

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: January 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 second report provided since the CM commenced the monitorship on January 20, 2025, following the CM’s initial report dated July 21, 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 July 21, 2025

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, since July 21, 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”). At each facility, the CM observed dedicated and hard-working on-site animal care staff.

In addition to the on-site visits, the CM reviewed documentation concerning operations at these two facilities, 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. Denver Facility Site Visit

The Denver Facility operates under a USDA Class A License (32-A-0774) (licensed entity: Envigo RMS LLC), a USDA Class B License (74-B-0332) (licensed entity: Envigo Global Services Inc.), and a National Pollutant Discharge Elimination System (“NPDES”) Permit (PA0084174) (permitted entity: Envigo Global Services Inc.). The Denver Facility includes a main campus location and a satellite location eight miles away. The CM was on-site at the Denver Facility from July 28 to 31, 2025.

At the main campus location, the CM reviewed buildings housing surgical services, maintenance and support services, a nonhuman primate (“NHP”) colony, and NHPs in quarantine. The CM also reviewed the water treatment plant and associated structures housing waste-water treatment support equipment and materials. The main campus location also has buildings with rodent and poultry colonies, as well as other buildings not used in Inotiv’s operations, which the CM did not include in its review of the Denver Facility.

At the satellite location, the CM reviewed a series of buildings housing rabbit production colonies and operations. The satellite location also has a decommissioned animal production building and a building housing backup electrical generation equipment, which the CM did not include in its review of the Denver Facility.

The CM conducted the review with three associated attorneys from KKB, a veterinarian and a veterinary technician who are experts on the requirements of the Animal Welfare Act, in addition to an expert on the Clean Water Act. Numerous Inotiv representatives attended, including the Compliance Officer, members of the Compliance Committee, members of Inotiv’s Animal Welfare Council, senior company leadership for NHPs and Small Animals, members of the Institutional Animal Care and Use Committees (“IACUCs”) for NHPs and Small Animals housed at the site, the Attending Veterinarian (“AV”) for operations at the Denver Facility, other staff veterinarians, NHP and Small Animal operations managers, and other support staff. Inotiv’s outside counsel also attended the on-site review.

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

B. Alice West Facility Site Visit

The Alice West Facility operates under a USDA Class B License (74-B-0773) (licensed entity: Inotiv LAMS West Inc.). It comprises multiple buildings dedicated to animal housing and care on a single property. The CM was on-site at the Alice West Facility from November 18 to 20, 2025.

The CM reviewed all buildings at the Alice West Facility that are in-use or planned for use to house or hold animals. These included indoor rooms for housing NHPs in and out of quarantine, indoor/outdoor structures with holding pens for NHPs, and new outdoor field cages, in which Inotiv planned to begin housing NHPs in December 2025. The CM also reviewed buildings with hospital, surgery, treatment and necropsy rooms, a laboratory, feed storage space, and spaces used to prepare enrichment devices and treats. There were decommissioned outdoor field cages on site that are not currently used to house or hold animals or animal feed, which the CM did not review.

The CM conducted the review with two 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 IACUC for the Alice West Facility, the acting AV for operations at the Alice West 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 West Facility on-site review, the CM discussed 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, and again on January 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

1. Care of Animals While Not Involved in Active Research

The Plea Agreement includes certain NHP and Small Animal 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. For small animals, they require providing species-appropriate housing with space, ability, diversity, and complexity for freedom of movement, retreat, exercise, stimulation and expression of natural behaviors; flooring to promote foot health and prevent sores; and additional substrate or bedding. They also require variety and novelty of enrichment objects and social housing, among other care provisions.

During the CM’s review of the Denver and Alice West Facilities, 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, some of which are described below.

a) NHPs

(1) Outdoor Access

The Plea Agreement 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. Inotiv was not in compliance with this requirement at the time of the CM’s visits to the Denver and Alice West Facilities.

All of the NHP enclosures at the Denver Facility are indoor rack cages. Inotiv is also heavily reliant on indoor rack cages at the Alice West Facility. None of these enclosures provide outdoor access, nor does Inotiv provide alternative regular outdoor access to the NHPs in these enclosures. Although many of the animals the CM observed in the rack cages were in quarantine, a substantial number were not, nor did the other exceptions apply.

