

Biannual Compliance Monitor Report

United States of America v. Envigo RMS, LLC and Envigo Global Services, Inc.

Case No. 6:24CR16

Prepared by John H. Fuson

Date: July 20, 2026

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I. Introduction

The Compliance Monitor (“CM”) submits this biannual report (“Report”) pursuant to section 12(d)(1) of the Final Plea Agreement (“Plea Agreement”) between the United States, by and through the United States Attorney for the Western District of Virginia and the Environmental Crimes Section of the Department of Justice (collectively “DOJ”), and Envigo RMS, LLC and Envigo Global Services, Inc. (collectively “Envigo”), as entered into between the parties on June 3, 2024.

This is the third report provided since the CM commenced the monitorship on January 20, 2025.

A. The Plea Agreement and the Resolution Agreement

The Plea Agreement and the related Resolution Agreement were entered into by the parties after Envigo pleaded guilty to conspiring to knowingly violate the Animal Welfare Act, 7 U.S.C. § 2131 *et seq.*, “by failing to provide adequate veterinary care, adequate staffing, and safe and sanitary living conditions for the dogs housed at [the Cumberland facility].” (§ 1). Further, Envigo pleaded guilty to conspiring to knowingly violate the Clean Water Act, 33 U.S.C. § 1251 *et seq.*, “by failing to properly operate and maintain the wastewater treatment plant at the Cumberland facility.” (*Id.*). The Resolution Agreement between DOJ and Envigo resolves the federal criminal investigation described in the Information to the Plea Agreement. (Plea Agreement, Attach. B, ¶ 1).

The Plea Agreement (§ 12(a)), among other things, requires that “a CM shall be appointed to ensure compliance with all Applicable Laws, the Plea Agreement, and the Resolution Agreement.”

The Plea Agreement (§ 5(c)) defines “Applicable Laws” as “all federal Animal Welfare Act and Clean Water Act laws, rules, and regulations, as well as all federal and applicable state and local animal welfare, animal cruelty, water, and sewage laws, rules, and regulations,” and it states that “ENVIGO recognizes it is the United States’ intent that [Envigo’s and Inotiv, Inc.’s (collectively the “Inotiv Entities” or “Inotiv”)] personnel and facilities shall exceed the minimum requirements under the Animal Welfare Act and Clean Water Act to ensure the health, safety, and well-being of animals under the care of the INOTIV ENTITIES.” (§ 5).

B. The Compliance Monitor

John H. Fuson of Kleinfeld, Kaplan & Becker LLP (“KKB”) is the designated CM.

Mr. Fuson is supported by other attorneys at KKB, two veterinarians and a veterinary technician who are experts on the requirements of the Animal Welfare Act, and an expert on the requirements of the Clean Water Act. Mr. Fuson, associated attorneys, and the subject matter experts comprise the Compliance Monitor Team.

II. Compliance Monitor Activity Since January 20, 2026

The Plea Agreement (§ 12(b)) directs that each year, the CM shall conduct on-site reviews of one-third of Inotiv’s facilities that currently hold or conduct activities under United States Department of Agriculture (“USDA”) licenses or hold permits regulated by the Clean Water Act. Consistent with this obligation, in 2025, the CM completed reviews of Inotiv’s facility located in Denver, Pennsylvania (the “Denver Facility”), and one of two facilities located in Alice, Texas

(the “Alice West Facility”). Since January 20, 2026, the CM has visited Inotiv’s second facility located in Alice, Texas (the “Alice East Facility”). It will visit a fourth facility later this year. As with the Denver and Alice West Facilities, the CM observed dedicated and hard-working animal care staff at the Alice East Facility.

In addition to the on-site visit, the CM reviewed documentation concerning operations at the Alice East Facility, as well as documentation relating to certain incidents Inotiv reported pursuant to section 13(i) of the Plea Agreement.

The CM also monitored other requirements set forth in the Plea Agreement and the Resolution Agreement, as described in this Report.

A. Alice East Facility Site Visit

The Alice East Facility operates under a USDA Class B License (74-B-0332) (licensed entity: Envigo Global Services Inc.). It comprises multiple buildings and structures dedicated to animal housing and care on a single property. The CM was on-site at the Alice East Facility from April 20 to 24, 2026.

