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AT LYNCHBURG, VA

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**IN THE UNITED STATES DISTRICT COURT FOR
THE WESTERN DISTRICT OF VIRGINIA
LYNCHBURG DIVISION**

UNITED STATES OF AMERICA,

Plaintiff,

v.

Case No. 6:22CV00028

ENVIGO RMS, LLC,

Defendant.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff, United States of America, by authority of the Attorney General of the United States and through its undersigned attorneys, files this Complaint and alleges as follows:

INTRODUCTION

1. This is a civil action against Envigo RMS, LLC (“Envigo”) for violations of the Animal Welfare Act (“AWA”), and its implementing regulations and standards.

2. Congress enacted the AWA for a number of purposes, including to ensure that animals intended for use in research facilities are provided humane care and treatment. 7 U.S.C. § 2131(1). The AWA imposes “minimum requirements” for handling, housing, feeding, watering, sanitation, and adequate veterinary care, among other requirements. *Id.* § 2143(a)(2)(A).

3. Envigo operates a facility in Cumberland, Virginia (“Cumberland Facility”), where it deals in beagles intended for use at research facilities. Since July 2021, the facility has housed up to 5,000 beagles. Envigo holds an AWA license to breed and sell dogs that was issued by the U.S. Department of Agriculture (“USDA”).

4. In less than a year, the company has amassed over 60 citations for non-

compliance with the AWA, which have affected thousands of beagles. More than half of those citations were deemed “critical” or “direct,” the most serious types of AWA citation. As relevant here, a “critical” noncompliance is one that has a “serious or severe adverse effect on the health and well-being of the animal[s].” Animal Welfare Inspection Guide, USDA, 2-10 (revised Nov. 2021), https://www.aphis.usda.gov/animal_welfare/downloads/Animal-Care-Inspection-Guide.pdf (“APHIS Animal Welfare Inspection Guide”) (last visited May 14, 2022). A “direct” noncompliance is a critical noncompliance that is having a serious or severe adverse effect on the health and well-being of the animal at the time of the inspection. *Id.* at 2-11.

5. Despite being on notice since July 2021 that the conditions at its Cumberland facility fall far below the AWA’s minimum standards, Envigo has failed to take the necessary steps to ensure that all of the beagles at its facility are provided humane care and treatment and that the Cumberland facility is operating in compliance with the AWA.

6. In fact, pursuant to a federal warrant, 145 beagles from the Cumberland Facility have been seized after they were determined to be in “acute distress.”¹

7. Rather than spend the money to meet the minimum standards set by the AWA and provide each beagle with the care that Envigo is legally obligated to provide, upon information and belief, Envigo has employed a paltry number of employees and elected to euthanize beagles or allowed beagles to die from malnutrition, treatable and preventable conditions, and injuries resulting from beagles being housed in overcrowded and unsanitary enclosures or enclosures that contain incompatible animals. When 300 beagle puppies died in 7 months due to “unknown causes,” Envigo failed to investigate and accurately diagnose the cause of death to spare other

¹ Acute distress means any animal requiring immediate veterinary treatment or other care to promptly alleviate a life-threatening illness, injury or any suffering, as deemed by a licensed veterinarian.

beagle puppies from similar deaths. *See* Ex. B (July 2021 Inspection Report Part 2) at 2.

Pursuant to the policy that Envigo's attending veterinarian established, Envigo staff were not even required to notify the attending veterinarian when beagle puppies were found dead. *Id.*

8. Envigo's disregard for the law and the welfare of the beagles in its care has resulted in the animals' needless suffering and, in some cases, death.

9. For the foregoing reasons, the United States complains and seeks a temporary restraining order as well as other injunctive relief.

JURISDICTION AND VENUE

10. The Court has jurisdiction over this action pursuant to 7 U.S.C. § 2146(c) (actions arising under the AWA); 28 U.S.C. § 1331 (federal question jurisdiction); and 28 U.S.C. § 1345 (United States as plaintiff).

11. Venue is proper in the United States District Court for the Western District of Virginia pursuant to 28 U.S.C. § 1391.

12. The Court may grant the requested relief under the AWA, 7 U.S.C. § 2146(c), and 28 U.S.C. §§ 2201, 2202 (declaratory and injunctive relief).

THE PARTIES

13. The Plaintiff is the United States of America. Authority to bring this action is vested in the Attorney General of the United States pursuant to 28 U.S.C. §§ 516, 519.

14. Defendant Envigo is a limited liability company whose business mailing address is 8520 Allison Pointe Blvd., Suite 400, Indianapolis, Indiana. On June 3, 2019, Envigo registered as a Virginia LLC.

15. Envigo holds AWA dealer license 32-A-0774. Envigo owns, deals in, and/or breeds the animals that are the subject of this action at the Cumberland Facility located in the

Western District of Virginia. The Cumberland Facility, which is located at 482 Frenchs Store Road, Cumberland, Virginia, is identified as Site 005 on the inspection reports prepared by USDA's Animal and Plant Health Inspection Service ("APHIS") for license 32-A-0774.

LEGAL BACKGROUND

16. The AWA establishes minimum standards of care and treatment to be provided for certain animals bred and sold for use as pets, used in biomedical research, transported commercially, or exhibited to the public. *See generally* 7 U.S.C. § 2131 *et seq.*

17. The AWA is administered by the Secretary of Agriculture or his representative. 7 U.S.C. § 2132(b). The AWA authorizes the Secretary to "promulgate such rules, regulations, and orders as he may deem necessary in order to effectuate the purposes of [the AWA]." 7 U.S.C. § 2151. The Secretary has delegated his authority to the APHIS Administrator.

18. The AWA defines a "dealer" as "any person who, in commerce, for compensation or profit, delivers for transportation, or transports, except as a carrier, buys, or sells, or negotiates the purchase or sale of, (1) any dog or other animal whether alive or dead for research, teaching, exhibition, or use as a pet." 7 U.S.C. § 2132(f); *see also* 9 C.F.R. § 1.1 (definition of dealer).

19. A "person" includes any "individual, partnership, firm, joint stock company, corporation, association, trust, estate, or other legal entity." 7 U.S.C. § 2132(a).

20. Anyone who falls within the statutory definition of a dealer must obtain and maintain a valid license from the Secretary. 7 U.S.C. § 2134; *see also* 9 C.F.R. § 2.1(a)(1) (licensing requirements).

21. The Secretary shall issue a license to a dealer upon application, provided that no such license shall be issued until the dealer has demonstrated that his facilities comply with the

standards promulgated by the Secretary pursuant to 7 U.S.C. § 2133.

22. By signing the application form, the applicant acknowledges that it has reviewed the AWA and its regulations and standards and “agrees to comply with them.” 9 C.F.R. § 2.2.

23. Regulated activities may be conducted only at sites that have been inspected and approved by APHIS. 9 C.F.R. § 2.1(b)(1).

24. The AWA makes it unlawful for any dealer to knowingly violate the AWA. 7 U.S.C. § 2149(d).

25. A Class “A” dealer must identify all live dogs “held on the premises, purchased, or otherwise acquired, sold or otherwise disposed of, or removed from the premises for delivery. . .to another dealer, or for sale, through an auction sale or to any person for use as a pet, . . .by an official tag . . .affixed to the animal’s neck by means of a collar made of material generally considered acceptable to pet owners as a means of identifying their pet dogs” or “by a distinctive and legible tattoo marking acceptable to and approved by the Administrator.” 9 C.F.R. § 2.50(a)(1).

26. The Secretary has promulgated regulations and standards to govern the humane handling, care, treatment, and transportation by dealers, which includes the minimum requirements for handling, housing, feeding, watering, sanitation, ventilation, shelter from extreme weather and temperatures, adequate veterinary care, and separation by species. 7 U.S.C. § 2143(a)(1)-(a)(2)(A). Dealers must comply in all respects with the regulations and standards for the humane handling, care, treatment, and transportation of dogs. 9 C.F.R. §§ 3.1-3.20.

