

Attachment 2 to Resolution Agreement
In re: Inotiv, Inc.

Plea Agreement

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
LYNCHBURG DIVISION**

CLERKS OFFICE U.S. DIST. COURT
AT LYNCHBURG, VA
FILED

6/3/2024

LAURA A. AUSTIN, CLERK
BY: s/ CARMEN AMOS
DEPUTY CLERK

UNITED STATES OF AMERICA)
)
 v.)
)
ENVIGO RMS, LLC)
ENVIGO GLOBAL SERVICES, INC.)

Case No. 6:24CR16

PLEA AGREEMENT

As part of a broader resolution set forth in the Resolution Agreement between the United States and Inotiv, Inc. (attached as Attachment B), ENVIGO RMS, LLC and ENVIGO GLOBAL SERVICES, INC., pursuant to authority granted by their Boards of Directors, have entered into this Plea Agreement with the United States of America, by and through the United States Attorney for the Western District of Virginia and the Environmental Crimes Section of the United States Department of Justice, Environment and Natural Resources Division (collectively referred to as the "United States"), pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure ("Fed. R. Crim. P."). For purposes of this Plea Agreement, "ENVIGO" includes ENVIGO RMS, LLC and ENVIGO GLOBAL SERVICES, INC. and "INOTIV ENTITIES" includes Inotiv, Inc. and all entities related to Inotiv, Inc., including, but not limited to, ENVIGO and all entities related to ENVIGO, and all successors in interest to any of the above listed entities. The terms and conditions of this Plea Agreement are as follows:

1. CHARGES TO WHICH ENVIGO IS PLEADING GUILTY AND WAIVER OF RIGHTS

ENVIGO RMS, LLC will enter a plea of guilty to Count One, and ENVIGO GLOBAL SERVICES, INC. will enter a plea of guilty to Count Two of an Information (attached as Attachment C).

Count One charges ENVIGO RMS, LLC with conspiring, in violation of 18 U.S.C. § 371, to knowingly violate Chapter 54 of Title 7 (the Animal Welfare Act), in violation of 7 U.S.C. § 2149(d), at its facility in Cumberland County, Virginia (the "Cumberland Facility"). The maximum statutory penalty is a term of probation of five years and a fine the greater of (a) \$200,000 (18 U.S.C. § 3571(c)(5)) or (b) twice the gross gain (18 U.S.C. § 3571(d)). Accordingly, the maximum fine is \$22,225,132 (twenty-two million two hundred twenty-five thousand one hundred thirty-two dollars) representing twice the gross gain. The gross gain figure is based on ENVIGO generating \$11,112,566 (eleven million one hundred twelve thousand five hundred sixty-six dollars) in revenue from sales of dogs from the Cumberland Facility during the offense.

*Plea Agreement
United States v. Envigo RMS, LLC & Envigo Global Services, Inc.*

*Authorized Corporate Officers' Initials:
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Count Two charges ENVIGO GLOBAL SERVICES, INC. with conspiring, in violation of 18 U.S.C. § 371, to knowingly violate the Clean Water Act in violation of 33 U.S.C. §§ 1311 and 1319(c)(2)(A), at the Cumberland Facility. The maximum statutory penalty is a term of probation of five years and a fine the greater of (a) not less than \$5,000 nor more than \$50,000 per day of violation (33 U.S.C. § 1319(c)(2)), (b) \$500,000 (18 U.S.C. § 3571(c)(3)), or (c) twice the gross gain (18 U.S.C. § 3571(d)). Accordingly, because the violation began no later than January 1, 2020, and continued daily through September 30, 2022, the minimum fine is \$5,020,000 (five million twenty thousand dollars) and the maximum fine is \$50,200,000 (fifty million two hundred thousand dollars).

The charges are being brought by the United States filing an information as opposed to a grand jury returning an indictment. ENVIGO hereby waives and gives up its right to be charged by indictment and have a grand jury vote on its probable guilt.

ENVIGO understands fees may be imposed to pay for probation and there will be a total special assessment of \$525 (\$125 on Count One and \$400 on Count Two), pursuant to 18 U.S.C. § 3013(a)(1)(B)(iii), (a)(2)(B). ENVIGO's attorneys have informed both defendants of the nature of the charges and the elements of the charges that must be proved by the United States beyond a reasonable doubt before ENVIGO could be found guilty as charged.

ENVIGO acknowledges ENVIGO has had all its rights explained to it. ENVIGO expressly recognizes, as a corporation, ENVIGO may have the following constitutional rights and by voluntarily pleading guilty, ENVIGO knowingly waives and gives up these valuable constitutional rights:

- The right to plead not guilty and persist in that plea.
- The right to a speedy and public jury trial.
- The right to assistance of counsel at that trial and in any subsequent appeal.
- The right to remain silent at trial.
- The right to testify at trial.
- The right to confront and cross-examine witnesses.
- The right to present evidence and witnesses.
- The right to compulsory process of the court.
- The right to compel the attendance of witnesses at trial.
- The right to be presumed innocent.
- The right to a unanimous guilty verdict.
- The right to appeal a guilty verdict.

ENVIGO is pleading guilty as described above because ENVIGO is in fact guilty and because ENVIGO believes it is in its best interest to do so and not because of any threats or promises, other than the terms of this Plea Agreement and its attachments, in exchange for its pleas of guilty.

*Attachment 2 to Resolution Agreement
In re: Inotiv, Inc.*

Plea Agreement

2. ENTRY OF PLEAS OF GUILTY

ENVIGO shall enter its guilty pleas on June 3, 2024, at 11:00 AM, at the United States District Court for the Western District of Virginia at Charlottesville, Virginia, unless the parties mutually agree in writing to an alternative date and time.

3. FACTUAL REPRESENTATIONS

ENVIGO stipulates and agrees that the facts and allegations set forth in the Information to which it is pleading guilty are true and correct and provide an adequate factual basis for acceptance of the pleas.

4. AGREEMENT NOT TO BREED OR SELL DOGS

ENVIGO agrees none of the INOTIV ENTITIES will breed or sell dogs. Each dog under the care of or in the possession or control of any of the INOTIV ENTITIES will be over the age of 90 days old.

5. AGREEMENT TO MEET CERTAIN STANDARDS

ENVIGO recognizes it is the United States' intent that the INOTIV ENTITIES' 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.

Accordingly, the INOTIV ENTITIES, at a minimum, shall:

- a. In hiring veterinarians, give preference, among otherwise equally qualified applicants, to applicants certified by the American Board of Veterinary Practitioners ("ABVP") and/or American College of Laboratory Animal Medicine ("ACLAM") in the relevant specialty.
- b. All veterinarians shall complete at least fifteen hours of continuing education, per year.
- c. Comply with: (1) 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 (collectively referred to as "Applicable Laws"), (2) the Plea Agreement, the Resolution Agreement, and their attachments, and (3) the Nationwide Compliance Plan ("NCP") (as more fully described below).
- d. Make 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 (such as with an adoptive family, sanctuary, or rescue organization, or other appropriate owner for that animal, and not including selling at auction or otherwise placing a retired animal with another facility for research or with a breeder for breeding purposes).

*Plea Agreement
United States v. Envigo RMS, LLC & Envigo Global Services, Inc.*

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- e. All staff must be trained to know and understand normal behaviors for the specific species of animals with which they are working.

In addition to the foregoing, the following will apply to all INOTIV ENTITIES that hold licenses pursuant to the United States Department of Agriculture or conduct activities under those licenses:

- a. **Care of Animals While Involved in Active Research:** During the period of testing being conducted by any of the INOTIV ENTITIES, the standard of care shall be consistent with applicable regulations and otherwise ensure the humane treatment of the test animals. This shall include, without limitation, animals on an active study protocol or operating procedure, including protocols and operating procedures concerning the preparation and pre-conditioning of animals for a study, which are reviewed and approved by an Institutional Animal Care and Use Committee ("IACUC").
- b. **Care of Animals While Not Involved in Active Research:**
- i. **For Nonhuman Primate Care**

Implement and comply with a written environmental enrichment plan, as reviewed and approved in writing by the Attending Veterinarian ("AV"), that incorporates at a minimum the following standards:

Must provide for each primate of a species known to be of a social nature to be housed with other primates. Behavior assessments and introduction procedures must be implemented by professionals with experience with creating and monitoring nonhuman primate social groups prior to determining social groups. Environmental enrichment plans must provide an explanation and justification for each diminished degree of social interaction. If a nonhuman primate is not able to be provided with social housing, other means of enrichment must be enhanced and reflected in the environmental enrichment plan. While nonhuman primates should be housed together whenever possible, the facility should not obtain more nonhuman primates solely to facilitate group housing.

Must allow for species-typical sensory, motor, psychological, and social development of infants by the mother/foster. Environmental enrichment plans will provide that infant primates will be left with their mothers until the species-typical age of weaning unless there is a medical necessity (such as mother is not caring for infant, infant is ill, mother is too ill to care for infant, etc.). Macaque age of weaning is at minimum 6 months, but the INOTIV ENTITIES may opt to leave macaques with their dams for longer periods. Environmental enrichment plans must account for appropriate interactions with other members of the same species that are not the mother. Environmental enrichment plans must include appropriate levels of social interaction with human caregivers to reduce stress for providing routine husbandry and veterinary care.

*Attachment 2 to Resolution Agreement
In re: Inotiv, Inc.*

Plea Agreement

Must provide nonhuman primates with species-specific expressions of natural behaviors, including, the ability to engage in species-typical postures and positions for resting, sleeping, feeding, exploration, and play, locomotion, and social adjustments.