The CM reviewed all buildings at the Alice East Facility that are used to house or hold animals. These included indoor rooms, indoor/outdoor structures, outdoor field cages, and outdoor corn cribs for housing nonhuman primates (“NHPs”). The CM also reviewed buildings with hospital, surgery/laboratory, treatment and necropsy rooms, feed storage space, and spaces used to prepare enrichment devices and treats.

The CM conducted the review with three associated attorneys from KKB, and two veterinarians and a veterinary technician who are experts on the requirements of the Animal Welfare Act. Numerous Inotiv representatives attended, including the Compliance Officer, members of the Compliance Committee, members of Inotiv’s Animal Welfare Council, members of the Institutional Animal Care and Use Committees (“IACUCs”) for the Alice East Facility, the Attending Veterinarian (“AV”) for operations at the Alice East Facility, other staff veterinarians and veterinary technicians, the NHP Behavior Manager, NHP operations managers, and other support staff. Inotiv’s outside counsel also attended the on-site review.

Following the Alice East Facility on-site review, the CM shared with Inotiv the CM’s observations about Inotiv’s compliance with obligations set forth in the Plea Agreement and the Nationwide Compliance Plan.

III. Animal Welfare Compliance Obligations

A. Agreement Not to Sell Dogs

The Plea Agreement (§ 4) states Envigo’s agreement that the Inotiv Entities will not breed or sell dogs and further that any dog under the care of or in the possession or control of the Inotiv Entities will be over the age of 90 days old.

On June 30, 2025, on January 16, 2026, and again on July 16, 2026, the Inotiv Entities confirmed in writing that they have not bred or sold dogs since entry of the Plea Agreement, and all dogs under their care are older than 90 days.

The CM will continue to monitor the Inotiv Entities' adherence to this commitment for the duration of the monitorship.

B. Agreement to Meet Certain Standards

The Plea Agreement includes certain NHP care standards, which establish requirements for all covered species under the care of Inotiv at Inotiv-operated sites that hold USDA licenses when such animals are not involved in active research. It further directs Inotiv to "implement and comply with" a written environmental enrichment plan for NHPs and a written enrichment plan for small animals "that incorporate[] at a minimum" the certain care standards.

The Guide for the Care and Use of Laboratory Animals (8th Ed.) (2011) (the "Guide") states:

The primary aim of environmental enrichment is to enhance animal well-being by providing animals with sensory and motor stimulation through structures and resources that facilitate the expression of species-typical behaviors and promote psychological well-being through physical exercise, manipulative activities, and cognitive challenges according to species-specific characteristics.

(pp.52-53 (citing National Research Council, *Psychological Well-being of Nonhuman Primates*, Washington: National Academy Press (1998); RJ Young, *Environmental Enrichment for Captive Animals*, UFAW Animal Welfare Series, London: Blackwell Science (2003))). It continues: "[w]ell-conceived enrichment provides animals with choices and a degree of control over their environment, which allows them to better cope with environmental stressors." (*Id.* p.53 (citing RC Newberry, *Environmental Enrichment: Increasing the Biological Relevance of Captive Environments*, Appl. Anim. Beh. Sci. (1995))). It further notes that "[e]nrichment programs should be reviewed by the IACUC, researchers, and veterinarian on a regular basis to ensure that they are beneficial to animal well-being and consistent with the goals of animal use. They should be updated as needed to ensure that they reflect current knowledge." (*Id.*).

These principles undergird much of the certain care standards, which, for NHPs, require provisions for social housing, outdoor access for non-quarantined animals, vertical climbing and space for species-typical postures, natural behaviors, foraging, access to a variety of substrates, opportunities to avoid frightening stimuli and other animals, and control of their own enrichment, among other care provisions. They also require variety and novelty of enrichment objects.

During the CM's review of the Alice East Facility, it evaluated Inotiv's animal care operations and noted conditions that did not comply with the certain care standards and other requirements of the Plea Agreement.