27. When construing or enforcing the provisions of this chapter, the act, omission, or failure of any person acting for or employed by a dealer is deemed the act, omission, or failure

of the dealer. 7 U.S.C. § 2139.

28. With regard to food, it must be uncontaminated, wholesome, palatable, and of sufficient quantity and nutritive value to maintain the normal condition and weight of the animal. 9 C.F.R. § 3.9(a). Further, supplies of food must be stored so as to minimize contamination by excreta and pests, and protected from rain and snow. 9 C.F.R. § 3.9(b). Measures must be taken to ensure that the food is not molding. *Id.*

29. With regard to water, potable water must be continuously available to the dogs unless restricted by the attending veterinarian. 9 C.F.R. § 3.10(a), and water receptacles must be kept clean and sanitized. 9 C.F.R. § 3.10(c).

30. With regard to cleaning and sanitation, primary enclosures must be cleaned and both primary enclosures and food and water receptacles must be sanitized. 9 C.F.R. § 3.11. The primary enclosures must be cleaned daily to remove excreta and food waste, and to reduce disease hazards, insects, pests, and odors. 9 C.F.R. § 3.11(a). Primary enclosures and food and water receptacles must be sanitized. 9 C.F.R. § 3.11(b). The surrounding buildings and grounds must be in good repair and free of trash and junk to protect the dogs from injury. 9 C.F.R. § 3.11(c). An effective program for pest control must be established and maintained to promote the health and well-being of the animals. 9 C.F.R. § 3.11(d).

31. With regard to facilities, indoor and outdoor housing facilities must be structurally sound and maintained in good repair to protect animals from injury and to contain the animals. 9 C.F.R. § 3.1(a). The surface of housing facilities must be constructed in a way that allows them “to be readily cleaned and sanitized, or removed or replaced when worn or soiled.” 9 C.F.R. § 3.1(c)(1). The housing facilities must have floors cleaned to ensure that all animals can avoid contact with excreta, 9 C.F.R. § 3.1(c)(3). The housing facilities must have food and

bedding supplies stored in a manner that protects them from “spoilage, contamination, and vermin infestation.” 9 C.F.R. § 3.1(e).

32. The primary enclosures of the dogs must be constructed and maintained so that they protect the dogs from injury. 9 C.F.R. § 3.6(a)(2)(ii). The primary enclosures must also have floors that protect the dogs’ feet and legs from injury, and that, if of mesh or slatted construction, do not allow the dogs’ feet to pass through any openings in the floor. 9 C.F.R. § 3.6(a)(2)(x).

33. Each dog housed in a primary enclosure, including weaned puppies, must be provided a “minimum amount of floor space.” 9 C.F.R. § 3.6(c)(1)(i). Each “bitch with nursing puppies” must be provided with “an additional amount of floor space” that is “in accordance with generally accepted husbandry practices as determined by the attending veterinarian.” 9 C.F.R. § 3.6(c)(1)(ii).

34. Dog enclosures must be constructed and maintained so that they keep other animals from entering the enclosure. 9 C.F.R. § 3.6(a)(iv).

35. All dogs that are housed in the same primary enclosure must be compatible. 9 C.F.R. § 3.7.

36. All interior surfaces within indoor housing facilities that are “in contact with the animals” must be “impervious to moisture,” and the ceilings of indoor housing facilities must be “impervious to moisture or be replaceable.” 9 C.F.R. § 3.2(d).

37. The sheltered part of sheltered housing facilities must be “sufficiently heated and cooled when necessary” to protect the dogs from temperature or humidity. 9 C.F.R. § 3.3(a). At “all times,” dogs must be provided with adequate shelter from the elements to “protect their health and well-being.” 9 C.F.R. § 3.3(d).

38. With regard to veterinary care, each dealer must employ an “attending veterinarian,” who “shall provide adequate veterinary care to [the dealer’s] animals in compliance with [the AWA].” 9 C.F.R. § 2.40(a); *see also* 9 C.F.R. § 1.1 (definition of “[a]ttending veterinarian”). The dealer must “assure that the attending veterinarian has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.” *Id.* § 2.40(a)(2).

39. The dealer “must follow an appropriate program of veterinary care for dogs that is developed, documented in writing, and signed by the attending veterinarian.” 9 C.F.R. § 3.13(a). The written program of veterinary care must be made available for inspection by APHIS inspectors. *Id.* The written program of veterinary care must include, among other things, a “complete physical examination from head to tail of each dog by the attending veterinarian not less than once every 12 months,” “[v]accinations for contagious and/or deadly diseases of dogs (including rabies, parvovirus and distemper) and sampling and treatment of parasites and other pests (including fleas, worms, coccidia, giardia, and heartworm) in accordance with a schedule approved by the attending veterinarian,” and “[p]reventative care and treatment to ensure healthy and unmatted hair coats, properly trimmed nails, and clean and healthy eyes, ears, skin, and teeth.” 9 C.F.R. § 3.13(a); *see also id.* § 2.40(b).

40. The dealer must “establish and maintain” a program of “adequate veterinary care” that addresses the “use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care.” *Id.* § 2.40(b)(2). The program of veterinary care must also include “[d]aily observation of all animals to assess their health and well-being” and, although the daily observation “may be accomplished by someone other than the attending veterinarian,” there must be a “mechanism of direct and

frequent communication” so that “timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian.” *Id.* § 2.40(b)(3).

41. With regard to the number of employees, a facility must include a sufficient number of employees who are practicing husbandry under the supervision of an individual who has the knowledge, background, and experience in proper husbandry and care of dogs to supervise others. 9 C.F.R. § 3.12.

42. With regard to handling, all licensees must ensure that animals are handled “in a manner that does not cause trauma, overheating, excessive cooling, behavioral stress, physical harm, or unnecessary discomfort.” 9 C.F.R. § 2.131(b)(1).

43. The AWA requires the Secretary to make investigations and inspections as necessary to determine whether any dealer has violated any provision of the AWA or any regulation or standard issued thereunder. 7 U.S.C. § 2146(a). The inspector shall have access to the places of business and the facilities, animals, and records. *Id.*; 9 C.F.R. § 2.126.

44. Dealers must make, keep, and retain records for at least one year pertaining to the purchase, sale, transportation, identification, and previous ownership of each dog, which fully and correctly disclose information concerning the animal purchased or otherwise acquired, owned, held, leased, or otherwise in his or her possession or under his or her control, or which is transported, sold, euthanized, or otherwise disposed of (including records of any offspring). 7 U.S.C. § 2140; 9 C.F.R. § 2.75(a)(1)-(3), (b)(1).

45. Dealers must also keep and maintain copies of medical records for dogs – including for at least one year after any given dog is euthanized—and make those records available for APHIS inspection. 9 C.F.R. § 3.13(b), (c)(2). These records must include the “identity of the animal, including identifying marks, tattoos, or tags on the animal and the

animal's breed, sex, and age." 9 C.F.R. § 3.13(b)(1). The medical records must also include "the date and a description" of any "disease, injury, or illness," as well as "examination findings, test results, plan for treatment and care, and treatment procedures performed." 9 C.F.R. § 3.13(b)(2).

46. A licensee "shall notify Animal Care² no fewer than 90 days and obtain a new license before any change in the name, address, substantial control or ownership of his business or operation, locations, activities, and number or type of animals." 9 C.F.R. § 2.1(b)(1).

47. Under the AWA, United States district courts "are vested with jurisdiction specifically to enforce, and to prevent and restrain violations of [the AWA], and shall have jurisdiction in all other kinds of cases arising under [the AWA]," except in one instance not applicable here. 7 U.S.C. § 2146(c).