Primary enclosures or housing and exercise must allow enclosure configurations that permit nonhuman primates: Vertical climbing opportunities with enough space to allow nonhuman primates to travel, feed, and rest in elevated space. Primary enclosures should also be spaces that allow for: access to a variety of substrates; avoidance of frightening stimuli and other individual animals; scent-retaining surfaces (with the exception of macaques); and address the needs of the nonhuman primates at a species, life-stage, and individual level, which must be addressed in individual environmental enrichment plans, including adaptations for nonhuman primates with physical impairments. As to any facility whose primary enclosures do not allow for outdoor access, the nonhuman primates will have alternative regular outdoor access, unless detrimental to the individual nonhuman primate as determined by the AV in writing, subject to quarantine, or prohibited by research protocol. As to any facility that does not comply with this condition, the INOTIV ENTITIES will provide to the Compliance Monitor ("CM") (as more fully described below) within 30 days of the CM's selection: (1) a listing of the facility's deficiencies; and (2) its plan to correct such deficiencies by June 3, 2025. All deficiencies must be corrected by June 3, 2025.

Must provide nonhuman primates with the opportunity to work for their food by providing daily opportunities for time-consuming foraging tasks. Food items should align with species' dietary needs and help each nonhuman primate to meet their daily nutritional needs, and should include a variety of tastes, textures, and smells. The environmental enrichment plan should address how certain food will be provided so as to enhance enrichment.

Must provide each nonhuman primate continuous and sufficient access to potable water that is not frozen or too hot and is free of feces, algae, and other contaminants, unless water restriction is deemed necessary by the AV in writing.

Must provide nonhuman primates with a variety of objects they can move and manipulate with their hands. Items must be species and age appropriate and must be changed often enough to maintain appropriate levels of novelty. It must be documented when new items are introduced.

Must provide an explanation and justification for each diminished degree of social interaction; changes in the needs of individual nonhuman primates; and assessment of the plan's effectiveness.

Must change enclosure furniture, such as perches, as needed to ensure they are properly sanitized and to ensure safety.

*Plea Agreement
United States v. Envigo RMS, LLC & Envigo Global Services, Inc.*

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Envigo Global Services, Inc.: AC*

*Attachment 2 to Resolution Agreement
In re: Inotiv, Inc.*

Plea Agreement

Must demonstrate enrichment devices are appropriate and address how they will keep enrichment items novel.

Must allow nonhuman primates a level of control over their own enrichment including but not limited to toys that allow opening doors and peep holes (or other toys substantially similar thereto), a primate nesting box or other similar space to provide the ability to remove themselves from stimuli, and the ability to avoid noxious stimuli, unless the health and well-being of the animal necessitates deviation, in which case the AV must record in writing the need for any modification. Animal care staff must provide for temperature and lighting in any nonhuman primate housing consistent with the nonhuman primate's diurnal cycles, unless the health and well-being of the animal necessitates deviation, in which case the AV must record in writing the need for any modification. As to any facility that does not comply with this condition, the INOTIV ENTITIES will provide to the CM within 30 days of the CM's selection: (1) a listing of the facility's deficiencies; and (2) its plan to correct such deficiencies by June 3, 2025. All deficiencies must be corrected by June 3, 2025.

Must include stimulation of the olfactory, visual, tactile, and auditory senses to stimulate species-specific behavior and allow for the opportunity to avoid stimuli, unless the health and well-being of the nonhuman primate necessitates deviation, in which case the AV must record in writing the need for any modification.

If the facility has a nonhuman primate in persistent psychological distress, a nonhuman primate behaviorist or a veterinarian with significant experience in nonhuman primates should assess the plan to understand how it may affect those individual nonhuman primates and make recommendations for adjusting that nonhuman primate's environmental enrichment plan. Recommendations must be duly considered by the AV for the environmental enrichment plan. The AV will then review and approve in writing the changes. If recommendations are not added and the environmental enrichment plan remains unchanged, the facility must provide a written justification for this decision.

Each nonhuman primate must receive adequate veterinary care, including prompt treatment of any disease, illness, or injury by the veterinary staff. Nonhuman primates must be checked twice daily by animal care staff and each nonhuman primate should be checked more thoroughly when transferring from dirty to clean enclosures. Protocols and AV-approved standard operating procedures for providing adequate veterinary care, daily checks, and any resulting procedures must be detailed in written instructions. All veterinary care staff must be trained under the supervision of a veterinarian.

Must complete a staffing study, commissioned by an outside, independent agency, within 60 days of June 3, 2024, to provide necessary and sufficient

*Plea Agreement
United States v. Envigo RMS, LLC & Envigo Global Services, Inc.*

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Envigo RMS, LLC: AC
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staffing to ensure each nonhuman primate receives appropriate feeding, sanitation, health assessments, and enrichment. Beginning not later than 60 days after completion of the study, the INOTIV ENTITIES must maintain adequate staffing to comply with the findings of the study.

If exemptions to enrichment exist for certain individual nonhuman primates, these plans must be documented and reviewed by the AV at least every 30 days for reassessment.

Written environmental enrichment plans must be visible and available to inspectors and regularly reviewed by the IACUC for quality and effectiveness. Plans should be modified and implemented based on IACUC recommendations.

ii. For Small Animal Care

Implement and comply with a written enrichment plan, as reviewed and approved in writing by the AV, that incorporates at a minimum the following standards:

As species-appropriate, 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); climate control and lighting; flooring to promote foot health and prevent sores; 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, climbing structures). As to any facility that does not comply with this condition, the INOTIV ENTITIES will provide to the CM within 30 days of the CM's selection: (1) a listing of the facility's deficiencies; and (2) its plan to correct such deficiencies by June 3, 2025. All deficiencies must be corrected by June 3, 2025.

Must be provided with a variety of objects. Items must be species and age appropriate and must be changed often enough to maintain appropriate levels of novelty. It must be documented when new items are introduced.

Provide for each animal of a species known to be of a social nature, such as cats, wild mice, rabbits, guinea pigs, gerbils, and hens, to be housed with other compatible members of the same species unless the health and well-being of the animal necessitates deviation, in which case the AV must record in writing the need for any modification. The determination about which species, beyond those explicitly listed in this Paragraph, should be socially housed and how that will be arranged will be made by professionals with experience with creating and monitoring species-specific social groups, as approved in writing by the AV. Provide an explanation and justification for each diminished degree of social interaction. If an animal is not able to be provided with social housing, other means of enrichment must be enhanced and reflected in the enrichment plan,

including visual, olfactory, tactile, and auditory contact with conspecifics, where appropriate. Solitary housing should be temporary. Plans for solitary housing must be documented and reviewed by the AV at least every 30 days for reassessment.

Must have visible and demonstrable components of the enrichment plan and cannot rely on self-reported indications of provided enrichment items or activities. Enrichment items, such as toys, play objects, and areas must be visible to inspectors and not merely indicated in the written plan.

Must provide appropriate, nutritious, and various food options for each animal, unless otherwise determined by the AV in writing, in an amount sufficient to maintain the good health and physical condition of each such animal.

Must provide each animal continuous and sufficient access to potable water that is not frozen or too hot and is free of feces, algae, and other contaminants, unless water restriction is deemed necessary by the AV in writing.

Must demonstrate enrichment devices are appropriate. As species-appropriate, must address how they will keep enrichment items novel and must document in writing the decision-making process.

Must complete a staffing study, commissioned by an outside, independent agency, within 60 days of June 3, 2024, to provide necessary and sufficient staffing to ensure each animal receives appropriate feeding, sanitation, health assessments, and enrichment. Beginning not later than 60 days after completion of the study, the INOTIV ENTITIES must maintain adequate staffing to comply with the findings of the study.

Each animal must receive adequate veterinary care, including prompt treatment of any disease, illness, or injury by the veterinary staff. Animals must be checked twice daily by animal care staff and each animal should be checked more thoroughly when transferring from dirty to clean enclosures. Protocols and AV-approved standard operating procedures for providing adequate veterinary care, daily checks, and any resulting procedures must be detailed in written instructions. All veterinary care staff must be trained under the supervision of a veterinarian.

If exemptions to enrichment exist for certain individual animals, these plans must be documented and reviewed by the AV at least every 30 days for reassessment.

Written enrichment plans must be visible and available to inspectors and regularly reviewed by the IACUC for quality and effectiveness. Plans should be modified and implemented based on IACUC recommendations.

6. SENTENCING GUIDELINES

The parties agree the 2023 version of the United States Sentencing Commission Guidelines Manual (“U.S.S.G.”) applies to any guidelines calculation made pertaining to the offenses to which ENVIGO is pleading guilty.

7. PAYMENTS

The parties agree and stipulate:

- a. ENVIGO shall make payments toward a fine of \$11,000,000 (eleven million dollars) on Count One and \$11,000,000 (eleven million dollars) on Count Two, for a total fine of \$22,000,000 (twenty-two million dollars), which shall be due and payable at sentencing and interest shall be computed daily on the entire unpaid balance from the date of sentencing at a rate equal to the weekly average 1-year constant maturity Treasury yield, as published by the Board of Governors of the Federal Reserve System, for the calendar week preceding the date of sentencing. However, ENVIGO will be in compliance with its obligation to pay the fine so long as it pays the following amounts on or before the dates set forth below:

- June 3, 2025 – \$5,000,000 (five million dollars)
- June 3, 2026 – \$5,000,000 (five million dollars)
- June 3, 2027 – \$5,000,000 (five million dollars)
- June 3, 2028 – \$7,000,000 (seven million dollars) plus all accrued interest since June 3, 2024.

