



Animal Welfare Institute

900 Pennsylvania Avenue, SE, Washington, DC 20003
awionline.org phone: (202) 337-2332 fax: (202) 446-2131

March 17, 2022

Via Email

Kevin Shea, Administrator
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
1400 Independence Avenue, S.W.
Washington, DC 20250
kevin.a.shea@usda.gov

**Re: The Need for Prompt Enforcement of the Animal Welfare Act to Address
Serious and Repeated Citations Regarding Envigo RMS, LLC**

Dear Mr. Shea:

We are writing to advise the United States Department of Agriculture (“USDA”) and its Animal and Plant Health Inspection Service (“APHIS”) of the need to promptly enforce the Animal Welfare Act (“AWA”), 7 U.S.C. § 2131 *et seq.*, in light of serious and repeated citations for noncompliance with the AWA and its implementing regulations, 9 C.F.R. §§ 2.1–3.142, by Envigo RMS, LLC (“Envigo”). Envigo’s numerous and serious instances of noncompliance with the AWA have caused—and absent rigorous enforcement of the AWA will continue to cause—serious harm to dogs at Envigo’s facility, including preventable suffering and death. Because Envigo’s citations under the AWA reflect serious and chronic problems, we believe that the USDA and APHIS should use the full extent of its enforcement authority to revoke Envigo’s license.

Envigo holds a Class A breeder license under the AWA with certificate number 32-A-0774. As documented in APHIS’s own Inspection Reports, Envigo’s Site 5 facility operated under this license houses “almost 5000 dogs.”¹ As APHIS has found, this facility has been cited for violating many AWA standards in extremely serious ways, causing severe harm or death to numerous dogs. Indeed, APHIS Inspection Reports for inspections conducted on July 20, 2021, and October 25, 2021, identified numerous “critical,” “direct,” and “repeat” citations for noncompliance with the AWA and its implementing regulations.²

¹ See Attachment 3, APHIS, Inspection Report of October 25, 2021, at 11.

² See Attachments 1–3. (APHIS conducted two inspections on July 20, 2021; one was a “routine inspection” and the other was a “focused inspection.”)

As defined in APHIS’s own Animal Welfare Inspection Guide, the citations documented in APHIS’s Inspection Reports are very serious: a “Critical” noncompliance is one “that had a serious or severe adverse effect on the health and well-being of the animal”; a “Direct” noncompliance is “a Critical noncompliance that is currently (at the time of the inspection) having a serious or severe adverse effect on the health and well-being of the animal”; and a “Repeat” noncompliance is one that is “cited in the same section and subsection on the last routine inspection or cited at least 2 times within the past three years.”³ Hence, the identification of numerous “Direct,” “Critical,” and “Repeat” instances of noncompliance with the AWA at Envigo’s facility reflects myriad instances in which animals have suffered serious harm and/or death.

In fact, the “Direct” and “Critical” AWA citations identified in APHIS’s Inspection Reports demonstrate horrifying conditions for dogs. For example, APHIS’s Inspection Reports about this facility, which are also attached to this letter, highlight the following serious issues:

- **Hundreds of dogs have died at Envigo’s facility for unexplained reasons.**
 - In the first seven months of 2021, “over 300 puppy deaths were attributed to unknown causes,” yet “the facility has not taken additional steps to determine the causes of death in order to prevent similar deaths of other puppies in the future.”⁴
 - 157 puppies were discovered dead and decaying, where “postmortem change . . . was recorded as the cause of death,” meaning “that postmortem decomposition (autolysis) was present and no other causes of death could be identified.”⁵
 - On October 25, 2021, APHIS found that Envigo’s facility “still does not have complete acquisition or disposition records for their animals.”⁶
- **Inadequate facilities and care have led to numerous injuries and deaths.**
 - In the first seven months of 2021, “71 dogs were injured when a body part (such as an ear or tail) was pulled through the wall of the kennel by a dog in an adjacent kennel and bitten.” Envigo “subsequently euthanized” all of these dogs—regardless of “however substantial or minor” their injuries were.⁷
 - Later that year—and after APHIS instructed Envigo to correct this issue—an additional 9 dogs were injured in a similar manner, and “regardless of whether it was a minor or substantial injury, these nine dogs were subsequently euthanized.”⁸
 - “Animals have not been handled as carefully and expeditiously as possible leading to subsequent death,” including a puppy found dead “with its head stuck

