at Envigo after the March 2022 inspection. Their last inspection occurred on May 3, 2022. We presume DOJ officials would have information about oversight activities at Envigo after that date.

Thank you for supporting strong and effective AWA enforcement. If you or your staff have further concerns, please contact Mr. Christopher Needham at (202) 799-7027 or at Christopher.M.Needham@usda.gov. A similar letter is being sent to Senator Kaine.

Sincerely,

Kevin Shea

Kevin Shea
Administrator
Animal and Plant Health Inspection Service