If ENVIGO and Inotiv, Inc. fail to pay any of the above listed amounts on or before the due dates, they will have (1) failed to comply with a provision of the Plea Agreement, and (2) failed to comply with a provision of the Resolution Agreement. Accordingly, the United States, immediately, may collect the entire remaining unpaid amount due of the \$22,000,000 fine plus interest and pursue any or all of the remedies available for failing to comply with a provision of the Plea Agreement.

- b. ENVIGO, no later than 10:00 AM EDT on June 3, 2024, shall have authorized the payment of \$1,143,991 (one million one hundred forty-three thousand nine hundred ninety-one dollars) to the Virginia Animal Fighting Task Force in recognition of direct assistance provided to the United States during the investigation. ENVIGO, no later than 5:00 PM EDT on June 3, 2024, shall release the payment of \$1,143,991 (one million one hundred forty-three thousand nine hundred ninety-one dollars) to the Virginia Animal Fighting Task Force.
- c. ENVIGO, no later than 10:00 AM EDT on June 3, 2024, shall have authorized the payment of \$1,856,009 (one million eight hundred fifty-six thousand nine dollars) to the Humane Society of the United States in recognition of direct assistance provided to the United States during the investigation. ENVIGO, no

- later than 5:00 PM EDT on June 3, 2024, shall release the payment of \$1,856,009 (one million eight hundred fifty-six thousand nine dollars) to the Humane Society of the United States.
- d. ENVIGO, no later than 10:00 AM EDT on June 3, 2024, shall have authorized the community service payment of \$3,500,000 (three million five-hundred thousand dollars) to the National Fish and Wildlife Foundation (“NFWF”), a nonprofit organization established pursuant to 16 U.S.C. §§ 3701–3710, to fund environmental projects, studies, and initiatives designed to benefit, preserve, and restore the riparian environment and ecosystems in Cumberland County, Virginia, in the vicinity of the former Cumberland Facility. ENVIGO, no later than 5:00 PM EDT on June 3, 2024, shall release the payment of \$3,500,000 (three million five-hundred thousand dollars) to the NFWF. At least \$500,000 of the \$3,500,000 shall be spent on purchasing riparian wetland and/or riparian land located in or near Cumberland, Virginia, with first preference to land adjacent to Maxey Mill Creek and its tributaries.
 - e. No later than June 3, 2024, ENVIGO shall pay a total of \$525 (five hundred twenty-five dollars) to the “Clerk of Court,” as payment of the special assessment in this case.
 - f. ENVIGO shall pay all costs associated with the CM described in this Plea Agreement.
 - g. ENVIGO, on or before the dates set forth below, shall expend not less than \$7,000,000 (seven million dollars), for improvements to its facilities and personnel to a standard beyond the bare minimum required to comply with the Animal Welfare Act laws, rules, and regulations as described in the Section of this Agreement titled “IMPROVEMENT TO FACILITIES AND PERSONNEL”:
 - \$2,500,000 (two million five hundred thousand dollars) – June 3, 2025
 - \$2,500,000 (two million five hundred thousand dollars) – June 3, 2026
 - \$2,000,000 (two million dollars) – June 3, 2027.

In addition, ENVIGO understands the Court may require ENVIGO to pay the costs of probation.

Prior to pleading guilty, ENVIGO agrees to provide a lien to the United States against sufficient company assets to secure any unpaid deferred payments. Such lien shall be junior in priority and subordinated to (1) the lien provided by ENVIGO to lenders under its existing credit facility (for the avoidance of doubt, including its revolving credit facility lenders), to the extent that lien was in place as of April 1, 2024, and (2) liens provided by ENVIGO to lenders after April 1, 2024, to the extent the debt secured by the liens, in total, does not increase ENVIGO’s total secured debt to creditors other than the United States by more than \$100,000,000 (one hundred million dollars) above its secured debt (including its revolving credit commitments) as of April 1, 2024. The United States shall release such lien upon full payment of the \$22,000,000 (twenty-two million dollar) fine.

8. PROBATION

The parties agree and stipulate:

- a. ENVIGO shall be placed on probation for a term of five years with the ability to move to have its probation ended three years after the CM commences its function if:
 - i. ENVIGO has complied with all conditions of probation, complied with all terms of this Plea Agreement, and has paid, in full, all monetary obligations imposed; and
 - ii. Inotiv, Inc. and the INOTIV ENTITIES have fully complied with the Plea Agreement and Resolution Agreement.
- b. The following special condition of probation shall be imposed:
 - i. ENVIGO and the INOTIV ENTITIES shall comply with all terms of the Plea Agreement and Resolution Agreement.

In addition, ENVIGO understands the Court will impose standards and may impose other special conditions and terms of probation as it deems appropriate. The parties will be free to argue at sentencing for what terms and conditions should or should not be included. ENVIGO understands and agrees if its probation is revoked, it may be resentenced and a total aggregate fine up to the statutory maximum of \$72,425,132 (seventy-two million four hundred twenty-five thousand one hundred thirty-two dollars) may be imposed.

ENVIGO may only seek to have its probation terminated if all the conditions in this Section of the Plea Agreement are met. If it seeks to terminate its probation, it shall so notify the Court, the CM, and the United States, in writing, not less than 60 days before the date on which it seeks to have its probation terminated. Prior to the Court ruling on the recommendation, the CM will present to the Court, the United States, and ENVIGO, a written report concerning the early termination request, which will include the CM's recommendation of whether or not probation should be terminated early.

9. IMPROVEMENT TO FACILITIES AND PERSONNEL

ENVIGO, in accordance with the schedule set forth in this Plea Agreement, shall expend not less than \$7,000,000 (seven million dollars) 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. Such improvements shall all be directly related to improving the welfare of animals at INOTIV ENTITIES and shall include, but not be limited to, the following:

- a. Maintain and, if necessary, hire sufficient and proficient veterinary staff at all facilities within the United States to ensure exceptional veterinary care for all animals in all INOTIV ENTITIES' care, custody, or control.
- b. Maintain and, if necessary, hire sufficient staff and secure facility space to ensure the following: enrichment, including, but not limited to, social contact; sufficient space; and sufficiently complex environment, to allow animals to perform species-specific natural behaviors.

10. PUBLIC STATEMENT

The INOTIV ENTITIES shall place a full-page public statement detailing the INOTIV ENTITIES' contrition for their conduct (a) in a nationally and widely distributed animal science journal, (b) in at least two national newspapers, (c) in two major Virginia newspapers (including one in Richmond), and (d) on the INOTIV ENTITIES' publicly accessible company websites. The full-page public statement shall be published in newspapers on or before June 13, 2024. The public statement must be posted and readily accessible on the INOTIV ENTITIES' public websites the day of the entry of ENVIGO's guilty pleas and for the duration of the probationary period. The language of the public statement must be agreed upon by the United States prior to the entry of ENVIGO's guilty pleas.

11. FINANCIAL RESPONSIBILITIES

a. Financial Obligations

ENVIGO agrees and understands none of the money paid pursuant to this Plea Agreement will be returned unless the Court rejects the Plea Agreement and ENVIGO withdraws its pleas within 10 days of receiving notice of the Court's rejection. Should the Court reject the Plea Agreement and ENVIGO withdraw its pleas within 10 days of receiving notice of the Court's rejection, any amounts ENVIGO has paid pursuant to Section 7(a)-(e) of this Plea Agreement shall be returned to ENVIGO.

ENVIGO must complete and submit a financial statement under oath to the United States no later than two weeks prior to the entry of ENVIGO's guilty pleas.

ENVIGO must notify the Court, the United States, and the United States Probation Office as soon as reasonably practicable, in writing by both email and certified mail with return receipt, of any event (including, but not limited to, sale, merger, dissolution, etc.) that would jeopardize its ability to pay any amounts under this Plea Agreement. In such event, the United States may immediately collect the entire fine and accrued interest from any INOTIV ENTITY.

In addition, in accordance with 18 U.S.C. § 3572(d)(3), ENVIGO will notify the Court of any material change in ENVIGO's economic circumstances that might affect ENVIGO's ability to pay any amounts payable under this Plea Agreement.

b. Financial Obligations are Not Dischargeable

The parties warrant, in evaluating whether to execute this Plea Agreement, they have (a) intended the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to ENVIGO, within the meaning of 11 U.S.C. § 547(c)(1); and (b) concluded these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the parties warrant the mutual promises, covenants, and obligations set forth herein are intended to, and do, in

fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which ENVIGO was or became indebted to on or after the date of entry of ENVIGO's guilty pleas, within the meaning of 11 U.S.C. § 548(a)(1). ENVIGO agrees its obligations under Section 7(a)-(e) of this Plea Agreement may not be avoided pursuant to 11 U.S.C. § 547, and ENVIGO shall not argue or otherwise take the position in any such case, action, or proceeding that: (1) ENVIGO's obligations under this Plea Agreement may be avoided under 11 U.S.C. § 547; (2) ENVIGO was insolvent at the time this Plea Agreement was entered into; or (3) the mutual promises, covenants, and obligations set forth in this Plea Agreement do not constitute a contemporaneous exchange for new value given to ENVIGO. ENVIGO acknowledges the agreements in this Paragraph are provided in exchange for valuable consideration provided in this Plea Agreement. ENVIGO agrees all obligations payable under Section 7(a)-(e) of this Plea Agreement are not dischargeable in bankruptcy and shall be considered debt for a fine, penalty, or forfeiture payable to and for the benefit of a governmental unit pursuant to 11 U.S.C. § 523(a)(7).