Inotiv said it will relocate some NHPs from the Denver Facility to the Alice West Facility, where it has indoor/outdoor enclosures and outdoor field cages. The CM recommends that Inotiv expand this effort. So long as it continues to rely on indoor rack cages, Inotiv must provide alternative regular outdoor access to the non-quarantined NHPs in such enclosures at all of its USDA-licensed facilities in order to comply with the Plea Agreement.

(2) Vertical Climbing, and Space for Species Typical Postures

The Plea Agreement 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 elevated space, as well as space for species typical postures and positions for resting, sleeping, feeding, exploration, play, locomotion, and social adjustments. Inotiv was not in compliance with this requirement at the time of the CM's visits to the Denver and Alice West Facilities.

At the Alice West Facility, Inotiv has indoor/outdoor pens and new outdoor field cages (which were not yet occupied at the time of the CM visit), which provide ample opportunities for vertical climbing and space for species typical postures.

However, as noted, Inotiv is still heavily reliant on indoor rack cages at the Alice West Facility, and relies exclusively on indoor rack cages at the Denver Facility. These cages are generally no more than 34.5" in height, which is less than the combined body and tail length of individual adult NHPs and thus do not provide vertical climbing opportunities or space for species typical postures.

At the Denver Facility, for some cages, Inotiv has attached "tunnels" that connect a lower cage to the cage above it, creating a limited vertical climbing space. Although Inotiv says it intends to expand its use of these tunnels, it does not currently have enough tunnels or space in the indoor rooms at the Denver Facility to provide all NHPs housed there access to a tunnel, and it has no similar tunnels that are compatible with the indoor rack cages at the Alice West Facility. Inotiv must develop alternative solutions to ensure that all NHPs, including NHPs in quarantine, have vertical climbing opportunities and space for species typical postures in order to comply with the Plea Agreement.

(3) Foraging, Access to a Variety of Substrates, Opportunities to Avoid Frightening Stimuli

The Plea Agreement requires Inotiv to provide NHPs with the opportunity 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. Inotiv was not in compliance with these requirements at the time of the CM's visits to the Denver and Alice West Facilities.

The indoor rack cages in use at the Denver and Alice West Facilities have stainless steel bar floors, and the indoor/outdoor pens at Alice West have concrete floors, with no additional substrates. While the new outdoor field cages at the Alice West Facility, which Inotiv intends to begin using this winter, provide a somewhat more varied array of substrates, with sand and concrete floors, the existing enclosures do not offer access to a variety of substrates as required by the Plea Agreement. NHPs are also not provided daily opportunities for time-consuming foraging tasks.

Inotiv has committed to add more complex feeding devices and to further assess its approach to enrichment and foraging. 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 regular access to time-consuming foraging tasks. Diverse substrates may also augment foraging opportunities. The CM also recommends

that Inotiv evaluate its foraging offerings to confirm and document that NHPs engage with them and that they account for a large proportion of the NHPs' daily activity.

The Plea Agreement also requires Inotiv to house NHPs in enclosures that provide space where they can avoid frightening stimuli and other individual animals. In general, the indoor rack cages in use at both the Denver and Alice West Facilities lack both space and structures that would allow NHPs to limit exposure to frightening stimuli and other animals. The CM recommends that Inotiv reassess its indoor enclosures and consider all possible sources of frightening stimuli to determine whether NHPs have both space and opportunity to avoid them.

(4) Item Novelty and Control of Own Enrichment

The Plea Agreement requires Inotiv to change enrichment items often enough to maintain novelty and to allow NHPs a level of control over their own enrichment. In general, however, the CM did not observe adequate complexity, novelty, or choice in the enrichment devices available to NHPs to comply with this requirement during its visits to the Denver and Alice West Facilities. Inotiv has committed to expand its use of puzzles and to train staff to assess and track NHP preferences for enrichment devices, to enable NHPs to expand their role in selecting desired forms of enrichment beneficial to their well-being. The CM intends to review this corrective measure.