³ See USDA, Animal Welfare Inspection Guide, 2-9-2-11, available at https://www.aphis.usda.gov/animal_welfare/downloads/Animal-Care-Inspection-Guide.pdf

⁴ Attachment 2, July 20, 2021 Focused Inspection Report, at 1.

⁵ *Id.* at 2.

⁶ Attachment 3, October 25, 2021 Inspection Report, at 4.

⁷ Attachment 2, July 20, 2021 Focused Inspection Report, at 6.

⁸ Attachment 3, October 25, 2021 Inspection Report, at 7.

in the swinging kennel door of a bedded whelping run,” and another puppy that “fell into the drain” below its kennel and “died later that day.”⁹

- Dogs are housed in incompatible groups leading to fights and death. For example, one dog “was found dead killed by a cage mate,” while another “48 dogs (over 5 weeks of age) . . . had fight wounds.”¹⁰
- On October 25, 2021, APHIS found that “[t]he facility is still having compatibility issues between dogs housed in groups,” leading to injuries and death, including one instance in which a “dog was found dead” due to “evisceration” and the “littermates had chewed on it.” Yet, APHIS found that Envigo had taken “no action” to “proactively identify and potentially house separately those dogs that are incompatible or have an aggressive disposition.”¹¹

- **Sick and injured dogs have not received prompt care.**

- In July 2021, APHIS identified “15 animals [that] had medical problems that had not been identified or treated by the facility prior to the inspection,” including: numerous animals with “severe dental disease”; a dog with an “abnormal right eye” secreting “thick greenish-yellow discharge”; dogs with untreated scabs, lesions, and cysts; and a dog with “a large amount of patchy hair loss encompassing 80% of her coat.” These animals had received no veterinary care for these conditions before APHIS’s inspection revealed their suffering.¹²
- In October 2021—after APHIS had instructed Envigo to correct this problem by providing daily observation of dogs’ welfare—APHIS identified more animals with “medical conditions that had not been identified or treated by the facility prior to the inspection.”¹³

- **Envigo has failed to keep adequate records regarding dogs’ injuries or deaths.**

- In July 2021, APHIS found that Envigo’s “[m]edical records are not complete for numerous dogs,” including animals with lacerations or fractures where the type of injury or cause of injury were not recorded, or where the cause of the dog’s death was recorded only as “other” with “no information about the animal’s death.”¹⁴
- In October 2021—after APHIS instructed Envigo to correct this issue through improved recordkeeping—APHIS found that “[v]eterinary medical records are incomplete for at least 7 dogs,” including puppies that had died with “no description of symptoms leading up to these animals’ deaths” and with no “exam findings . . . or test results” from their necropsies.¹⁵

⁹ Attachment 3, October 25, 2021 Inspection Report, at 5–6.

¹⁰ Attachment 2, July 20, 2021 Focused Inspection Report, at 7.

¹¹ Attachment 3, October 25, 2021 Inspection Report, at 8–9.

¹² Attachment 1, July 20, 2021 Inspection Report, at 1–5.

¹³ Attachment 3, October 25, 2021 Inspection Report, at 2–5.

¹⁴ Attachment 2, July 20, 2021 Focused Inspection Report, at 11–13.