c. Corporate Form

Except as may otherwise be agreed by the parties in connection with a particular transaction, ENVIGO agrees if, during the term of this Plea Agreement, it undertakes any material change in corporate form, including if it sells, merges, or transfers business operations material to ENVIGO's consolidated operations as they exist as of the date of this Plea Agreement, whether such change is structured as a sale, asset sale, merger, transfer, or other material change in corporate form, it shall include in any contract for sale, merger, transfer, or other change in corporate form a provision binding the purchaser, or any successor in interest thereto, to the obligations described in this Plea Agreement. ENVIGO shall provide notice to the United States at least 30 days prior to undertaking any such sale, merger, transfer, or other change in corporate form. Nothing herein shall restrict ENVIGO from indemnifying (or otherwise holding harmless) the purchaser or successor in interest for penalties or other costs arising from any conduct that may have occurred prior to the date of the transaction, so long as such indemnification does not have the effect of circumventing or frustrating the enforcement purposes of this Plea Agreement, as determined by the United States. Nothing herein shall restrict ENVIGO from making changes in corporate form, so long as such changes do not have the effect of circumventing or frustrating the Plea Agreement or the Resolution Agreement.

d. Treatment of Payments

None of the INOTIV ENTITIES shall seek any reduction in its tax obligations on the basis of the payments made pursuant to Section 7(a)-(e) of the Plea Agreement or Resolution Agreement, nor shall they characterize, publicize, or refer to these payments as voluntary donations or contributions. Additionally, the INOTIV ENTITIES shall not seek or take credit for any project performed using funds disbursed by NFWF pursuant to this

Plea Agreement in any related civil or administrative proceeding, including, but not limited to, the Natural Resources Damages Assessment process.

12. COMPLIANCE MONITOR

a. Selection Process

The parties agree a CM shall be appointed to ensure compliance with all Applicable Laws, the Plea Agreement, and the Resolution Agreement.

Within twenty-one calendar days of the date of entry of ENVIGO's guilty pleas, ENVIGO shall submit to the United States a written proposal identifying three CM candidates. Each CM candidate shall have the following attributes, which ENVIGO and the CM candidates will detail in the written submission and certification submitted to the United States:

- i. Subject to U.S. jurisdiction.
- ii. Integrity, credibility, and professionalism.
- iii. General background, education and training, professional experience, professional commendations and honors, licensing, reputation in the relevant professional community, and any experience as a monitor.
- iv. Expertise or experience with issues related to the Applicable Laws.
- v. Relevant skills and experience necessary to discharge the duties of the CM.
- vi. The ability to create a properly composed monitorship team and access and deploy resources as necessary to discharge the duties of the CM.
- vii. Sufficient expertise and competence to assess whether the INOTIV ENTITIES have adequate management systems in place to ensure regulatory compliance, document such non-compliance, and prevent future non-compliance.
- viii. Name and qualification of any outside professional the CM will retain.
- ix. The commitment to serve as the CM for the entire monitorship term.
- x. The CM, the CM's firm, and any members of the entire monitorship team have no conflicts of interests that would prevent them from accepting the monitorship and is not a current or recent (that is, within the prior two years) employee, agent, or representative of any of the INOTIV ENTITIES and holds no interest in, and has no relationship with, any of the INOTIV ENTITIES, or any of the INOTIV ENTITIES employees, officers, directors, or outside counsel retained for purposes of this matter.
- xi. Have (1) notified any clients they represent in any matter involving the United States; and (2) obtained a waiver from those clients or withdrawn representation in the other matter(s).
- xii. Will agree (1) not to seek, offer, accept, or discuss additional work from any of the INOTIV ENTITIES during the monitorship or within three years from the date of the termination of the monitorship; and (2) not receive any payments, other than for payments received pursuant to a contract for its CM

work described herein, from any of the INOTIV ENTITIES, except for the payments set forth under Paragraph (c) of this Section.

ENVIGO will provide a written certification that the INOTIV ENTITIES will not employ or be affiliated with the CM, the CM's firms, or other professionals who are part of the entire monitorship team during the entire monitorship term and for a period of not less than three years from the date of the termination of the monitorship.

ENVIGO shall provide a written statement identifying the CM candidate that is ENVIGO's first choice to serve as the CM and the reasons for that choice.

The United States reserves the right to disallow any proposed candidate. If the United States disallows a candidate, ENVIGO, shall, within twenty business days of receiving notice of the disallowance, submit an additional name to the United States. The submission and disallowance process will continue until at least three candidates remain. The CM candidates shall be subject to interview(s) by the United States. The United States, upon consideration of the three remaining candidates, shall select the CM. The United States may disqualify any CM candidate during the selection process, and at all times, there must be three candidates under consideration until the CM is selected by the United States. ENVIGO and the United States will endeavor to complete the selection process for the CM within sixty days of entry of ENVIGO's guilty plea.

Notwithstanding the foregoing, nothing in this Plea Agreement shall prevent ENVIGO from proposing that two monitors, one with expertise with the Animal Welfare Act laws, rules, and regulations, and one with expertise with the Clean Water Act laws, rules, and regulations, perform the function of the CM.

b. Powers

The scope of the CM shall be limited to review of the care of any "animal" as defined by 9 C.F.R. § 1.1 by those components of the INOTIV ENTITIES that hold licenses pursuant to the United States Department of Agriculture or conduct activities under those licenses and, for purposes of ensuring 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, 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 delegated-state program.

Within the scope, the CM shall, for each year of probation, limit its on-site review to one-third of the INOTIV ENTITIES' facilities, rounded to the nearest whole number. Notwithstanding the previous sentence, the CM must complete its on-site review of 100% of the within-scope INOTIV ENTITIES' facilities in three years. For any non-compliance identified during the CM's on-site review of any facility, the CM may revisit that facility at any time to ensure corrective measures have been taken.

Within the scope, the CM shall be empowered to:

- i. Freely review all records of the INOTIV ENTITIES.

*Attachment 2 to Resolution Agreement
In re: Inotiv, Inc.*

Plea Agreement

- ii. Freely communicate with all employees, contractors, and agents of the INOTIV ENTITIES.
- iii. Take all steps necessary to determine if the INOTIV ENTITIES are fully complying with all Applicable Laws.
- iv. Take all steps necessary to determine if the INOTIV ENTITIES are fully complying with all (1) obligations set forth in the Plea Agreement and Resolution Agreement, (2) terms of probation, and (3) terms of the NCP (as defined below).
- v. Report any matter to any INOTIV employee or any appropriate governmental or regulatory body, if the CM believes it to be in the interest of advancing the purposes of the Plea Agreement and Resolution Agreement.
- vi. Promptly notify the Court and the United States if the CM is being denied access to information, resources, or employees or agents necessary to fulfill the CM's responsibilities.

c. Payment

ENVIGO shall pay all reasonable costs of the CM, including any costs incurred in the selection of the CM. If ENVIGO finds that any costs submitted by the CM are unreasonable, ENVIGO may bring any such disputes before the Court, with notice to the United States, for review and resolution.

d. Reporting to Parties

The CM shall, at minimum, make the following reports to the Court, United States, the United States Probation Office, and ENVIGO, but report more often if it so chooses:

- i. Every six months, a report detailing the INOTIV ENTITIES' compliance record and efforts to improve their facilities.
- ii. Within 10 days of discovery by the CM, a report detailing any significant failure to comply with the Plea Agreement, Resolution Agreement, or a term of probation, unless the failure to comply is remedied within five days of discovery.

e. Replacement

In the event the CM is unable or unwilling to perform his/her duties, the CM shall immediately provide written notice to the Court, the United States, the United States Probation Office, and ENVIGO. Within 30 days of such notice, ENVIGO must submit at least three candidates to replace the CM, and the selection of the replacement CM shall follow the procedures set forth under Paragraph (a) of this Section.

*Plea Agreement
United States v. Envigo RMS, LLC & Envigo Global Services, Inc.*

*Authorized Corporate Officers' Initials:
Envigo RMS, LLC: AC
Envigo Global Services, Inc.: AC*

*Attachment 2 to Resolution Agreement
In re: Inotiv, Inc.*

Plea Agreement

In the event the CM seeks to retain any outside professional not identified in its written submission, the CM shall provide written notice to the Court, the United States, the United States Probation Office, and ENVIGO immediately. Any party can provide a written objection within fifteen days of such notice, in which case the CM shall propose another outside professional. If any party continues to object, the dispute shall be resolved by the Court.

f. Term

The CM shall serve for the entire monitorship term, except as provided under Paragraph (e) of this Section. The monitorship term shall expire five years after the completion of the selection process for the CM. If ENVIGO is released from probation prior to completion of the five-year term, the monitorship term shall expire three years after the completion of the selection process for the CM, or two months after the completion of probation, whichever is later.

13. NATIONWIDE COMPLIANCE PLAN

ENVIGO shall develop, adopt, implement, fund, and comply with a comprehensive NCP governing compliance of all the INOTIV ENTITIES' facilities within the United States with all Applicable Laws.