(5) Social Housing

The Plea Agreement requires Inotiv to socially house each NHP of a species known to be of a social nature. An explanation and justification for each diminished degree of social interaction must be provided, and other means of enrichment must be enhanced and reflected in the environmental enrichment plan if any NHP is not able to be provided with social housing. Inotiv was not in compliance with these requirements at the time of the CM's visits to the Denver and Alice West Facilities.

The NHPs at the Denver and Alice West Facilities are of species known to be of a social nature. At the Alice West Facility, the indoor/outdoor pens and new outdoor field cages can house large groups of NHPs. However, as noted, Inotiv is still heavily reliant on indoor rack cages at the Alice West Facility, and relies exclusively on indoor rack cages at the Denver Facility.

Although most of the indoor rack cages have doors that allow animals in adjoining cages to be paired, socially housing NHPs in such small enclosures is challenging, and, as a result, some of the animals in the rack cages were individually housed. Inotiv is taking steps to reduce the number of singly housed NHPs at the Denver Facility by assigning its NHP Behavior Manager to work with staff and observe animals to find compatible pairs. Relocating animals from the Denver Facility to the Alice West Facility, where there are larger spaces to accommodate group housing, is also expected to reduce the number of singly housed NHPs at the Denver Facility. The CM intends to monitor and review the impact of these corrective measures.

Inotiv has also introduced a new software platform, which it says will enable it to better document when and why animals are singly housed. The CM recommends that Inotiv utilize this opportunity to develop and disseminate regular reports to NHP operations and care managers that identify singly housed NHPs, the length of time they have been singly-housed, and the justification for continuing to singly house such animals, with the goal of ensuring that NHPs are housed together whenever possible and that any NHPs that are not socially housed are provided with consistent enhanced enrichment as required by the Plea Agreement.

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

b) Small Animals

(1) Housing

The Plea Agreement directs that small animal housing must provide “the space, ability, diversity, and complexity for freedom of movement, retreat, exercise, stimulation, and expression of natural behaviors (such as but not limited to denning, foraging, jumping, playing, running, digging, climbing, flying, swimming, swinging, nesting, retreating, or hiding).” Inotiv was not in compliance with this requirement at the time of the CM’s visit to the Denver Facility.

Inotiv houses New Zealand White and Dutch Belted rabbits at the Denver Facility in cages with a 14” interior height, which did not provide adequate space for the rabbits to rear, climb or jump, among other requirements in the Plea Agreement.

Inotiv has committed to purchasing larger cages for their rabbits when it replaces existing caging or when expansion cages are acquired. The CM recommends that Inotiv evaluate and confirm that new cages will have adequate space to comply with the Plea Agreement’s directive to provide for freedom of movement, retreat, exercise, stimulation, and expression of natural behaviors and then expedite its efforts to acquire and deploy new cages.

(2) Flooring

The cages used to house rabbits at the Denver Facility have wire mesh flooring, which poses risks to rabbit foot health, in particular for pre-wean rabbits whose legs may be small enough to slip through the mesh, resulting in serious injuries, including some that Inotiv documented in section 13(i) reports.

The Plea Agreement requires that housing for small animals must provide flooring to promote foot health and prevent sores. The CM interprets this as an affirmative prevention measure, not merely mitigation through careful monitoring. Inotiv was not in compliance with this requirement at the time of the CM’s visit to the Denver Facility.

The CM understands Inotiv is trialing and installing alternative flooring and additional substrate to ensure that its rabbit enclosures promote foot health and prevent sores and other injuries. The CM intends to review this corrective measure.

(3) Additional Substrate and Diversity of Enrichment Objects

The Plea Agreement requires that housing must provide additional substrate or bedding and use of diverse enrichment objects (such as, but not limited to, play structures, toys, chew objects, nesting materials, dig boxes, and climbing structures). Although nesting material is provided in nest boxes for rabbit does with litters, the CM did not observe any additional

substrate or bedding provided to other rabbits. The CM also did not observe adequate diversity of enrichment objects.

Inotiv is assessing the use of long-stem hay to supplement nutrition and foraging, expanding the use of sizzle nesting, and revamping its provision and rotation of enrichment objects, which it recently expanded for rabbits at the Denver Facility. The CM intends to review these corrective measures.