¹⁵ Attachment 3, October 25, 2021 Inspection Report, at 12–14

- **Envigo has been cited for violating numerous AWA standards for the welfare of dogs.**
 - Over 400 dogs “were housed in cages that did not provide the minimum floor space for the dam and her litter as required by the AWA.”¹⁶
 - Over 1,000 dogs were housed in buildings that “exceeded 85 degrees Fahrenheit for at least 5 hours,” which does not comply with AWA regulations.¹⁷
 - “There is an extensive, widespread pest problem throughout all animal-housing buildings at the facility,” including “live spiders and house flies,” “large numbers of ants,” and “live black hairy worm-type insects and live black beetles . . . in the metal self-feeders . . . [that] were the only source of food for the dogs.”¹⁸ This problem persisted in October 2021, when APHIS found that “[t]here are still large numbers of dead flies and spiders noted throughout the facility” and that “general housekeeping including dead pest removal is not being performed in accordance with the AWA regulations.”¹⁹
 - The facility has a waste-disposal problem causing “a large accumulation of feces, urine, standing water, insects (both dead and alive) and uneaten food” and “an overpowering ammonia and fecal odor that emanates from below the kennels.”²⁰ This problem persisted in October 2021, when APHIS found that “[t]he facility continues to have general sanitation problems,” such as “accumulations of waste and an overpowering fecal odor that emanates from below the kennels.”²¹
- **Envigo has not employed sufficient staff to care for its dogs.**
 - In July 2021, APHIS found that Envigo employed “[o]nly one attending veterinarian” for all of the “over 5000 dogs” at its facility, and that this veterinarian is also responsible for “assisting in research projects.” Likewise, APHIS found that Envigo “employs 39 personnel for over 5000 dogs,” which APHIS noted is “not sufficient” to address the issues identified in the agency’s inspection.²²
 - In October 2021, APHIS found that “[t]here continue to be severe staffing shortages and currently there are approximately 32 employees at the facility, with only 17 staff members directly responsible for all husbandry, daily observations, and medical treatments for almost 5000 dogs.” Likewise, APHIS found that “[t]here is still only one full-time veterinarian to oversee the daily medical care of all the animals as well as assisting with research projects.” Accordingly, APHIS found that Envigo “continues to have insufficient numbers of employees to successfully care for the animals.”²³

¹⁶ Attachment 1, July 20, 2021 Inspection Report, at 9–10

¹⁷ *Id.* at 6–9.

¹⁸ Attachment 2, July 20, 2021 Focused Inspection Report, at 10.

¹⁹ Attachment 3, October 25, 2021 Inspection Report, at 11

²⁰ Attachment 2, July 20, 2021 Focused Inspection Report, at 7–8.

²¹ Attachment 3, October 25, 2021 Inspection Report, at 9–11.

²² Attachment 2, July 20, 2021 Focused Inspection Report, at 12.

²³ Attachment 3, October 25, 2021 Inspection Report, at 11–12.

As summarized above and detailed in the attached Inspection Reports, APHIS has amply documented numerous, serious, and repeated failures to comply with the AWA at Envigo's facility. Likewise, APHIS has documented how Envigo's failures to comply with the AWA and its regulations have led to needless and preventable suffering and/or death for hundreds of animals.

However, despite the number and severity of AWA citations at Envigo's facility, APHIS does not appear to be engaging in any rigorous effort to enforce the AWA in this instance—or even to comport with its own policies and practices for investigating such serious AWA noncompliance. For example, APHIS's Animal Welfare Inspection Guide states that “[a] complete or focused reinspection of a facility with a ‘Direct’ [Noncompliant Item] **must** be completed within 14 days of the inspection date.”²⁴ However, despite identifying numerous “direct” noncompliances in July 2021, APHIS did not reinspect Envigo's facility until October 2021—roughly three months later.

In light of its own findings regarding the dire conditions dogs have suffered at Envigo's facility, we believe that APHIS should immediately use the full extent of its enforcement authorities to revoke Envigo's license under the AWA and to seek appropriate civil penalties. Indeed, APHIS's history of enforcement regarding Dan Moulton, License Number 41-B-0239, and Daniel Gingerich, License Number 42-A-1632, demonstrates the propriety of a similarly rigorous enforcement action against Envigo. In those prior instances, APHIS undertook enforcement action that resulted in the revocation of AWA licenses and the payment of civil penalties. In light of the analogous situation here in which there is chronic and serious noncompliance with the AWA and its regulations, USDA should take comparable action by bringing a rigorous enforcement action against Envigo, revoking its AWA license, and seeking appropriate civil penalties.