ENVIGO will develop the NCP in coordination with the CM. The NCP shall be filed with the Court and provided to the United States within 90 days of the appointment of the CM. Terms of the NCP shall include, but are not limited to, the following:

- a. *Compliance Officer.* Inotiv, Inc., itself one of the INOTIV ENTITIES, and the parent of the other INOTIV ENTITIES, shall maintain a Compliance Officer. The Compliance Officer shall, in conjunction with the CM, be authorized and have the necessary funding to oversee compliance by all the INOTIV ENTITIES with all Applicable Laws. The Compliance Officer is, and shall continue to be, responsible for developing and implementing policies, procedures, and practices designed to address compliance with the requirements set forth in the NCP. The Compliance Officer shall be a member of senior management of Inotiv, Inc., and shall report directly to the President and Chief Executive Officer ("CEO") of Inotiv, Inc. The Compliance Officer shall make periodic (at least quarterly) reports regarding compliance matters directly to the President and CEO and shall be authorized to report on such matters to Inotiv, Inc.'s Board of Directors at any time. In addition to the reporting obligations set out in this Paragraph, the Compliance Officer will report directly to the President and CEO and will not be subordinate to any other employee. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by the INOTIV ENTITIES as well as for any obligations created under the NCP. Any non-compliance job responsibilities of the

*Plea Agreement
United States v. Envigo RMS, LLC & Envigo Global Services, Inc.*

*Authorized Corporate Officers' Initials:
Envigo RMS, LLC: AC
Envigo Global Services, Inc.: AC*

Compliance Officer must not interfere with the Compliance Officer's ability to perform the duties outlined in the NCP.

- b. *Compliance Committee.* Prior to the entry of ENVIGO's guilty plea, Inotiv, Inc. will form and maintain a Compliance Committee which, in conjunction with the Compliance Officer, shall assist in the implementation and enhancement of the NCP. The Compliance Committee shall include, at a minimum, the Compliance Officer and other members of senior management necessary to meet the requirements of the NCP (e.g., senior executives of relevant departments, such as legal, regulatory, audit, human resources, and operations). The Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the INOTIV ENTITIES' risk areas and shall oversee monitoring of internal and external compliance-related audits and investigations). The Compliance Committee shall meet at least quarterly, with such meetings to include the presence or input of the CM, and report at least quarterly to the Board of Directors of Inotiv, Inc. regarding the status of the NCP.
- c. *Board of Directors Compliance Obligations.* Effective from the date of the entry of ENVIGO's guilty pleas and continuing throughout the term of probation, the Board of Directors of Inotiv, Inc. will oversee the NCP. Such oversight by the Board of Directors shall include, at a minimum:
 - i. Reviewing the INOTIV ENTITIES' compliance with their obligations under the NCP;
 - ii. Receiving updates about adoption and implementation of policies, procedures and practices designed to ensure compliance with the Applicable Laws; and
 - iii. Evaluating the effectiveness of the NCP.
- d. The INOTIV ENTITIES shall evaluate their current business to ensure they are not currently violating the Applicable Laws. Should one of the INOTIV ENTITIES find it is violating any of the Applicable Laws, it must report the violations to the CM and take necessary steps to remediate any such conduct.
- e. The INOTIV ENTITIES shall maintain, and, if necessary, enhance their training programs to ensure that pertinent employees are familiar with the requirements of the Applicable Laws, as well as the required standards set forth under Section 5 herein, and how those requirements apply to the INOTIV ENTITIES' conduct.
- f. The INOTIV ENTITIES shall ensure they have, and maintain, processes to (a) encourage employees to report suspected non-compliant activities by the INOTIV ENTITIES, customers, or others, and to (b) acknowledge or otherwise recognize employees for reporting confirmed non-compliant activity.

- g. The INOTIV ENTITIES shall maintain, and, if necessary, enhance, policies and procedures designed to ensure effective investigation of any complaints and/or potential deficiencies relating to compliance with the Applicable Laws. Such policies and procedures shall include, but are not limited to:
 - i. Training and providing guidance to all pertinent employees as to the requirement to report all information regarding potential non-compliance with the Applicable Laws to the Compliance Officer, who in turn, in consultation with the CM, will review and determine whether corrective actions are required.
 - ii. Tracking allegations and remediation action plans regarding potential non-compliance with the Applicable Laws to identify issues that may require corrective actions.
- h. Within 60 days of the end of Inotiv Inc.'s fiscal year, for the duration of the probationary period, Inotiv Inc.'s President and CEO shall certify under oath to the United States and to the United States Probation Office, 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. Any listing of non-compliant activity shall not be considered by the United States or the United States Probation Office as a *per se* violation of the terms of probation or the Plea Agreement. Instead, other factors may be considered, including whether the conduct violated policies the INOTIV ENTITIES had adopted, whether the INOTIV ENTITIES provided training addressing the subject matter of the reported conduct, whether it was an isolated or systemic occurrence, the INOTIV ENTITIES' response, and any remedial actions taken after the INOTIV ENTITIES learned of the conduct reported.
- i. 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, ENVIGO shall notify the CM, the United States, and the United States Probation Office of such violation, ENVIGO's findings, and corrective action taken, if any.

14. NOTICE TO PERSONNEL OF INOTIV ENTITIES

Within 30 days of pleading guilty, all INOTIV ENTITIES shall require each employee or full-time or part-time employee equivalent to read the Information, Plea Agreement, and Resolution Agreement.

For five years after entry of this Plea Agreement, within 30 days of one of the INOTIV ENTITIES employing or engaging an employee or full-time or part-time employee equivalent, ENVIGO shall require such person to read the Information, Plea

Plea Agreement

United States v. Envigo RMS, LLC & Envigo Global Services, Inc.

Authorized Corporate Officers' Initials:
Envigo RMS, LLC: AC
Envigo Global Services, Inc.: AC

*Attachment 2 to Resolution Agreement
In re: Inotiv, Inc.*

Plea Agreement

Agreement, and Resolution Agreement. ENVIGO shall maintain a record, for inspection by the CM and the United States, documenting that these requirements have been met.

15. PUBLIC ACCESS TO INFORMATION

The INOTIV ENTITIES shall facilitate, for the period of probation, the posting of copies of final United States Department of Agriculture inspection reports of INOTIV ENTITIES' facilities, the certifications submitted by Inotiv Inc.'s President and CEO as provided herein, and reports prepared by the CM, on the INOTIV ENTITIES' free and publicly accessible company websites, within fourteen days of receipt of each document. Subject to the time limits set forth herein and the approval of the CM, the INOTIV ENTITIES may redact any confidential business information or any information it reasonably believes can impair the security of its operations before such documents are posted for public access.

Upon the INOTIV ENTITIES' posting of the documents, both unredacted and redacted copies shall be provided to the Court, the United States, and the United States Probation Office. The INOTIV ENTITIES may seek to have the filings placed under seal to protect any information the CM has determined warrant redaction.

16. REJECTION OF PLEA AGREEMENT

The parties agree that if the Court refuses to accept this Plea Agreement with the agreed-upon sentence, ENVIGO will be free to withdraw its guilty pleas. In the event the Court refuses to accept this Plea Agreement and ENVIGO withdraws its guilty pleas within 10 days of being notified of the Court's refusal, nothing in this Plea Agreement shall be deemed a waiver of the provisions of Federal Rule of Evidence 410. Under these circumstances, the United States will move to dismiss the Information without prejudice and the United States may pursue any or all of the remedies set forth in the Plea Agreement or Resolution Agreement, as if ENVIGO had failed to comply with a term of the Plea Agreement or as if Inotiv, Inc. had failed to comply with a term of the Resolution Agreement.

17. JUDGMENT AND CONVICTION ORDER PROVISIONS

The parties agree that the Court's Judgment and Conviction Order will include the following language:

A. In "SPECIAL CONDITIONS OF SUPERVISION":

"ENVIGO and the INOTIV ENTITIES must comply with all provisions of this Plea Agreement and all provisions of the related Resolution Agreement entered into with Inotiv, Inc."

*Plea Agreement
United States v. Envigo RMS, LLC & Envigo Global Services, Inc.*

*Authorized Corporate Officers' Initials:
Envigo RMS, LLC: AC
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B. In “ADDITIONAL TERMS FOR CRIMINAL MONETARY PENALTIES”:

ENVIGO shall make payments toward a fine of \$11,000,000 (eleven million dollars) on Count One and \$11,000,000 (eleven million dollars) on Count Two, for a total fine of \$22,000,000 (twenty-two million dollars), which shall be due and payable at sentencing and interest shall be computed daily on the entire unpaid balance from the date of sentencing at a rate equal to the weekly average 1-year constant maturity Treasury yield, as published by the Board of Governors of the Federal Reserve System, for the calendar week preceding the date of sentencing. However, ENVIGO will be in compliance with its obligation to pay the fine so long as it pays the following amounts on or before the dates set forth below:

- June 3, 2025 – \$5,000,000 (five million dollars)
- June 3, 2026 – \$5,000,000 (five million dollars)
- June 3, 2027 – \$5,000,000 (five million dollars)
- June 3, 2028 – \$7,000,000 (seven million dollars) plus all accrued interest since June 3, 2024.

If ENVIGO and Inotiv, Inc. fail to pay any of the above listed amounts on or before the due dates, they will have (1) failed to comply with a provision of the Plea Agreement, and (2) failed to comply with a provision of the Resolution Agreement. Accordingly, the United States, immediately, may collect the entire remaining unpaid amount due of the \$22,000,000 fine plus interest.

18. ADDITIONAL OBLIGATIONS

Unless the Court rejects this Plea Agreement and, as a result, ENVIGO withdraws its plea, ENVIGO agrees to: (1) accept responsibility for its conduct; (2) not attempt to withdraw its guilty plea; (3) not deny it committed the crimes to which it has pled guilty; and (4) not make or adopt any arguments or objections to the presentence investigation report that are inconsistent with this Plea Agreement.

ENVIGO will not, through its present or future directors, officers, employees, agents, or attorneys, (1) make any public statement or (2) make any statement or take any position in litigation in which any United States department or agency is a party, in either case, contradicting any statement or provision set forth in the Plea Agreement, Resolution Agreement, Information, or their attachments. If ENVIGO makes a public statement that in whole or in part contradicts any such statement or provision, ENVIGO may avoid being in violation of this Plea Agreement by promptly publicly repudiating such statement. For the purposes of this Paragraph, the term “public statement” means any statement made or authorized by ENVIGO’s directors, officers, employees, agents, or attorneys and includes, but is not limited to, a statement in (1) a press release, (2) public relations material, (3) required disclosures under securities laws, or (4) ENVIGO’s publicly accessible company websites. Notwithstanding the above, ENVIGO may avail itself of any legal or factual arguments available in defending litigation brought by a party other than the United States.