FACTUAL BACKGROUND

48. Envigo applied to USDA for a Class A license around June 2019. By signing the application form, Envigo acknowledged that it had reviewed the AWA and its implementing regulations and standards and agreed to comply with them. *See* 9 C.F.R. § 2.2. USDA issued Class A license 32-A-0774 to Envigo.

49. On June 3, 2019, Envigo acquired LabCorp's Covance Research Products' business, which included the Cumberland Facility.

50. The first inspection by APHIS of the Cumberland Facility following Envigo's acquisition of the site took place in July 2021. During the routine inspection,³ APHIS documented violations of 18 different AWA provisions, of which 10 of the violations were

² Animal Care is a program under APHIS, which, as relevant here, is tasked with ensuring the humane treatment of animals covered by the AWA.

³ A "routine" inspection is an unannounced, complete inspection of every aspect of the facility that is regulated under the AWA.

deemed to be “direct” or “critical.”

51. APHIS conducted a “focused” inspection⁴ of the Cumberland Facility in October 2021. During this focused inspection, APHIS documented violations of 13 different AWA provisions. Seven of the violations were direct or critical violations that APHIS had already identified during the July 2021 inspection.

52. On November 5, 2021, Inotiv, Inc. announced that it had acquired Envigo. Nevertheless, the Cumberland Facility remained an approved site under Envigo’s AWA license 32-A-0774.

53. APHIS conducted another routine inspection of the Cumberland Facility in November 2021. APHIS inspectors observed numerous noncompliances, including serious violations of the AWA. During the inspection, APHIS documented violations of 26 different AWA provisions, of which 14 were deemed to be “direct” or “critical.” Of the 14 “direct” or “critical” violations, 10 were repeat violations.

54. In March 2022, APHIS conducted a focused inspection of the Cumberland Facility. During the inspection, APHIS officials documented violations of five different AWA provisions, of which two were direct violations. Envigo had been on notice that it needed to correct those serious issues for eight months at that point, with the violations being identified on the previous inspection reports.

55. USDA Office of Inspector General agents and other law enforcement officers began executing a federal search warrant at the Cumberland Facility on May 18, 2022. As of the

⁴ A “focused” inspection may include: re-inspection for direct noncompliances identified during a previous inspection; re-inspection for a specific noncompliance identified during a previous inspection; a partial inspection of the facility, such as animals only or records only; or a partial inspection to follow up on a public complaint concerning animal welfare. *See* APHIS Animal Welfare Inspection Guide at 3-24.

filing of this Complaint, the United States has seized 145 dogs and puppies determined by veterinarians to be in acute distress.

I. Envigo is Failing to Provide the Beagles at the Cumberland Facility Adequate Veterinary Care.

56. Envigo's attending veterinarian is failing to provide and oversee the provision of adequate veterinary care to the beagles at the Cumberland Facility.

57. Envigo has delayed the provision of veterinary care for beagles, including those with severe and painful medical conditions. During the November 2021 inspection, APHIS inspectors identified 30 beagles ranging from two to seven years old with severe dental disease, who had not been treated despite Envigo staff observing the condition in some of the beagles as early as August 2021. The beagles' symptoms included loose teeth that moved with light pressure, exposed roots of teeth, pus along the gum lines, bleeding gums, hair and foreign material embedded in the gum lines, severe recession of the gums, missing teeth and significant accumulations of dark colored calculus along the teeth. *See* Ex. D (November 2021 Inspection Report) at 3.

58. Of the 30 beagles with severe dental disease, 12 had additional issues for which they had not received adequate veterinary care. One nursing female was in poor body condition, with extremely prominent bones in the shoulders, ribs, hips, and back. Records show she had been underweight for three months but had not been provided any treatment for either condition. Seven beagles had foot conditions, including masses between their toes that were inflamed and often oozing discharge. One beagle had an ear infection and another had large areas of hair loss along the entire length of the back and reddened skin. *See* Ex. D at 3-4.

59. As of November 2021, Envigo's veterinary staff had not completed the required annual hands-on physical examination for a number of beagles over the age of one year. The

failure to have a veterinarian examine a dog at least annually can result in delays in the diagnosis and treatment of underlying medical conditions. *See* Ex. D at 20.

60. Upon information and belief, Envigo authorizes animal care technicians, whose responsibilities include cleaning buildings and enclosures, feeding the beagles, and recordkeeping, to provide medical treatment for beagles at the Cumberland Facility. Upon information and belief, at least some animal care staff providing medical treatment for beagles are not veterinarians or licensed veterinary technicians.

61. Upon information and belief, Envigo also authorizes animal care technicians, whose responsibilities include cleaning buildings and enclosures, feeding the beagles, and recordkeeping, to euthanize beagles at the Cumberland Facility.

62. Envigo staff are failing to follow approved procedures for euthanizing beagles, which has caused pain and discomfort to the beagles. The facility's program of veterinary care and guidance on euthanizing dogs requires that all dogs be unconscious when performing intra-cardiac euthanasia achieved by using medication and a sedative. However, when inspectors reviewed 171 medical records documenting the euthanasia of 196 beagles and beagle puppies during the November 2021 inspection, they found that many young beagle puppies were not receiving anesthesia prior to being euthanized via intra-cardiac injection. Intra-cardiac injections have been found to be painful, stressful, and uncomfortable. *See* Ex. D at 2-3.

63. Medical records reviewed by APHIS inspectors during the October 2021 inspection indicated that animal care technicians had identified three beagles as being too thin. The records further indicated that the beagles were given medication but there was no record that a veterinarian had been consulted regarding the diagnosis of poor body condition or the prescription of medication to these beagles. Further, the program of veterinary care did not allow

animal care staff to start medication for beagles determined to be thin. APHIS inspectors brought the matter to the attention of the attending veterinarian who then examined the beagles and directed that the medication be stopped. *See* Ex. C (October 2021 Inspection Report) at 2.

64. Daily observations of each dog are required to ensure the health and welfare of every animal at the Cumberland Facility. *See* 9 C.F.R. § 2.40(b)(3). Envigo staff are failing to observe medical problems in the dogs that require veterinary attention. Upon information and belief, the Envigo staff are not conducting daily observations of all beagles at the Cumberland Facility or, if Envigo staff are conducting daily observations, the staff are unqualified to assess the condition of the beagles.

65. During the July 2021 inspection, APHIS inspectors identified 15 beagles who had medical problems that had not been identified or treated prior to the inspection. The medical problems included eye conditions, ear conditions, skin infections, wounds and lesions, and severe dental disease. One female beagle suffering from severe dental disease had swollen gums that had pulled back from some of the teeth exposing the roots of the teeth. Another beagle had patchy hair loss encompassing approximately 80% of her entire coat and several small yellow scabs spread throughout the hair loss. Despite the skin condition affecting the majority of the beagle's body and the daily observation requirement, Envigo's attending veterinarian stated that no one had observed the condition prior to the inspection. Ex. A (July 2021 Inspection Report Part 1) at 2-5.

66. APHIS reminded Envigo that animals "with medical conditions including eye, skin, ear, and dental problems, may suffer from pain, discomfort, infection, and stress." Envigo was directed to immediately comply with the daily observation requirement "by observing animals on a daily basis to identify physical, medical or behavioral problems, and communicate

all findings to the attending veterinarian promptly.” Ex. A at 6.

67. Nevertheless, when APHIS inspectors returned in October 2021, they observed a male beagle puppy with an abnormal eye, a female beagle with swollen tissue between the toes of her right rear paw, and another female beagle with multiple skin lesions and swelling on all four feet. Envigo staff had not previously identified these medical issues and, thus, the beagles were not receiving any treatments for the conditions. *See* Ex. C at 3-5.