(4) Climate Control

The Plea Agreement requires small animal housing to provide climate control. Inotiv, however, struggles to maintain temperatures and humidity in ranges that are appropriate for rabbits in the structures where they are housed at the Denver Facility.

The CM understands that Inotiv is working to upgrade monitoring systems in structures used to house rabbits, which should enable it to quickly respond to and mitigate temperatures and humidity when deviations occur. The CM intends to review these corrective measures.

(5) Social Housing

The Plea Agreement directs that rabbits be housed with compatible members of the same species unless the health and well-being of the animal necessitates deviation, in which case the attending veterinarian must record in writing the need for any modification. Inotiv was not in compliance with this requirement at the time of the CM’s visit to the Denver Facility, as most weaned rabbits were individually housed without written record from the AV of the need for modification.

The CM understands Inotiv is modifying some cage enclosures at the Denver Facility to better enable Inotiv to socially house the rabbits. The CM intends to review this corrective measure and efforts to increase social housing at the Facility.

* * *

To ensure that Inotiv has taken appropriate corrective measures described here and as otherwise needed to comply with the certain care standards, the CM intends to revisit the small animal operations at the Denver Facility pursuant to its authority under section 12(b) of the Plea Agreement.

2. Staffing

While the animal care staff the CM observed at both the Denver and Alice West Facilities appeared dedicated and hard-working, in both Facilities, for both NHP and Small Animal operations, there did not appear to be sufficient staffing to satisfy the heightened standards of care set by the NHP and Small Animal care standards in the Plea Agreement.

The Plea Agreement (§§ 5(b)(i) and (ii)) required Inotiv to complete a staffing study commissioned by an “outside, independent agency” within 60 days of June 3, 2024. Inotiv provided a finalized staffing study to the United States on August 2, 2024 (60 days from June 3, 2024) (the *Report of Findings from Assessments of Adequacy of Staffing Levels at Inotiv/Envigo Animal Production Facilities*, dated July 26, 2024 (“*Staffing Study*”). The CM reviewed the Staffing Study and evaluated the sufficiency of animal care staffing during its visits to the

Denver and Alice West Facilities. The CM found several shortcomings in the Staffing Study and does not think it establishes an appropriate baseline for staffing at Inotiv's USDA-licensed facilities.

First, there were substantial inconsistencies between certain cage counts in the Staffing Study and the actual number of such cages at Inotiv's Facilities. The staffing expert who performed the Staffing Study subsequently clarified that he based his assessment on population counts Inotiv provided to him, which the CM understands were accurate at the time of the expert's visit. However, the inconsistencies were not explained.

Second, while Inotiv notes that the populations at its facilities are dynamic and fluctuate with operations, the Staffing Study only considered staffing levels in relation to the populations of animals then present at each facility. The staffing expert was not provided with the maximum population capacity at each facility, and did not consider staffing levels needed if a facility was fully occupied. Indeed, the staffing expert's conclusions were based on animal populations that were well below the populations on site during the CM's visits.

Third, the staffing expert was not provided with a copy of the Plea Agreement and does not appear to have considered the heightened standards of care in his evaluation of staffing at the Inotiv Facilities. The care standards set by the Plea Agreement exceed the requirements of the Animal Welfare Act, and thus increase the burdens on staff.

The CM acknowledges that Inotiv is working to fill existing vacancies among staff responsible for animal care. However, the CM is concerned that Inotiv's target staffing levels, which mirror those recommended by the Staffing Study, are insufficient to ensure compliance with the NHP and Small Animal care standards prescribed in the Plea Agreement.

Therefore, the CM recommends that Inotiv reassess staffing levels at all of its USDA-licensed facilities, ideally with support from an outside, independent staffing expert. 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 care standards set by the Plea Agreement.

C. CEO Certification

The Plea Agreement (§ 13(h)) requires Inotiv's President and CEO, for the duration of the probationary period, to certify under oath that, "to the best of their knowledge after a diligent inquiry, (1) the INOTIV ENTITIES fully complied with all Applicable Laws in the preceding year, or in the alternative, (2) the INOTIV ENTITIES fully complied with all Applicable Laws in the preceding year, with the exception of attached detailed non-compliant activity and the steps taken to remedy such non-compliant activity."