*Attachment 2 to Resolution Agreement
In re: Inotiv, Inc.*

Plea Agreement

This Paragraph does not apply to any statement made by any individual in the course of any actual or contemplated criminal, regulatory, administrative, or civil case initiated by any governmental or private party against such individual.

19. GUARANTEE AND JURISDICTION

The parties agree and acknowledge that ENVIGO's parent corporation, Inotiv, Inc., shall guarantee all monetary penalties (criminal fine, payments for direct assistance, community service, and mitigation) imposed upon ENVIGO and the funding and performance of all obligations set forth in this Plea Agreement. The parties further agree and acknowledge that the INOTIV ENTITIES hereby consent to the jurisdiction of the United States District Court for the Western District of Virginia for the purpose of enforcing the Resolution Agreement and Plea Agreement.

20. WAIVER OF RIGHT TO APPEAL AND COLLATERALLY ATTACK THE JUDGMENT AND SENTENCE IMPOSED BY THE COURT

If the Court accepts this Plea Agreement, ENVIGO agrees ENVIGO will not appeal the conviction or sentence imposed. ENVIGO is knowingly and voluntarily waiving any right to appeal and is voluntarily willing to rely on the Court in sentencing it, pursuant to the terms of Fed. R. Crim. P. 11(c)(1)(C). ENVIGO expressly waives its right to appeal as to any and all issues in this matter and waives any right it may have to collaterally attack, in any future proceeding, any order issued in this matter, unless such appeal or collateral attack cannot be waived, by law. ENVIGO understands the United States expressly reserves all its rights to appeal, but if the United States initiates a direct appeal of the sentence imposed, ENVIGO may file a cross appeal of that same sentence. ENVIGO agrees and understands if it files any court document (except for an appeal or collateral attack based on an issue that cannot be waived, by law) seeking to disturb, in any way, any order imposed in the case such action shall constitute a failure to comply with a provision of this Plea Agreement.

21. INFORMATION ACCESS WAIVER

ENVIGO waives all rights, whether asserted directly or by a representative, to request or receive from the United States Department of Justice, United States Department of Agriculture – Office of Inspector General, and Virginia Office of the Attorney General any records pertaining to the investigation or prosecution of this case, including, without limitation, any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, the Privacy Act of 1974, 5 U.S.C. § 552a, or the Virginia Freedom of Information Act, Va. Code § 2.2-3700- 3714.

*Plea Agreement
United States v. Envigo RMS, LLC & Envigo Global Services, Inc.*

*Authorized Corporate Officers' Initials:
Envigo RMS, LLC: AC
Envigo Global Services, Inc.: AC*

22. ADMISSIBILITY OF STATEMENTS

ENVIGO understands any statements made on its behalf (including, but not limited to, this Plea Agreement, the Information, and its admission of guilt) during or in preparation for any guilty plea hearing, sentencing hearing, or other hearing and any statements made, in any setting, may be used against ENVIGO by the United States in this or any other proceeding. ENVIGO knowingly waives any right it may have under the Constitution, any statute, rule, or other source of law to have such statements, or evidence derived from such statements, suppressed, or excluded from being admitted into evidence in this or any other proceeding. If, and only if, the Court rejects this Plea Agreement, and, as a result, ENVIGO withdraws its pleas, ENVIGO will not be bound by the waivers set forth in this Section of the Plea Agreement.

23. COMPLETION OF PROSECUTION

The parties agree they are bound by all terms of the Resolution Agreement, including those concerning completion of prosecution.

24. LIMITATION OF PLEA AGREEMENT

This Plea Agreement is limited to the United States Attorney's Office for the Western District of Virginia and the Environmental and Natural Resources Division of the United States Department of Justice and does not bind any other component of the Department of Justice, other federal agency, or any state, local, or foreign law enforcement or regulatory agency, or any other authority.

25. COOPERATION

ENVIGO will fully cooperate with all investigations and prosecutions, if any, by the Department of Justice or Virginia Office of the Attorney General. ENVIGO's cooperation in the investigation and prosecution of individuals and entities pursuant to this Paragraph includes, but is not limited to, using best efforts promptly to secure the attendance and testimony of any current or former officer, director, agent, or employee of ENVIGO at any meeting or interview or before the grand jury or at any trial or other court proceeding; and truthfully disclosing all factual information, documents, records, or other tangible evidence not protected by a valid claim of privilege or work product. ENVIGO's cooperation is subject to applicable laws and regulations, including relevant data privacy and national security laws and regulations, as well as valid claims of attorney-client privilege or attorney work product doctrine. ENVIGO expressly understands, to the extent there is conduct disclosed by ENVIGO that does not relate to the conduct covered by the Information, such conduct will not be exempt from prosecution and is not within the scope of the non-prosecution terms of this Plea Agreement.

Nothing in this Plea Agreement shall be construed to require ENVIGO to waive any attorney-client privilege or work-product protection.

26. REMEDIES FOR FAILURE TO COMPLY WITH ANY PROVISION OF THIS PLEA AGREEMENT

ENVIGO understands if: (1) ENVIGO attempts to withdraw its plea (in the absence of the Court refusing to accept this Plea Agreement); (2) ENVIGO fails to comply with any provision of this Plea Agreement; (3) any of the INOTIV ENTITIES fail to comply with any provision of the Resolution Agreement; (4) ENVIGO's conviction is set aside, for any reason; and/or (5) ENVIGO fails to execute all required paperwork, the United States may, at its election, pursue any or all of the following remedies: (a) declare this Plea Agreement and/or the Resolution Agreement void; (b) file against any entity, by indictment or information, any charges which were filed and/or could have been filed concerning the matters involved in the instant investigation; (c) refuse to abide by any stipulations and/or recommendations contained in this Plea Agreement or the Resolution Agreement; (d) not be bound by any obligation of the United States set forth in this Plea Agreement or the Resolution Agreement, and (e) take any other action provided for under this Plea Agreement, the Resolution Agreement, or by statute, regulation, or court rule.

The remedies set forth above are cumulative and not mutually exclusive. If the United States pursues any of its permissible remedies as set forth in this Plea Agreement, ENVIGO will still be bound by its obligations under this Plea Agreement. ENVIGO hereby waives its right under Fed. R. Crim. P. 7 to be proceeded against by indictment and consents to the filing of an information against it concerning any charges filed pursuant to this Section of this Plea Agreement. ENVIGO hereby waives any statute of limitations argument as to any such charges.

27. EXCLUSION

ENVIGO understands that as a consequence of pleading guilty pursuant to this Plea Agreement, government agencies may exclude ENVIGO from participating in activity involving federal government funds and/or contracts; may refuse to issue or revoke licenses to ENVIGO; and may take other action.

If ENVIGO is in compliance with the Plea Agreement, Inotiv, Inc. is in compliance with the Resolution Agreement, and the United States is asked by the United States Environmental Protection Agency, Office of Suspension and Debarment ("OSD") or other equivalent office, the United States will advise OSD or other equivalent office that ENVIGO waived indictment, accepted responsibility for the underlying criminal conduct, and is cooperating with the related investigation. ENVIGO understands that all decisions related to suspension and debarment are committed to the discretion of OSD.

28. EFFECTIVE REPRESENTATION

ENVIGO has discussed the terms of this Plea Agreement and all matters pertaining to the charges against it with its attorneys and is fully satisfied with its attorneys and its attorneys' advice. At this time, ENVIGO has no dissatisfaction or complaint with its attorneys' representation. ENVIGO agrees to make known to the Court no later than at the time of sentencing any dissatisfaction or complaint ENVIGO may have with its attorneys' representation.

29. EFFECT OF ENVIGO'S SIGNATURE

ENVIGO understands its Authorized Corporate Officers' (the "Officers'") signatures on this Plea Agreement constitute binding offers by them to enter into this Plea Agreement. ENVIGO understands the United States has not accepted ENVIGO's offers until all of the authorized representatives of the United States have signed this Plea Agreement and the Resolution Agreement.

30. GENERAL UNDERSTANDINGS

ENVIGO understands a presentence investigation may be conducted and sentencing recommendations independent of the United States may be made by the presentence preparer.

ENVIGO understands the United States and ENVIGO retain the right, notwithstanding any provision in this Plea Agreement, to inform the United States Probation Office and the Court of all facts, to address the Court with respect to the nature and seriousness of the offense and the offender, to respond to any questions raised by the Court, to correct any inaccuracies or inadequacies in the presentence report, and to respond to any statements made to the Court.

ENVIGO willingly stipulates there is a sufficient factual basis for the Court to accept the plea.

ENVIGO understands this Plea Agreement does not apply to any crimes or charges not addressed in this Plea Agreement.

ENVIGO has not been coerced, threatened, or promised anything other than the terms of this Plea Agreement, which is part of a larger resolution set forth in the Resolution Agreement, in exchange for its pleas of guilty. ENVIGO understands its attorneys will be free to argue any mitigating factors on its behalf to the extent they are not inconsistent with the terms of this Plea Agreement. ENVIGO understands ENVIGO will have an opportunity to have a representative address the Court prior to sentence being imposed.