68. When APHIS inspectors returned in November 2021, they identified 34 beagles with medical conditions that had not been observed by Envigo staff and, thus, had not been treated. *See* Ex. D at 4. This was in addition to the 30 beagles whose medical conditions had been identified but Envigo veterinary staff had failed to treat. *Id.*; *see supra* 57. Envigo staff had failed to observe the following conditions: seven beagles with severe dental disease; one beagle and two beagle puppies with serious conditions resulting in weakness; eight beagle and beagle puppies with traumatic wounds; eight beagles with lameness or foot injuries; and two beagles with masses, including a beagle puppy with a large, soft fluid-filled mass on top of his head. The inspectors observed beagles with untreated eye, ear, and skin conditions as well. *See* Ex. D at 4-5.

69. Medical records also indicated that a female beagle had recently been found dead. The necropsy showed that she had died as a result of a ruptured uterus. However, the beagle’s medical records did not contain any observations that would be expected with this diagnosis, such as abdominal pain, vaginal discharge, difficulty whelping, or other similar signs. *See* Ex. D at 5.

70. Additionally, the mortality and medical records for certain puppies who supposedly died from conditions that present with clinical signs prior to death contained no such

observations. The lack of documentation prior to the puppies' deaths indicates that Envigo staff had failed to comply with the daily observation requirement.

71. Envigo also has failed to use appropriate methods to prevent, control, diagnose, and treat diseases and injuries in beagles at the Cumberland Facility. *See* 9 C.F.R. § 2.40(b)(2).

72. Hundreds of beagle puppies have been found dead at the Cumberland Facility. Mortality records show that, between January 1, 2021, and July 22, 2021, the deaths of over 300 beagle puppies were attributed to "unknown causes." The attending veterinarian does not require Envigo staff to notify her when beagle puppies are found dead. Rather, animal care technicians, who upon information and belief have no formal veterinary training, are permitted to make the decision whether a necropsy should be performed. Envigo's failure to consistently apply methods to accurately diagnose the cause of the deaths of hundreds of beagle puppies has limited the Cumberland Facility's ability to implement changes that would prevent future deaths. *See* Ex. B at 2.

73. Medical records reviewed during the July 2021 inspection indicate that, for an additional 173 beagle puppies, Envigo staff could not identify a cause of death because the bodies had already begun decomposing. *See* Ex. B at 3.

74. Envigo has failed to provide adequate veterinary care to the puppies at the Cumberland Facility, including daily observations and implementation of appropriate methods to diagnose disease post-mortem, which has resulted in the deaths of hundreds of young puppies.

75. Upon information and belief, Envigo has opted to euthanize beagles rather than provide adequate veterinary care for easily treatable conditions or injuries.

76. APHIS inspectors reviewed records during the July 2021 inspection, which showed that, between January 1, 2021, and July 22, 2021, 71 beagles were injured when a body

part, such as an ear or tail, was pulled through the wall of the kennel by a beagle in an adjacent kennel. According to the records, however substantial or minor the injury, Envigo euthanized all the beagles rather than provide them veterinary care. *See* Ex. B at 7.

77. During the October 2021 inspection, APHIS inspectors once again reviewed mortality records, which showed that nine beagles had been injured after a body part was pulled through the wall by a dog in an adjacent kennel. Regardless of whether the injury was minor or substantial, Envigo euthanized all the beagles rather than provide them veterinary care. *See* Ex. C at 8.

II. Envigo is Failing to Provide Each Beagle With Uncontaminated, Wholesome, Palatable Food of Sufficient Quantity and Nutritive Value and to Make Potable Water Continuously Available.

78. Upon information and belief, Envigo routinely fails to provide each beagle at the Cumberland Facility with food of sufficient quantity and nutritive value to meet the beagle's nutritional needs.

79. During the July 2021 inspection, APHIS inspectors discovered that nursing females were being denied food for 42 hours to reduce milk production. The inspectors noted that, during the 42-hour period, food receptacles were left on the door of the enclosure but were turned around so that the beagles could see and smell the food but could not eat it. The inspectors observed several nursing females reaching their front paws through the doors of the cages to try to reach the food, but were only able to retrieve the occasional piece. One nursing female was observed to be vigorously licking the back of the food receptacle. *See* Ex. A at 6-7.

80. The beagle puppies' only source of food is to nurse on their mothers. Envigo does not provide the beagle puppies any supplemental food. Thus, if the nursing female is not producing sufficient milk to meet the puppies' nutritional needs, the puppies' nutritional needs

are not being met. As a result, those beagle puppies may experience hunger, dehydration, stress, low blood sugar, and increased susceptibility to infections.

81. During the July 2021 inspection, APHIS inspectors observed 13 litters of six-week old beagle puppies who were kept with their mothers during the period in which the mothers were denied food. Puppies were observed vocalizing and nursing on their mothers, while the mothers stood and tried to gain access to the food outside their cages. *See* Ex. A at 12.

82. Envigo also has failed to make food receptacles available to all dogs. Most of the feeders at the Cumberland Facility accommodate only one adult beagle's head at a time. Enclosures with four to 11 dogs contain only one food receptacle. As a result, many beagles exhibited food-guarding behaviors during the November inspection. Envigo was directed to correct the problem and make the food "readily accessible to all dogs" by February 11, 2022. *See* Ex. D at 15-16.

83. The food that Envigo does provide the beagles at the Cumberland Facility is contaminated and is not considered wholesome or palatable. During the July 2021 inspection, food in the receptacles in the beagles' enclosures and in the feed silo in certain buildings contained live insects, including small black worm-type insects, small black beetle-type insects, and flies. APHIS inspectors observed flies in the food receptacles and crawling on the food. *See* Ex. B at 11-12.

84. During the July 2021 inspection, APHIS inspectors also observed large numbers of ants on the floor and adjacent to food receptacles mounted on the front of enclosures. Live ants were observed going in and out of the receptacles containing the beagles' food. *See* Ex. B at 11.

85. APHIS reminded Envigo that food contaminated with insects can decrease the

nutritive value of the food and can result in reduced food consumption. Envigo was directed to correct the issue by August 15, 2021.

86. However, during the November 2021 inspection, APHIS inspectors checked a random sample of food receptacles in two rooms housing a total of 85 nursing females and 488 puppies. Every food receptacle contained food that was wet, caked, and/or moldy. Two receptacles also contained “large numbers of live maggots.” APHIS inspectors directed Envigo staff to clean the food receptacles and replace the food as soon as possible. But when APHIS inspectors returned three days later, the receptacles again contained moldy and/or caked feed. *See Ex. D at 15.*

87. When APHIS inspectors returned to the Cumberland facility in March 2022, they again found that Envigo was not adequately cleaning food receptacles. The food receptacles in one building contained moldy, wet food. Excessive grime was also found in some feeders. *See Ex. E (March 2022 Inspection Report) at 6.*

88. Envigo also has failed to ensure that food receptacles are located so as to minimize contamination by excreta and pests. *See 9 C.F.R. § 3.9(b).* APHIS inspectors observed “grossly contaminated” food during the November 2021 inspection. The food receptacles in all buildings are mounted with the opening where the beagles access food located only one-to-two inches from the enclosure floor. When Envigo staff pressure wash the enclosures, back-splashed water mixed with feces is being sprayed into the food receptacles and contaminating the food. There are also excessive amounts of grime in the receptacles because Envigo staff are not cleaning them frequently enough. *See Ex. D at 16.*

89. Upon information and belief, the puppies who are no longer housed with their mothers cannot access potable water from the waterers in the enclosures.

III. Envigo is Failing to Maintain the Minimum Standards for Handling and Housing Necessary to Keep the Beagles Safe.

90. Envigo is failing to meet the minimum standards for handling and housing the beagles, resulting in the unnecessary suffering and, at times, death of beagles at the Cumberland Facility.

91. Upon information and belief, beagles at the Cumberland Facility are killing each other because Envigo has failed to ensure that all beagles housed in an enclosure are compatible and that all dogs have access to food of sufficient quantity and nutritive value, and because the enclosures are overcrowded.