Indeed, a rigorous enforcement action is especially appropriate in this instance because Envigo has already demonstrated an unwillingness to work collaboratively with the USDA to correct its noncompliance with the law. For example, after APHIS meticulously documented numerous instances of noncompliance with the AWA and instructed Envigo to correct those issues by a date certain, Envigo failed to do so, as documented in APHIS's October 25, 2021 Inspection Report.²⁵ Likewise, at a related research facility, Envigo has refused to furnish APHIS inspectors with the full information necessary to assess the facility's compliance with the

²⁴ USDA, Animal Welfare Inspection Guide, at 2-11; *see also id.* at 3-31 (“Reinspect for correction of a “Direct” noncompliant item no later than 14 days after the date of inspection.”).

²⁵ *See, e.g.*, Attachment 3, October 25, 2021 Inspection Report, at 4 (“The facility still does not have complete acquisition or disposition records”); *id.* at 8 (“The facility is still having compatibility issues between dogs housed in groups”); *id.* at 10 (“In at least 50% of the rooms being used within Buildings G1 and G2 there are still accumulations of waste and an overpowering fecal odor that emanates from below the kennels”); *id.* at 11 (“The facility continues to have insufficient numbers of employees to successfully care for the animals.”).

AWA.²⁶ Additionally, Envigo's predecessor-in-interest, Huntingdon Life Sciences, previously resisted any public disclosure of records under the Freedom of Information Act regarding prior noncompliance with the AWA in a manner that a federal court found "comes mighty close" to "blatantly contradicting the record."²⁷ Indeed, the public was only able to obtain information relevant to Huntingdon's noncompliance with the AWA after a protracted legal battle in which federal courts repeatedly ruled in favor of disclosure of the information at issue.²⁸ In light of this history of failure to correct AWA noncompliance and resistance of disclosure of relevant information to APHIS or the public, we believe that a rigorous enforcement action is the only realistic means for USDA to follow through on the responsibilities with which Congress entrusted the agency in enacting the AWA.

Thank you for your time and consideration of how to achieve the AWA's goals of humane treatment of animals through rigorous enforcement in this matter.

Sincerely,


Cathy Liss
President

cc:

Betty J. Goldentyer, DVM
Deputy Administrator
USDA APHIS Animal Care
Betty.J.Goldentyer@usda.gov

Robert M. Gibbens, DVM
Director, Animal Welfare Operations
USDA APHIS Animal Care
Robert.M.Gibbens@usda.gov

Todd Kim, Assistant Attorney General
Todd.kim@usdoj.gov
Mary Hollingsworth, Senior Trial Attorney
Mary.hollingsworth@usdoj.gov
Shampa A. Panda, Trial Attorney
Shampa.panda@usdoj.gov
United States Department of Justice
Environment & Natural Resources Division

²⁶ As APHIS documented, "the facility refused to provide full copies of the study records which include the procedures performed on dogs while they are on a study." And although the facility eventually allowed APHIS's inspectors to "briefly remotely view some of the study data that had previously been requested," APHIS noted that "[t]his review did not allow for a complete and thorough assessment of the facility's compliance with AWA regulations." See Attachment 4, July 20, 2021 Inspection Report for License Number 23-R-0187, at 7–8.

²⁷ See *In Defense of Animals v. USDA*, 501 F. Supp. 2d 1, 8 (D.D.C. 2007).

²⁸ See *id.*; see also *In Defense of Animals v. USDA*, 587 F. Supp. 2d 178, 183 (D.D.C. 2008) (rejecting as irrelevant or hearsay evidence submitted by Huntingdon in resistance to disclosure of information under FOIA); *In Defense of Animals v. USDA*, 589 F. Supp. 2d 41, 43 (D.D.C. 2008) (finding Huntingdon judicially estopped from an "unfairly prejudicial" effort to introduce a new issue on the eve of trial); *In Defense of Animals v. USDA*, 656 F. Supp. 2d 68, 82 (D.D.C. 2009) (compelling disclosure of the information at issue).