1. Social Housing, Outdoor Access, Vertical Climbing, and Space for Species Typical Postures

The Plea Agreement requires Inotiv to socially house each NHP of a species known to be of a social nature. It also requires Inotiv to provide NHPs whose enclosures do not provide outdoor access with "alternative regular outdoor access" unless subject to quarantine, prohibited by research protocol, or detrimental to the individual animal as determined by the attending veterinarian in writing. It further requires Inotiv to provide all NHPs in its care, including NHPs in quarantine, with vertical climbing opportunities that provide enough space to travel, feed, and

rest in an elevated space, as well as space for species-typical postures and positions for resting, sleeping, feeding, exploration, play, locomotion, and social adjustments.

The Alice East Facility has extensive outdoor structures for housing NHPs (specifically, field cages, indoor/outdoor housing structures, and corn cribs), which can accommodate large troops. The CM observed the animals housed in such enclosures make ample use of the vertical space. Although the majority of NHPs at the facility at the time of the CM's visit were housed outdoors, like the Denver and Alice West Facilities, the Alice East Facility still uses indoor rack cages to house some NHPs, particularly from October to April. As noted in previous reports, as currently used, these rack cages do not provide NHPs with regular outdoor access, vertical climbing opportunities, or space for species-typical postures. Thus, for such animals that are not subject to an applicable exception as determined by the AV, Inotiv was not in compliance with these requirements at the time of the CM's visit to the Alice East Facility. The CM further notes that the rack cages also pose challenges for social housing and lack spaces that meaningfully allow for the avoidance of frightening stimuli and other individual animals.

Inotiv has stated that it is putting into place procedures and electronic systems that will enable it to better track individual animals that do not have regular outdoor access and/or which are individually housed, with the aim of ensuring that such conditions are limited to specific individual needs and to the shortest possible time. The CM intends to assess the implementation of these systems and monitor their effectiveness.

2. Foraging, Access to a Variety of Substrates, Item Novelty, and Control of Own Enrichment

Captive primates are highly motivated to search for and process food even when identical food is freely available. Denying that motivation is associated with the emergence of abnormal behavior. (See, e.g., Viktor Reinhardt & Adam Roberts, *Effective Feeding Enrichment for Non-Human Primates: A Brief Review*, 6 ANIMAL WELFARE 265-72 (1997)). Novel manipulanda serve a parallel function, giving animals continuing opportunities for the exploration and object manipulation that make up a large part of a wild primate's behavioral repertoire, though their benefit depends on regular rotation, since interest in a static object predictably declines within days. (See, e.g., Corrine K. Lutz & Melinda A. Novak, *Environmental Enrichment for Nonhuman Primates: Theory and Application*, 46 ILAR JOURNAL 178, 180-81 (2005)).

Consistent with such husbandry practices, the environmental enrichment program directed by the Plea Agreement requires Inotiv to allow NHPs to work for their food by providing daily opportunities for time-consuming foraging tasks. It also directs that NHPs should be housed in spaces that allow access to a variety of substrates. It further requires Inotiv to change enrichment items often enough to maintain novelty and to allow NHPs a level of control over their own enrichment.

Although the effort and dedication demonstrated by the animal care staff with the resources available at the Alice East Facility during the CM's visit were evident, the CM cannot conclude that Inotiv has devoted sufficient resources to provide daily time-consuming foraging tasks, varieties of substrates, or varieties of manipulanda that were more than intermittent. While the animal care staff provide some foraging opportunities, such as browse, and have developed and built items like PVC "flower" feeders and purchased some purpose-built puzzle feeders, they are not providing such opportunities daily or to all of the animals housed at the site, and do not appear to be sufficiently resourced to do so. Accordingly, Inotiv was not in compliance with these requirements at the time of the CM's visits to the Alice East Facility.

We understand that Inotiv is working to add more complex feeding devices and to further assess its approach to enrichment and foraging. As in our previous report, the CM recommends that Inotiv significantly expand its use of puzzle feeders, pools or other tubs with substrates, foraging boards, and similar diverse methods of food presentation to ensure that all NHPs have daily access to time-consuming foraging tasks. It also needs to ensure more frequent rotations of manipulanda to maintain novelty. These efforts will likely require more resources than were available at the time of the CM's visit to the Alice East Facility.