92. Records from January 2021 to July 2021 showed that 48 beagles had fight wounds. Two female beagles were found dead from fight wounds, while another female beagle was found dead after being killed by a cage mate. APHIS directed Envigo to ensure that there was a mechanism of observation in place to ensure compatibility and prevent fighting. *See* Ex. B at 8.

93. When APHIS inspectors returned to the Cumberland facility in October 2021, they found that there continued to be issues with beagles fighting each other. For example, two female beagles housed together had multiple puncture and other wounds. Envigo staff had failed to notice that the dogs were fighting or that either dog had wounds. Records showed that two additional female beagles were being treated for fight wounds. One of the beagles had wounds on her rear end and shoulder, while the other beagle had wounds on her chest and left ear. *See* Ex. C at 9.

94. APHIS inspectors noted on the October 2021 inspection report that Envigo had taken no steps in the three months to address the issue of beagles attacking each other at the Cumberland Facility. *See* Ex. C at 9-10.

95. Records also showed that another female beagle was found dead on October 14, 2021, and her littermates had chewed on her. The mortality log attributed the beagle's death to evisceration. Records showed that she was being co-housed with nine other beagles of the same age—10 weeks. Envigo staff could not provide any additional details about the beagle's death and there was no record of post-mortem examination findings. When APHIS asked to speak with the employee who found the beagle, the inspectors were told that the employee was unreachable due to leave. *See* Ex. C at 10.

96. APHIS noted on the inspection report that “[d]ogs attacking/chewing on another dog, whether alive or deceased, is an uncommon behavior for dogs with adequate nutrition and likely indicates a compatibility issue.” *See* Ex. C at 10.

97. During the November 2021 inspection, APHIS inspectors observed that Envigo's facility continued to have “severe compatibility problems amongst the adult dogs and puppies.” Inspectors observed “numerous serious dog fights during the inspection, found dogs with injuries from recent fights, and observed dogs aggressively guarding food from cage mates.” At times, the inspection had to be stopped temporarily to separate fighting beagles. Envigo records also documented injuries due to fighting among the beagles. *See* Ex. D at 14.

98. In addition to the widespread compatibility issues, APHIS inspectors also found during the November 2021 inspection that Envigo was failing to provide 742 beagles and weaned puppies the minimum space required by the AWA. Some of the buildings house 10 to 11 beagles in enclosures that are approximately 20 square feet too small for that number of dogs. APHIS noted that overcrowded enclosures can lead to increased and long-term aggression and reduced compatibility, a widespread issue at the Cumberland Facility. *See* Ex. D at 13-14.

99. APHIS inspectors also observed aggressive behavior in the form of food

guarding, which the inspectors attributed to Envigo failing to make a sufficient number of food receptacles available to the beagles. Enclosures with four to 11 dogs contain only one food receptacle and most of those receptacles can be accessed by only one beagle at a time. *See* Ex. D at 15-16.

100. In March 2022, APHIS inspectors identified an additional 97 beagles who had suffered injuries, sometimes severe, consistent with a fight. Envigo medical records identified 59 dogs as having injuries attributable to a fight. An additional 38 beagles were treated for wounds of an unknown cause, including lacerations to ears and tail injuries.

101. Envigo is also failing to keep beagle puppies safe by allowing the puppies to become wet when staff hose down the enclosures with cold water. Under the AWA, Envigo is required to handle animals as carefully and expeditiously as possible to prevent excessive cooling. Allowing puppies to become wet and chilled during cleaning or failing to provide them sufficient heating may result in illness or death.

102. On November 16, 2021, 21 beagle puppies were found damp, shivering, and cold in building G3. The enclosures that housed these puppies had recently been cleaned. The enclosures had no solid resting surface or bedding, and no heat lamps were installed. APHIS inspectors re-checked building G3 three days later and found additional beagle puppies shivering and either no heat lamps installed or no heat lamps plugged in. *See* Ex. D at 7.

103. According to Envigo's records, as of the November 2021 inspection, an additional 25 puppies had been found dead with cause of death attributed to cold exposure in building G3 in the previous eight weeks. *See* Ex. D at 7.

IV. Envigo is Exposing Beagles to Unsafe and Unsanitary Conditions.

104. Envigo is exposing the beagles at the Cumberland Facility to unsafe and

unsanitary conditions.

105. Envigo has been on notice for over nine months that the beagles' enclosures fail to protect them from injury. *See* 9 C.F.R. §§ 3.1(a), 3.6(a)(2).

106. The majority of enclosures are constructed using either metal wire or mesh to separate beagles in adjacent enclosures. However, the gaps in the enclosure walls allow beagles to attack the beagles in adjacent enclosures.

107. Based on the records APHIS reviewed during the July 2021 inspection, 71 beagles were injured after each was attacked by a beagle in an adjacent enclosure who pulled a body part through the gaps in the enclosure walls. Envigo then euthanized all the injured beagles even if they sustained only minor injuries. APHIS directed Envigo to ensure that primary enclosures protect the beagles from injury, including injury by beagles in adjacent enclosures. *See* Ex. B at 7-8.

108. During the next inspection, APHIS inspectors reviewed mortality records from August 2, 2021, to October 3, 2021, and discovered that nine beagles were injured from having a body part, such as a limb or tail, pulled through the enclosure wall. Envigo then euthanized all of the injured beagles even if they sustained only minor injuries. *See* Ex. C at 8.

109. When APHIS inspectors returned in November 2021, they once again determined that Envigo's enclosures failed to protect the beagles at the facility from injury. Inspectors noted "numerous examples of body parts being pulled into adjacent enclosures by neighboring dogs causing injuries to the dogs involved." During the inspection, APHIS inspectors observed one beagle grab the ear of a beagle in a neighboring enclosure who then "vocalized loudly indicating pain while the other dog continuously pulled his ear." Two additional beagles were identified in the mortality logs from November with similar severe ear injuries, which resulted in those

beagles being euthanized. The inspection report noted that openings in the dividers between the enclosures were large enough that feet, tails, and ears could be pulled through by beagles in adjacent enclosures. APHIS inspectors determined that the enclosures were particularly dangerous in light of the “widespread compatibility problems” identified at the facility. *See* Ex. D at 12.

110. Because the enclosures failed to keep the beagles safe from unnecessary pain, suffering, and death, Envigo was once again directed to ensure that all enclosures were constructed and maintained in a manner that prevents injury to the animals.

111. Envigo has also violated the AWA by housing many beagles, including puppies, in enclosures containing dangerous flooring that contains gaps wide enough for a limb, paw, or digit to pass through, and which has resulted in beagles becoming trapped or injured.

112. During the July 2021 inspection, APHIS inspectors observed that over 200 beagle puppies were housed in enclosures that contained flooring with openings large enough for the beagle puppies’ feet to pass through up to their shoulders in violation of 9 C.F.R. § 3.6(a)(2)(x). *See* Ex. A at 9-10.

113. APHIS inspectors also observed an adult female beagle whose front left paw was caught in the flooring. The beagle was unable to free her foot and was panting rapidly and making small movements as the other beagles in her enclosure jumped around her excitedly. It took two Envigo employees approximately three minutes to free the beagle. After the beagle was freed, her foot was examined and two toes were red and swollen. Envigo employees did not know how long the dog had been trapped in the flooring, but it is likely that the beagle had been trapped for some time as medical records indicated that she was mildly dehydrated. *See* Ex. A at 10.

114. Envigo was warned that when an animal becomes entrapped it can become distressed, dehydrated, and injured. Envigo was directed to take measures to ensure that the flooring at the Cumberland Facility did not allow the beagles' feet or legs to pass through.