The Plea Agreement, Resolution Agreement, and their attachments are the complete and only agreements between the United States and ENVIGO concerning resolution of this matter. In addition, ENVIGO has no objection to the filing of the Information. The Plea Agreement, Resolution Agreement, and their attachments set forth the entire understanding between the parties and constitute the complete agreement between the United States and

*Attachment 2 to Resolution Agreement
In re: Inotiv, Inc.*

Plea Agreement

ENVIGO and no other additional terms or agreements shall be entered except and unless those other terms or agreements are in writing and signed by the parties. These agreements supersede all prior understandings, promises, agreements, or conditions, if any, between the United States and ENVIGO. ENVIGO consents to public disclosure of the Plea Agreement, Resolution Agreement, and their attachments.

ENVIGO has consulted with its attorneys and fully understands its rights. ENVIGO has read this Plea Agreement and carefully reviewed every part of it with its attorneys. ENVIGO understands this Plea Agreement and ENVIGO voluntarily agrees to it. Being aware of all the possible consequences of its pleas, ENVIGO has independently decided to enter these pleas of its own free will and is affirming that agreement on this date by the signature of the Officer below.

The Officers, by signing below, each hereby certify to the following:

- (1) The Officer is fully authorized by ENVIGO's Board of Directors to enter into this Plea Agreement on behalf of ENVIGO.
- (2) The Officer has read the entire Plea Agreement and its attachments and discussed them with ENVIGO's Board of Directors.
- (3) ENVIGO understands all the terms of this Plea Agreement and those terms correctly reflect the results of plea negotiations.
- (4) ENVIGO is fully satisfied with ENVIGO's attorneys' representation during all phases of this case.
- (5) ENVIGO is freely and voluntarily pleading guilty in this case.
- (6) ENVIGO is pleading guilty as set forth in this Plea Agreement because it is guilty of the crime to which it is entering its plea.
- (7) ENVIGO understands it is waiving its right to appeal the judgment and conviction in this case.

ENVIGO acknowledges its acceptance of this Plea Agreement by the signature of its counsel and Officers. A copy of a certification by ENVIGO's Boards of Directors authorizing the Officers to execute this Plea Agreement and all other documents to resolve this matter on behalf of ENVIGO are attached as Attachment A.

*Plea Agreement
United States v. Envigo RMS, LLC & Envigo Global Services, Inc.*

*Authorized Corporate Officers' Initials:
Envigo RMS, LLC: AC
Envigo Global Services, Inc.: AC*

Attachment 2 to Resolution Agreement
In re: Inotiv, Inc.

Plea Agreement

Agreed to:

ENVIGO RMS, LLC:

BY: Andrea Castetter
Andrea Castetter
Senior Vice President – General Counsel
and Corporate Secretary, Inotiv, Inc
Authorized Corporate Officer
For Envigo RMS, LLC

June 1, 2024
DATE

Counsel has fully explained to the Board of Directors of ENVIGO RMS, LLC the facts and circumstances of the case; all rights with respect to the offense charged in the Information; possible defenses to the offense charged in the Information; all rights with respect to the applicability of the U.S.S.G.; and the consequences of entering into this Plea Agreement and entering a guilty plea. Counsel has reviewed this entire Plea Agreement and its attachments with the client, through its Officer. ENVIGO RMS, LLC understands the terms and conditions of this Plea Agreement, and ENVIGO RMS, LLC's decision to enter into this Plea Agreement is knowing and voluntary. ENVIGO RMS, LLC's execution of and entry into this Plea Agreement is done with Counsel's consent.

Daniel Suleiman

06/01/2024
DATE

Daniel Suleiman
Christopher M. Denig
Jeannie M. Perron, DVM
Daniel T. Grant
COVINGTON & BURLING LLP

Counsel for Envigo RMS, LLC

*Attachment 2 to Resolution Agreement
In re: Inotiv, Inc.*

Plea Agreement

Agreed to:

ENVIGO GLOBAL SERVICES, INC.:

BY: <u>Andrea Castetter</u> Andrea Castetter Senior Vice President – General Counsel and Corporate Secretary, Inotiv, Inc <i>Authorized Corporate Officer for Envigo Global Services Inc.</i>	<u>June 1, 2024</u> DATE
--	-----------------------------

Counsel has fully explained to the Board of Directors of ENVIGO GLOBAL SERVICES, INC. the facts and circumstances of the case; all rights with respect to the offense charged in the Information; possible defenses to the offense charged in the Information; all rights with respect to the applicability of the U.S.S.G.; and the consequences of entering into this Plea Agreement and entering a guilty plea. Counsel has reviewed this entire Plea Agreement and its attachments with the client, through its Officer. ENVIGO GLOBAL SERVICES, INC. understands the terms and conditions of this Plea Agreement, and ENVIGO GLOBAL SERVICES, INC.'s decision to enter into this Plea Agreement is knowing and voluntary. ENVIGO GLOBAL SERVICES, INC.'s execution of and entry into this Plea Agreement is done with Counsel's consent.

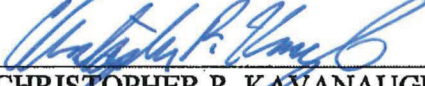
<u>D. M. Denig Suleiman</u> Daniel Suleiman Christopher M. Denig Jeannie M. Perron, DVM Daniel T. Grant COVINGTON & BURLING LLP	<u>06/01/2024</u> DATE
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Counsel for Envigo Global Services, Inc.

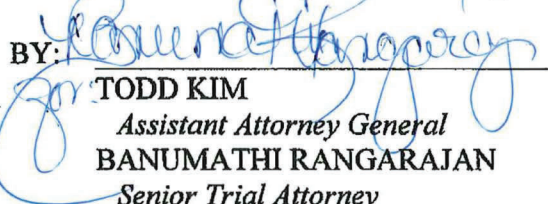
Attachment 2 to Resolution Agreement
In re: Inotiv, Inc.

Plea Agreement

The United States Attorney's Office for the Western District of Virginia:

BY:  6/3/2024
 CHRISTOPHER R. KAVANAUGH DATE
United States Attorney
 RANDY RAMSEYER
Assistant United States Attorney
 MICHELLE WELCH
Special Assistant United States Attorney
 COREY HALL
Assistant United States Attorney
 CARRIE MACON
Assistant United States Attorney

The United States Department of Justice, Environmental Crimes Section:

BY:  7/3/2024
 TODD KIM DATE
Assistant Attorney General
 BANUMATHI RANGARAJAN
Senior Trial Attorney
 SARAH BROWN
Trial Attorney

CERTIFICATE OF CORPORATE RESOLUTION

WHEREAS, Envigo RMS, LLC (“Envigo RMS”) and Envigo Global Services, Inc. (“EGSI”) (collectively, “Envigo”) and Inotiv, Inc. (“Inotiv”) have been in discussions with the United States Attorney for the Western District of Virginia and the Environmental Crimes Section of the United States Department of Justice, Environment and Natural Resources Division (collectively, the “United States”) to resolve the United States’ investigation by, among other things, having Envigo enter into a Plea Agreement, and having Inotiv enter into a Resolution Agreement;

WHEREAS, Envigo RMS and EGSI are wholly-owned subsidiaries of Inotiv;

WHEREAS, management of Envigo and Inotiv, together with outside counsel, have advised the Board of Directors of Inotiv (in its capacity as the Board of Directors of Inotiv and on behalf of Inotiv as the ultimate shareholder of Envigo RMS and EGSI) (“Board”) of the detailed terms of the Plea Agreement and the Resolution Agreement, the obligations of Envigo and Inotiv under the Plea Agreement and the Resolution Agreement, and the consequences of entering into the Plea Agreement and the Resolution Agreement; and

WHEREAS, the Board has carefully reviewed the terms of the Plea Agreement and Resolution Agreement and after considering relevant facts and circumstances, including in consultation with certain stakeholders and advisors, has determined that (i) it is advisable and in the best interests of Envigo and their shareholders, including Inotiv and its shareholders, for Envigo to enter into the Plea Agreement, and (ii) it is advisable and in the best interests of Inotiv and its shareholders to enter into the Resolution Agreement.

NOW, THEREFORE, BE IT RESOLVED, that the terms and provisions of each of the Plea Agreement and the Resolution Agreement, including all exhibits and schedules attached thereto, in the respective form presented to the Board, be, and hereby are, authorized, approved and adopted; and further

RESOLVED, that the officers of Envigo RMS are hereby each severally authorized in the name and on behalf of Envigo RMS to execute and deliver the Plea Agreement in the name and on behalf of Envigo RMS, the officers of EGSI are hereby each severally authorized in the name and on behalf of EGSI to execute and deliver the Plea Agreement in the name and on behalf of EGSI, and the executive officers of Inotiv (such officers of Envigo RMS and EGSI and such executive officers of Inotiv, the “Authorized Officers”) are hereby each severally authorized in the name and on behalf of Inotiv to execute and deliver the Resolution Agreement in the name and on behalf of Inotiv, in each case, subject to Inotiv entering into an agreement with its lenders under the credit agreement, in such form and with such terms as are approved by the Board, to address terms of the Resolution Agreement and Plea Agreement that impact the credit agreement; and further

RESOLVED, that Envigo RMS and EGSI each is hereby authorized and directed to plead guilty to the charges specified in the Plea Agreement in the U.S. District Court for the Western District of Virginia; and further

RESOLVED, that each of the Authorized Officers of Envigo RMS and EGSI is hereby authorized and directed to appear on behalf of Envigo RMS and EGSI, respectively, and enter such guilty plea; and further