* * *

To ensure that Inotiv has taken appropriate corrective measures described here and as otherwise needed to comply with the NHP Care Standards, the CM intends to revisit the NHP operations at the Alice East Facility pursuant to its authority under section 12(b) of the Plea Agreement.

C. Staffing

Like the animal care staff at both the Denver and Alice West Facilities, the animal care staff that the CM observed at the Alice East Facility appeared dedicated and hard-working. However, as with the Denver and Alice West Facilities, there did not appear to be sufficient staffing at the Alice East Facility to meet the heightened standards of care set by the NHP Care Standards in the Plea Agreement.

As we have previously observed, the staffing study Inotiv commissioned did not appear to consider those heightened standards, and thus its conclusions appear not to accurately assess staffing needs at the Inotiv sites.

Therefore, the CM reasserts its recommendation that Inotiv reassess staffing levels at all of its USDA-licensed facilities, ideally with support from an outside, independent staffing expert. As noted in the January 2026 report, the assessment should consider whether Inotiv has sufficient staff to manage each facility's maximum population capacity and ensure that each animal receives appropriate feeding, sanitation, health assessments, and enrichment consistent with the heightened care standards set by the Plea Agreement.

D. Veterinary Training

The Plea Agreement (§ 5(a)) requires all veterinarians employed by the Inotiv Entities to complete at least fifteen hours of continuing education per year. The CM reviewed records provided by Inotiv, including descriptions for the underlying coursework done by the veterinarians, and confirmed this requirement was met in 2025.

E. Notice of Plea Agreement to Personnel of Inotiv Entities

The Plea Agreement (§ 14) requires all Inotiv Entities to require each full-time and part-time employee equivalent to read the Plea Agreement, the Information (Attachment C to the Plea Agreement), and the Resolution Agreement (Attachment B to the Plea Agreement) within 30 days of entry of the guilty plea. Further, it requires all new full-time and part-time equivalent employees to read the Information, Plea Agreement, and Resolution Agreement, within 30 days of the start of their employment with one of the Inotiv Entities.

The CM reviewed data reflecting that as of July 17, 2026, Inotiv's completion rate was over 99.5%. Inotiv reported that these gaps reflect recent new hires and persons on long-term leave and that managers are notified to ensure these gaps are promptly closed. The CM will continue to assess Inotiv's compliance with this requirement over the course of the monitorship.

F. Rehoming

The Plea Agreement (§ 5(d)) directs Inotiv, for all animals in its care, to "[m]ake reasonable efforts, and document such efforts, to find humane placement for dogs, cats, nonhuman primates, and exotics who are no longer used in research or breeding and are able to be retired..." The CM understands that Inotiv's initial efforts to find placement for retired NHPs has stalled; accordingly, Inotiv has recently proposed an alternative approach that the CM is assessing. To the knowledge of the CM, Inotiv has not rehomed any dogs, cats, or NHPs since entry of the Plea Agreement. The CM will continue to assess Inotiv's compliance with this requirement of the Plea Agreement during subsequent visits and throughout the course of the monitorship.

G. Notification of Potential or Actual Violations

The Plea Agreement (§ 13(i)) requires Envigo, "within 60 days of receiving notice of a potential or actual violation of the Applicable Laws, any federal criminal law, or a term of the Plea Agreement at any of the INOTIV ENTITIES," to "notify the CM, the United States, and the United States Probation Office of such violation, ENVIGO's findings, and corrective action taken, if any." This requirement is restated in the NCP. (NCP p.26).

From January 1, 2026, through June 30, 2026, Inotiv provided 11 reports pursuant to section 13(i). The CM reviewed each report, submitted follow-up information and document requests to Inotiv on all 11 reports, and reviewed relevant underlying documentation. The CM has also discussed certain reports with Inotiv's Compliance Officer, members of the Compliance Committee, and veterinary staff.

For all incident reports, the CM intends to follow up and observe relevant facilities, enclosures, and equipment, review affected procedures and corrective actions taken, and speak with relevant personnel during its on-site visits.