115. Nevertheless, during the October 2021 inspection, APHIS inspectors observed multiple beagle puppies with legs and feet passing through the openings in the floors of their enclosures. APHIS inspectors also observed two enclosures that did not have the cardboard cage liners that Envigo had previously stated it would install as a temporary measure until it could permanently address the noncompliant flooring. *See* Ex. C at 8.

116. During the November inspection, APHIS inspectors determined that approximately 75% of enclosures had gaps between the flooring and fencing of up to two inches wide. Inspectors observed beagles falling or stepping into the gaps in the flooring. Envigo records documented at least 10 additional beagles and beagle puppies that were significantly injured by improperly constructed and maintained enclosures. *See* Ex. D at 7-8. Other enclosures had flooring that was not secured to the framework beneath it or lacked support from underneath. In those enclosures, the floors bounced up and down, shifted, tilted, or sank under the weight of the beagles as they moved within the enclosure. *See id.* at 8-9.

117. APHIS inspectors also observed six beagles actively stuck in the flooring, requiring Envigo staff to manually remove them. Based on Envigo's records, at least nine additional beagles were found trapped in the flooring between August 1, 2021, and November 3, 2021, several of which were injured and required treatment for lameness and wounds. Young beagle puppies are also being housed in enclosures with the same flooring. Rather than installing flooring that would keep the beagle puppies safe, Envigo put down butcher paper to cover the gaps. However, APHIS inspectors observed the beagle puppies urinating on and tearing the

paper. The puppies were exposed to the “dangerous flooring within minutes of paper being put into the enclosure.” *See* Ex. D at 12-13.

118. The beagles’ continued exposure to dangerous flooring is particularly concerning in light of Envigo’s failure to employ sufficient staff. *See infra* at V. Envigo’s severe staffing shortage increases the risk that a beagle or beagle puppy will be trapped in the noncompliant flooring, possibly with injuries, for an extended amount of time.

119. In March 2022, APHIS inspectors again found that Envigo had failed to implement effective corrections to eliminate the risk of entrapment and injury from the dangerous flooring installed in enclosures for beagles over 12 weeks of age. Inspectors observed two beagles stuck in the flooring, one of which had to be removed by facility representatives. Medical records indicated that at least 12 additional dogs were injured after becoming trapped in the flooring. The injuries ranged from mild soreness to pressure wounds that required over two weeks of treatment. *See* Ex. E at 4.

120. During the March 2022 inspection, the inspectors also identified at least 130 enclosures with gaps large enough for a foot or leg to pass through. In some areas, inspectors also identified gaps in the fencing where the chain link had become detached. In one spot, the gap extended the length of the enclosure sidewall. The fencing was so loose that a beagle could have pushed its way under the gap to enter the adjacent enclosure. *See* Ex. E at 3.

121. Envigo has been on notice for over nine months that the primary enclosures fail to provide the beagles at the Cumberland Facility sufficient space to keep the beagles safe and healthy. *See* 9 C.F.R. § 3.6(c).

122. Mother beagles and puppies without adequate floor space in an enclosure may suffer from distress, discomfort, crowding, poor sanitation, increased trauma, and mortality.

123. During the July 2021 inspection, APHIS inspectors observed that 62 nursing female beagles with a total of 393 beagle puppies were in enclosures that did not provide the minimum amount of floor space for the number of beagles in the enclosure. *See* Ex. A at 11.

124. In November 2021, APHIS inspectors determined that Envigo was failing to provide a total of 742 beagles and weaned puppies with the minimum space required by the AWA. Envigo housed as many as nine puppies in an enclosure measuring 16 square feet. The AWA requires that enclosures containing that many puppies be at least 21.8 square feet. APHIS inspectors found additional overcrowded enclosures in another building containing 15 enclosures with four-to-five-month-old beagles. APHIS inspectors determined that those enclosures measured a total of 39.7 square feet. However, some of the enclosures housed as many as 10 beagles each, which would require 60.4 square feet per enclosure. Sixty enclosures in another room measured around 39.7 feet. However, Envigo co-housed as many as 11 dogs in each enclosure, which would require a minimum of 58.9 square feet of space. *See* Ex. D at 13-14.

125. In addition to causing discomfort, distress, poor sanitation, and increased incidence of illness, housing dogs in overcrowded enclosures can also lead to long-lasting negative behaviors, such as increased aggression and future incompatibility with other dogs, behaviors that are widespread at the Cumberland Facility.

126. Envigo has been on notice for over nine months that the Cumberland facility is unsanitary. *See* 9 C.F.R. § 3.11(a). The buildup of feces, urine, food waste, and water waste are a breeding ground for pests and insects, expose dogs to unnecessary disease hazards, and cause noxious odors.

127. During the July 2021 inspection, APHIS inspectors observed that the waste gutters below the main sheltered housing in Buildings G1, G2, and G3 contained large quantities

of feces, urine, standing water, dead and live insects, and uneaten food under the raised indoor and outdoor kennel floors. Near the outside gutters, there was an “overpowering ammonia and fecal odor that emanates from below the kennels inside the buildings.” *See* Ex. B at 8. Envigo staff claimed that the gutters were usually cleaned every other day, but that the pump that cleans the gutters had been broken for six days. *Id.* at 9.

128. During the July 2021 inspection, APHIS inspectors also observed a “build up of brown organic material” in the enclosures where nursing mothers and their puppies are housed. Ex. B at 10. Envigo’s facility operations manager admitted that the enclosures are disinfected only between litters or every six weeks. *Id.* Envigo was reminded that “[i]nadequate cleaning and disinfection may lead to animal sickness, outbreaks of disease, or proliferation of pests.” *See id.* at 11.

129. Inspectors also noted that “[a]round the entire facility are large populations [of] live insects including house flies, drain flies, water bugs, cockroaches, and spiders with cobwebs.” *See* Ex. B at 9. Inspectors further noted that “[t]here is an extensive, widespread pest problem throughout all animal-housing buildings at the facility.” *See id.* at 11. In particular, “a very large number of live flies” were observed in all of the whelping rooms in Building 97 where dogs were present. The flies were observed on the walls and ceilings, flying in the air, and in the drains in the rooms housing dogs. *See id.* at 12.

130. Envigo was directed to correct these sanitation issues. *See* Ex. B at 9, 12. Nevertheless, Envigo continued to have sanitation issues in subsequent visits. In October 2021, they observed that the Cumberland Facility continued to have sanitation problems. In at least 50% of the rooms being used within Buildings G1 and G2, there were still “accumulations of waste and an overpowering fecal odor” emanating from below the enclosures. APHIS inspectors

also noted that significant accumulations of animal waste on top of two pulley systems used to scrape solid waste underneath the enclosures were contributing to the excessive odor in the facility. *See* Ex. C at 11.

131. In November 2021, APHIS inspectors found once again that Envigo was failing to clean waste under the primary enclosures frequently enough to prevent the accumulation of feces and food waste to reduce disease hazards, odors, and the proliferation of pests. Many rooms had white, moldy accumulations of spilled feed and excreta in the pits that were several inches high and created areas of standing liquid. A majority of rooms in two buildings had significant accumulations of dropped feed and excreta on the ledges just underneath the suspended flooring. APHIS inspectors observed that the waste had been there long enough that in many rooms it was either white, brown, or black with mold, and flies were congregating on the waste. Envigo was once again directed to correct the problem. *See* Ex. D at 16-17.

132. Consistent with the sanitation issues, APHIS inspectors also observed insect infestations in multiple buildings at the Cumberland Facility. Small gnat-sized black flies and large flies were observed throughout the facility, including on food receptacles and around the enclosures. Large numbers of small white fly larvae or maggots were present in spilled feed under enclosures and many areas of wet flooring appeared to be almost completely covered in maggots. Large numbers of small, white thread-like worms were also seen in several rooms throughout a building where there was pooled water. Envigo was once again directed to correct the pest problem. *See* Ex. D at 18-19.