The NCP incorporates this requirement, stating that "[t]he CEO will certify annually Inotiv's compliance with Animal Welfare Requirements and Environmental Requirements, excepting and detailing any instances of noncompliance." (NCP p.16).

Inotiv's President and CEO, Robert Leasure, has signed two statements, dated November 26, 2024 (covering the fiscal year from October 1, 2023 through September 30, 2024) and November 28, 2025 (covering the fiscal year from October 1, 2024 through September 30, 2025) pursuant to section 13(h), certifying "to the best of my knowledge, after diligent inquiry, that the Inotiv Entities fully complied with all Applicable Laws." Both certifying statements

specifically except certain matters specified in an appendix to such document (each of which was separately covered by an incident report pursuant to section 13(i) of the Plea Agreement), including the steps taken by the Company to address such non-compliant activity. Inotiv maintains a website (<https://www.inotiv.com/about/certification-reports>) on which it has published copies of the CEO certifications.

D. 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 July 1, 2025, through December 31, 2025, Inotiv provided 16 reports pursuant to section 13(i). The CM reviewed each report, submitted follow-up information and document requests to Inotiv on all 16 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.

E. 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 have been updated with nine USDA inspection reports, the most recent dated December 18, 2025, for a New Site Inspection for a site in Greenfield, IN, and the certification by Inotiv’s President and CEO dated November 28, 2025 (for the Fiscal Year dated October 1, 2024, through September 30, 2025), respectively.

Inotiv has now also added 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. It includes the first, and so far only, Biannual Compliance Monitor Report, dated July 21, 2025.

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.

IV. Environmental Compliance Obligations

The Plea Agreement (§ 12(b)) directs the CM to ensure compliance with the Clean Water Act laws, rules, and regulations, as well as all federal and applicable state and local water and sewage laws, rules, and regulations at “those components of the INOTIV ENTITIES that hold permits regulated by the Clean Water Act, including, but not limited to, National Pollutant Discharge Elimination System (“NPDES”) permits and indirect discharge permits and related activities, and any comparable permit issued through a state delegated program.”

The Denver facility holds an NPDES permit (NPDES Permit No. PA0084174), authorizing it to “discharge from a facility known as Envigo Global Services Inc., located in West Cocalico Township, Lancaster County, to Unnamed Tributary to Cocalico Creek (WWF) in Watershed(s) 7-J.” The CM, together with its Clean Water Act expert, reviewed the NPDES permit and other relevant documents, including the NPDES Permit Fact Sheet for Permit No. PA0084174, the SOP for the facility’s wastewater treatment plan operations, Wastewater Treatment Certifications, Pennsylvania Department of Environmental Protection Discharge Monitoring Reports, and laboratory testing reports for total solids required for analysis in an NPDES permit. The CM and its Clean Water Act expert also reviewed the wastewater system onsite at the Denver Facility on July 29 to 30, 2025.

While the NPDES Fact Sheet noted prior instances of white billowy foam in the chlorine contact tank along with the accumulation of solids and hair visible at the outfall pipe cited by Pennsylvania DEP during routine inspections in 2019 and 2021, the CM did not observe these issues during its onsite visit. The NPDES Fact Sheet also indicated a prior pH exceedance, four prior total phosphorus exceedances, and one prior total zinc exceedance during certain months in 2023. The CM reviewed underlying test reports supporting more recent monthly DMR submissions and confirmed that measurements did not exceed applicable limits.

Overall, wastewater processes at the Denver Facility appeared to be properly functioning and equipment regularly maintained. The CM did not observe any Clean Water Act noncompliances during its onsite visit of the Denver Facility.

The CM intends to continue to evaluate the Inotiv Entities’ compliance with the Clean Water Act laws, rules, and regulations, as well as all federal and applicable state and local water and sewage laws, rules, and regulations at these facilities as directed by the Plea Agreement during its planned on-site visits.

Prepared By:

Dated: January 20, 2026



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