H. Improvements to Facilities

The Plea Agreement (§ 7(g)) requires Envigo to expend at least \$7 million on improvements to facilities and personnel to a standard *beyond* the bare minimum required to comply with the Animal Welfare Act and implementing regulations, including expenditures of not less than \$2,500,000 by June 3, 2025, and an aggregate sum of not less than \$5,000,000 by June 6, 2026.

The Plea Agreement (§ 9) further states that for an expenditure to be counted against the total dollar amounts required as listed in section 7(g), it must be "directly related to improving the welfare of animals at INOTIV ENTITIES." (Emphasis added). Accordingly, each expenditure must satisfy this requirement to be appropriately classified as a qualifying expenditure under the Plea Agreement. For instance, expenditures to improve facilities to ensure compliance with Clean Water Act standards would not count as qualifying expenditures if they are not directly related to improving the welfare of animals in Inotiv's care. In addition, expenditures to bring non-compliant facilities into compliance with the AWA would not count as qualifying

expenditures because they are not “for improvements to its facilities and personnel to a standard beyond the minimum required to comply with the Animal Welfare Act laws, rules, and regulations.”

Additionally, the Plea Agreement provides that Inotiv’s improvements to facilities and personnel must include, but are not limited to, maintaining and, if necessary, hiring sufficient:

(a) “veterinary staff at all facilities within the United States to ensure exceptional veterinary care for all animals in [Inotiv’s] care, custody, or control”; and (b) “staff and secure facility space to ensure...enrichment, including, but not limited to, social contact, sufficient space, and sufficiently complex environment to allow animals to perform species-specific natural behaviors.”

A communication from Inotiv’s counsel dated June 3, 2026, represents that the Inotiv Entities have spent \$4,614,935.51 since June 3, 2025, towards improvements of its facilities and personnel. Combining these expenditures with the \$4,446,433.09 previously described by Inotiv in its June 3, 2025 letter, Inotiv now asserts that it has spent \$9,061,368.60 in satisfaction of its obligations under sections 7 and 9 of the Plea Agreement.

The CM reviewed the appendix to the June 3, 2026, communication, which details the expenditures that Inotiv claims to be qualifying expenditures. For each facility expenditure, Inotiv has identified the site, the amount of each expenditure, and provided a brief description of the improvement of the facilities related to each expenditure. For each personnel expenditure, Inotiv has identified the site, the type of expenditure (generally, the position title), the start date of the expenditure, and the total amount spent.

The CM has requested additional information from Inotiv regarding the claimed expenditures and is continuing to assess whether Inotiv’s reported expenditures and improvements meet the requirements of sections 7 and 9 of the Plea Agreement.

I. Public Access to Information

The Plea Agreement (§ 15) requires Inotiv to “facilitate, for the period of probation, the posting of copies of final [USDA] inspection reports of INOTIV ENTITIES’ facilities, the certifications submitted by Inotiv Inc.’s President and CEO ..., and reports prepared by the CM, on the INOTIV ENTITIES’ free and publicly accessible company websites, within fourteen days of receipt of each document.”

As noted in the previous biannual report, Inotiv maintains on its website a page (located at <https://www.inotiv.com/about/inspection-reports>) where it posts copies of final USDA inspection reports and a page (located at <https://www.inotiv.com/about/certification-reports>) where it posts copies of certifications submitted by Inotiv’s President and CEO. These pages include USDA inspection reports, the most recent dated July 14, 2026, for a Re-License Inspection for a site in Indianapolis, IN.

Inotiv also has a page (located at <https://www.inotiv.com/regulatory-compliance-compliance-monitor-reports>) on its website where it posts copies of reports prepared by the CM. This page includes both previous biannual reports prepared by the CM.

All three of the above webpages are linked from a [Regulatory Compliance Reports webpage](#). These postings appear to satisfy the requirements of section 15 of the Plea Agreement.

Prepared By:

Dated: July 20, 2026

A handwritten signature in blue ink, appearing to read 'John H. Fuson', with a stylized, elongated horizontal stroke at the end.

John H. Fuson
Compliance Monitor
*United States v. Envigo RMS, LLC and
Envigo Global Services, Inc.*