V. Envigo is Failing to Employ a Sufficient Number of Qualified Employees to Care for the Thousands of Beagles at the Cumberland Facility.

133. Envigo is failing to meet the minimum standards for handling, feeding, sanitation, and adequate veterinary care by employing an insufficient number of qualified employees to care

for the thousands of beagles at the Cumberland Facility.

134. Adequate staffing is essential for carrying out the level of husbandry and care required by the AWA to maintain the health and welfare of the dogs and maintain safe and sanitary facilities. *See* 9 C.F.R. § 3.12.

135. Envigo also does not employ a sufficient number of staff with adequate training and experience to provide humane care and treatment to the thousands of beagles at the Cumberland Facility.

136. Envigo was first cited for failure to adequately staff the Cumberland Facility in July 2021. APHIS noted that Envigo employed only one attending veterinarian to oversee veterinary care for over 5,000 beagles. In addition, Envigo employed only 39 employees total for over 5,000 dogs. Of those 39 employees, Envigo employed only six trained staff members to complete the required daily observations of the 5,000 dogs, with three-four employees conducting daily observations. These employees had additional duties, including providing treatments to dogs and carrying out husbandry practices. *See* Ex. A at 13.

137. The lack of adequate staffing of the Cumberland Facility has contributed to Envigo's failure to meet other AWA requirements, including daily observations of all dogs to assess their health and well-being. During the July 2021 inspection, APHIS inspectors noted that Envigo failed to identify 15 beagles with medical issues prior to the inspection. Several of those beagles were found in need of critical care, including a beagle puppy found by inspectors under the enclosure in the tray used for urine and feces collection. *See* Ex. A at 13.

138. Envigo was given until August 31, 2021, to correct the issue by employing a sufficient number of personnel to carry out the level of care and husbandry practices required by the AWA. Not only did Envigo fail to correct the issue but, when APHIS inspectors returned in

October 2021, Envigo employed even fewer employees than it had in July 2021. APHIS inspectors found that there continued to be “severe staffing shortages” with only approximately 32 employees at the facility. Moreover, APHIS inspectors discovered that only 17 staff members were directly responsible for all husbandry, daily observations, and medical treatments for almost 5,000 beagles. APHIS inspectors identified four beagles with medical conditions that required treatment that should have been discovered by staff during daily observations. Additionally, “numerous dogs ... have been identified with severe periodontal disease by veterinarians and still require prescribed dental cleanings.” APHIS inspectors also noted that “basic husbandry such as cleaning out kennels daily to remove feces, cleaning contact surfaces to prevent buildup of debris, and general housekeeping including dead pest removal is not being performed in accordance with the AWA regulations.” *See* Ex. C at 12.

139. In November 2021, Envigo was once again cited for failure to have a sufficient number of employees to meet the requirements of the AWA. At the time, Envigo employed only 21 full-time and three part-time employees who are responsible for all husbandry and daily observations for 4,652 beagles and beagle puppies. APHIS concluded that the failure to employ a sufficient number of employees was contributing to Envigo’s failure to undertake required daily observations of the beagles, medical treatments, cleaning and sanitization, and facility maintenance. Envigo was once again directed to correct the problem. *See* Ex. D at 19.

VI. Envigo is Failing to Make and Retain Accurate and Complete Records.

140. Envigo has failed to keep accurate records regarding the identification and disposition of dogs. In addition, medical records are frequently inaccurate and incomplete.

141. Accurate and complete recordkeeping of all acquisitions, including births, and dispositions is important for animal identification, traceability of animals, and investigation of disease outbreaks or animal theft.

142. Envigo has been cited by APHIS for poor recordkeeping since July 2021. During the July 2021 inspection, a review of disposition records showed that three beagles were marked “missing” and an additional 21 beagle puppies were recorded as “miss.” The attending veterinarian claimed that the records noting the beagle puppies as “miss” were likely due to administrative error and would be corrected when the beagles were identified. *See* Ex. B at 4-5. APHIS directed Envigo to correct the issue by August 30, 2021. *See id.* at 5.

143. When APHIS inspectors returned in October 2021, once again Envigo still did not have complete acquisition or disposition records for the beagles at the Cumberland Facility. APHIS inspectors noted that Envigo’s inventory for the Cumberland Facility continued to list beagles who were no longer present. *See* Ex. C at 5.

144. One beagle puppy was listed in the original litter count but was no longer present as of October 14, 2021. Envigo had no record of the beagle puppy dying or being euthanized. When asked about the missing puppy, Envigo staff stated that they did not know if the beagle puppy existed in the first place or was missing. *Id.*

145. Envigo staff later mentioned that a newborn beagle puppy had been found in a drain under an enclosure on October 13, 2021, and died later that day. Envigo failed to record the birth (or acquisition) of the beagle puppy. Envigo also failed to record the death of the puppy on the mortality log and, thus, no disposition record exists for the puppy. *See id.* at 5-6. Thus, Envigo had no record of the existence of a beagle puppy that died as a result of Envigo’s failure to ensure that the enclosures are safe for the dogs at the Cumberland Facility.

146. In November, APHIS inspectors determined that acquisition, disposition, and inventory records were incomplete and inaccurate for at least 937 beagles and beagle puppies. Envigo identified an additional 99 beagles and beagle puppies with inaccurate disposition

records. *See* Ex. D at 6.

147. Envigo has also failed to create and maintain accurate and complete medical records in violation of 9 C.F.R. § 3.13(b). The lack of accurate and complete medical records may hide adverse trends in animal health, medical errors, and the failure to provide adequate medical care to the beagles at the Cumberland Facility. Specifically, the lack of accurate and complete medical records prevents Envigo staff from learning from any mistakes they are making in caring for the beagles at the Cumberland facility and prevents USDA from determining Envigo's compliance with certain AWA regulations and standards.

148. During the July 2021 inspection, APHIS inspectors found that medical records for numerous beagles were incomplete. For example, medical records showed that four beagles suffered from a fracture, though the record failed to specify the location and type of fracture. An additional two beagles were euthanized for fractures, including one beagle that was euthanized for a broken tail. When asked the cause of the fractures, the attending veterinarian stated that she had investigated a nutritional cause, but was unable to determine with certainty the cause. Another beagle suffered a laceration when his leg got caught in the enclosure, but the record did not indicate the location of the laceration or describe the injury with detail. The APHIS inspection report noted that "[f]ractures and lacerations may result from improper handling, unsafe primary enclosures, incompatibility of animals, improper nutrition, or many other causes." *See* Ex. B at 12-13.

149. The mortality log failed to identify the cause of death for two beagles. Although the attending veterinarian stated that Envigo staff is supposed to notify her whenever an adult beagle is found dead so that she can perform a necropsy examination, there is no record of the results of any necropsy for these two beagles. The mortality log listed the cause of death of

another beagle as “pull,” but the beagle’s individual record contained no information about the beagle’s death. *See* Ex. B at 13-14.

150. Envigo was directed to correct the recordkeeping issues by August 30, 2021, by maintaining records for all beagles that include a date and description of any problems identified, examination findings, test results, plans for treatment and care, and treatments performed.

151. When APHIS inspectors returned in October 2021, they found additional mortality records for dead beagle puppies. For some, the records noted that necropsies had been performed but no exam findings or test results were recorded. In addition, the medical records contained no description of symptoms leading up to the beagle puppies’ deaths. The APHIS inspectors concluded that, for at least some of the diagnoses listed on the mortality records, they could not be made without either a history of symptoms or further diagnostic testing. *See* Ex. C at 13.

152. Medical records for another beagle puppy indicated that the beagle was “lame on all four legs” and had a “broken left femur” but failed to contain additional physical examination findings, diagnostics, or test results. The staff member who found the beagle said that they had not observed obvious limping on any specific leg. However, a manager stated that, when the attending veterinarian examined the beagle, she felt a pop in the beagle puppy’s left femur, suspected a fracture, and recommended euthanasia. The medical records, however, did not include any of the veterinarian’s examination findings but rather only a presumptive diagnosis. *See* Ex. C at 14.

153. Envigo was once again reminded that, as a result of the incomplete records, Envigo could not determine the exact cause of death and, therefore, ensure the health of the rest of the beagle puppies. Further, if the diagnoses are accurate, the Envigo staff appear to have

missed the clinical signs—including weakness, lethargy, coughing, heavy breathing, lack of appetite, diarrhea, and vomiting—which would have been apparent if they were undertaking the required daily observations. *See* Ex. C at 14-15.

154. APHIS inspectors again found incomplete and inaccurate medical records in November 2021. Envigo’s medical records omitted critical information such as descriptions of the medical problem, treatments administered, and procedures performed to diagnose the condition or provide care. Envigo claimed that it did not understand that records describing physical examinations, medical procedures, treatments, deaths, and the administration of controlled substances constituted medical records that must comply with 9 C.F.R. § 3.13(b)(1). Envigo was directed to ensure by February 11, 2022, that every medical record included the identity of the animal, including identifying marks, tattoos, or tags, and the animal’s breed, sex, and age.

CLAIMS FOR RELIEF

First Claim For Relief

Injunctive Relief: Failure to provide adequate veterinary care in violation of 7 U.S.C. § 2143(a)(1), (2) and 9 C.F.R. §§ 2.40, 3.13(a)

155. The United States incorporates by reference the allegations in paragraphs 1 through 154 as though set forth fully herein.

156. As set forth above, Envigo is violating the AWA and its implementing regulations and standards by failing to provide the beagles at the Cumberland Facility with adequate veterinary care in violation of 7 U.S.C. § 2143(a)(1), (2) and 9 C.F.R. §§ 2.40, 3.13(a).

157. Unless enjoined, Envigo will continue to violate the AWA, and its regulations and standards, causing needless suffering and, in some cases, the death of beagles at the Cumberland Facility.

158. The United States is entitled to an injunction to prevent and restrain Envigo from operating in violation of the AWA and its implementing regulations and standards. 7 U.S.C. § 2146(c).

Second Claim for Relief

**Injunctive Relief: Failure to provide each dog with uncontaminated, wholesome, palatable food of sufficient quantity and nutritive value and to make potable water continuously available in violation of
7 U.S.C. § 2143(a)(1), (2) and 9 C.F.R. §§ 3.9; 3.10**

159. The United States incorporates by reference the allegations in paragraphs 1 through 158 as though set forth fully herein.

160. As set forth above, Envigo is violating the AWA and its implementing regulations and standards by failing to provide each beagle at the Cumberland Facility with uncontaminated, wholesome, palatable food of sufficient quantity and nutritive value and to make in violation of 7 U.S.C. § 2143(a)(1), (2) and 9 C.F.R. §§ 3.9; 3.10.

161. Unless enjoined, Envigo will continue to violate the AWA, and its regulations and standards, causing needless suffering and, in some cases, the death of beagles at the Cumberland Facility.

162. The United States is entitled to an injunction to prevent and restrain Envigo from operating in violation of the AWA and its implementing regulations and standards. 7 U.S.C. § 2146(c).

Third Claim for Relief

Injunctive Relief: Failure to meet minimum standards for handling and housing in violation of 7 U.S.C. § 2143(a)(1), (2); 9 C.F.R. §§ 2.131(b); 3.7

163. The United States incorporates by reference the allegations in paragraphs 1 through 162 as though set forth fully herein.

164. As set forth above, Envigo is failing to meet the minimum standards for handling

and housing the beagles in violation of the AWA and its regulations and standards, resulting in the unnecessary suffering and, at times, death of beagles at the Cumberland Facility. 7 U.S.C. § 2143(a)(1), (2); 9 C.F.R. §§ 2.131(b), 3.7.

165. Unless enjoined, Envigo will continue to violate the AWA, and its regulations and standards, causing needless suffering and, in some cases, the death of beagles at the Cumberland Facility.

166. The United States is entitled to an injunction to prevent and restrain Envigo from operating in violation of the AWA and its implementing regulations and standards. 7 U.S.C. § 2146(c).

Fourth Claim For Relief
Injunctive Relief: Failure to maintain safe and sanitary conditions in violation of 7 U.S.C. § 2143(a)(1), (2); 9 C.F.R. §§ 3.1, 3.6, 3.11

167. The United States incorporates by reference the allegations in paragraphs 1 through 166 as though set forth fully herein.

168. As set forth above, Envigo is exposing the beagles at the Cumberland Facility to unsafe and unsanitary conditions in violation of the AWA and its implementing regulations and standards. See 7 U.S.C. § 2143(a)(1), (2); 9 C.F.R. §§ 3.1, 3.6, 3.11.

169. Unless enjoined, Envigo will continue to violate the AWA, and its regulations and standards, causing needless suffering and, in some cases, the death of beagles at the Cumberland Facility.

170. The United States is entitled to an injunction to prevent and restrain Envigo from operating in violation of the AWA and its implementing regulations and standards. 7 U.S.C. § 2146(c).

Fifth Claim For Relief

Injunctive Relief: Failure to meet the minimum standards for handling, feeding, sanitation, and adequate veterinary care by employing an insufficient number of qualified employees to care for the thousands of beagles at the Cumberland Facility in violation of 7 U.S.C. § 2143(a)(1), (2); 9 C.F.R. § 3.12

171. The United States incorporates by reference the allegations in paragraphs 1 through 170 as though set forth fully herein.

172. As set forth above, Envigo is failing to meet the minimum standards for handling, feeding, sanitation, and adequate veterinary care by employing an insufficient number of qualified employees to care for the thousands of beagles at the Cumberland Facility in violation of the AWA and its implementing regulations and standards. 7 U.S.C. § 2143(a)(1), (2); 9 C.F.R. § 3.12.

173. Unless enjoined, Envigo will continue to violate the AWA, and its regulations and standards, causing needless suffering and, in some cases, the death of beagles at the Cumberland Facility.

174. The United States is entitled to an injunction to prevent and restrain Envigo from operating in violation of the AWA and its implementing regulations and standards. 7 U.S.C. § 2146(c).

Sixth Claim for Relief

Injunctive Relief: Failure to create and maintain complete and accurate records in violation of 7 U.S.C. § 2140 and 9 C.F.R. §§ 2.75(a)(1), (2) and 3.13(b)

175. The United States incorporates by reference the allegations in paragraphs 1 through 174 as though set forth fully herein.

176. As set forth above, Envigo is violating the AWA, and its implementing regulations and standards, by failing to create and maintain complete and accurate records in violation of 7 U.S.C. § 2140 and 9 C.F.R. §§ 2.75(a)(1), (2) and 3.13(b).

177. Unless enjoined, Envigo will continue to violate the AWA, and its regulations and standards, causing needless suffering and, in some cases, the death of beagles at the Cumberland Facility.

178. The United States is entitled to an injunction to prevent and restrain Envigo from operating in violation of the AWA and its implementing regulations and standards. 7 U.S.C. § 2146(c).

REQUEST FOR RELIEF

WHEREFORE, the United States respectfully requests that the Court:

1. Declare that Envigo has violated and continues to violate the AWA, 7 U.S.C. § 2143(a)(1), (2), and its implementing regulations and standards;
2. Declare that Envigo has violated and continues to violate the AWA, 7 U.S.C. § 2140, and its implementing regulations and standards;
3. Preliminarily and permanently enjoin and restrain Envigo from violating the AWA, 7 U.S.C. § 2146(c);
4. Award the United States its costs in this action; and
5. Grant other relief that the Court deems just and proper.

DATED: May 19, 2022

Respectfully Submitted,

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