RESOLVED, that the Authorized Officers are, and each is, hereby authorized and directed, in the name and on behalf of Envigo and Inotiv, as applicable, to execute and deliver all other documents necessary to carry out the provisions of the Plea Agreement and the Resolution Agreement and to perform any and all acts as may be necessary or desirable to perform fully the obligations under the Plea Agreement and the Resolution Agreement, and to execute, file and deliver all agreements, instruments and other documents as any such Authorized Officer may deem necessary or desirable to carry out the purposes and intent of the foregoing resolutions; and further

RESOLVED, that the Authorized Officers of Envigo RMS and EGSI hereby are, and each hereby is, authorized and directed to acknowledge on behalf of Envigo that the Plea Agreement and related documents (the "Plea Documents") fully set forth the agreement made between Envigo and the United States, and that no additional promises or representations have been made to Envigo by any United States officials in connection with the Plea Agreement, other than those set forth in the Plea Documents; and further

RESOLVED, that the Authorized Officers of Inotiv hereby are, and each hereby is, authorized and directed to acknowledge on behalf of Inotiv that the Resolution Agreement and related documents (the "Resolution Documents") fully set forth the agreement made between Inotiv and the United States, and that no additional promises or representations have been made to Inotiv by any United States officials in connection with the Resolution Agreement, other than those set forth in the Resolution Documents; and further

RESOLVED, that the Authorized Officers of Inotiv are authorized and directed in the name and on behalf of Envigo and Inotiv to make any and all payments required in connection with the Plea Agreement and the Resolution Agreement; and further

RESOLVED, that the Authorized Officers be, and each hereby is, authorized, directed and empowered, in the name and on behalf of Envigo and Inotiv, as applicable, to make all such arrangements, to do and perform all such acts and things, and to execute and deliver all such certificates and such other instrument and documents as they may deem appropriate in order to effectuate fully the purpose of each and all of the foregoing resolutions, and that any and all actions taken heretofore and hereafter to accomplish such purposes, all or singular, be, and they hereby are approved, ratified and confirmed; and further

RESOLVED, that any actions taken by any of the officers of Envigo and Inotiv prior to the date of the foregoing resolutions adopted hereby that are within the authority conferred hereby are ratified, confirmed and approved as the act and deed of Envigo and Inotiv, respectively.

Attachment A to the Plea Agreement
United States v. Envigo RMS, LLC & Envigo Global Services, Inc.

Corporate Resolution

I, Andrea Castetter, being Inotiv’s Senior Vice President – General Counsel and Corporate Secretary, hereby certify that the resolutions set out above are the resolutions that were passed by the Board at a board meeting duly held on Wednesday, May 22, 2024.

Dated: May 22, 2024

DocuSigned by:
Andrea Castetter
84BAB6988150414...

Andrea Castetter
Senior Vice President – General Counsel
and Corporate Secretary
Inotiv, Inc.

Attachment A to the Plea Agreement

Corporate Resolution

United States v. Envigo RMS, LLC & Envigo Global Services, Inc.

OFFICER'S CERTIFICATE

June 2, 2024

In my capacity as Senior Vice President, General Counsel and Corporate Secretary of Inotiv, Inc. ("Inotiv"), and not in any personal capacity, I confirm that effective June 2, 2024, Inotiv has entered into that certain Fifth Amendment to Credit Agreement with its lenders, on terms that the Board of Directors of Inotiv have approved, which facilitates the agreement reached with the United States Department of Justice as set out under the Resolution Agreement and the Plea Agreement entered as of the date hereof.

[signature page follows]

Attachment 1 to the Resolution Agreement

In re: Inotiv, Inc.

Attachment A to the Plea Agreement

Corporate Resolution

United States v. Envigo RMS, LLC & Envigo Global Services, Inc.

IN WITNESS WHEREOF, I have hereunto set my hand as of the date first set forth above.

INOTIV, INC.

By: _____

DocuSigned by:
Andrea Castetter
84BAB6988150414...

Name: Andrea Castetter
Title: Senior Vice President, General Counsel
and Corporate Secretary

Attachment 1 to the Resolution Agreement
In re: Inotiv, Inc.

In re: Inotiv, Inc.

Resolution Agreement

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
LYNCHBURG DIVISION**

IN RE:)
)
 INOTIV, INC.) **Case No. 6:24MC00001**
)
)

RESOLUTION AGREEMENT

1. The United States Attorney’s Office for the Western District of Virginia and the Environmental Crimes Section of the United States Department of Justice, Environment and Natural Resources Division (collectively referred to as the “United States”) and Inotiv, Inc. (“INOTIV”), pursuant to authority granted by its Board of Directors, enter into this Resolution Agreement (“Agreement”) to resolve the federal criminal investigation related to the conduct described in the Information (attached as Attachment 3) to the Plea Agreement between the United States and Envigo RMS, LLC and Envigo Global Services, Inc. (collectively “ENVIGO”). For purposes of this Agreement, “INOTIV ENTITIES” includes INOTIV and all entities related to INOTIV, including, but not limited to, ENVIGO and all entities related to ENVIGO, and all successors in interest to any of the above listed entities. This Agreement is binding only on the United States Attorney’s Office for the Western District of Virginia and the Environmental and Natural Resources Division of the United States Department of Justice; it does not bind any other component of the Department of Justice, other federal agencies, or any state, local, or foreign law enforcement or regulatory agency, or any other authority.

2. The United States enters into this Agreement based on the individual circumstances presented by this case, including that this resolution coupled with the United States’s Plea Agreement with INOTIV’s wholly owned subsidiary, ENVIGO, will result in disbursements of more than \$35,500,000 (thirty-five million five hundred thousand dollars) and various obligations as set forth in the Plea Agreement and this Agreement.

3. INOTIV stipulates and agrees that the facts and allegations set forth in the Information to which ENVIGO is pleading guilty are true and correct.

4. INOTIV agrees it and all of the INOTIV ENTITIES will:

a. Comply with all terms of the Plea Agreement (attached as Attachment 2),

In re: Inotiv, Inc.

Resolution Agreement

including guaranteeing the payment of all financial obligations agreed to by ENVIGO and the fulfillment of all obligations of all INOTIV ENTITIES as set forth therein.

- b. Be subject to the same Compliance Monitor arrangement as set forth in the Plea Agreement.
- c. Fulfill all terms of this Agreement.
- d. Comply with (1) 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 (collectively referred to as "Applicable Laws"), (2) the Plea Agreement, this Agreement, and their attachments, and (3) the Nationwide Compliance Plan, as set forth in the Plea Agreement.

Prior to pleading guilty, INOTIV agrees to provide a lien to the United States against sufficient company assets to secure any unpaid deferred payments. Such lien shall be junior in priority and subordinated to (1) the lien provided by INOTIV to lenders under its existing credit facility (for the avoidance of doubt, including its revolving credit facility lenders), to the extent that lien was in place as of April 1, 2024, and (2) liens provided by INOTIV to lenders after April 1, 2024, to the extent the debt secured by the liens, in total, does not increase INOTIV's total secured debt to creditors other than the United States by more than \$100,000,000 (one hundred million dollars) above its secured debt (including its revolving credit commitments) as of April 1, 2024. The United States shall release such lien upon full payment of the \$22,000,000 (twenty-two million dollar) fine.

5.

6. If any payment required to be made by INOTIV and ENVIGO is not timely made, INOTIV will be in violation of this Agreement. If INOTIV and ENVIGO fail to pay any of the amounts listed in the Plea Agreement on or before the due dates, they will have (1) failed to comply with a provision of the Plea Agreement, and (2) failed to comply with a provision of this Agreement. Accordingly, the United States, immediately, may collect the entire remaining unpaid amount due of the \$22,000,000 fine plus interest and pursue any or all of the remedies available for failing to comply with a provision of the Plea Agreement.

7. INOTIV expressly releases any and all claims it may have to the money paid under this Agreement or the Plea Agreement. INOTIV will not file any claim or otherwise contest the payment of money set forth in this Agreement or the Plea Agreement, and it will not assist anyone in asserting a claim to the money. No money paid by INOTIV or ENVIGO will be returned, unless the Court rejects the Plea Agreement and ENVIGO withdraws its plea within 10 days of receiving notice of the Court's rejection. Should the

*Attachment B to Plea Agreement
United States v. Envigo RMS, LLC & Envigo Global Services, Inc.*

Authorized Corporate Officer's Initials: AC

In re: Inotiv, Inc.

Resolution Agreement

Court reject the Plea Agreement and ENVIGO withdraw its pleas within 10 days of receiving notice of the Court's rejection, any amounts INOTIV or ENVIGO has paid pursuant to Section 7(a)-(e) of the Plea Agreement shall be returned to INOTIV or ENVIGO.

8. Nothing in this Agreement or any related document is an admission by the United States that the amounts paid by INOTIV or any of the INOTIV ENTITIES are the maximum amounts that could, in the absence of this Agreement, be recovered. If INOTIV does not comply with all of its obligations under this Agreement, the United States is not precluded from arguing or presenting evidence that the total amount to be paid by INOTIV should be higher.

9. Except as may otherwise be agreed by the parties in connection with a particular transaction, INOTIV agrees if, during the term of this Agreement, it undertakes any material change in corporate form, including if it sells, merges, or transfers business operations material to INOTIV's consolidated operations as they exist as of the date of this Agreement, whether such change is structured as a sale, asset sale, merger, transfer, or other material change in corporate form, it shall include in any contract for sale, merger, transfer, or other change in corporate form a provision binding the purchaser, or any successor in interest thereto, to the obligations described in this Agreement. INOTIV shall provide notice to the United States at least 30 days prior to undertaking any such sale, merger, transfer, or other change in corporate form. Nothing herein shall restrict INOTIV from indemnifying (or otherwise holding harmless) the purchaser or successor in interest for penalties or other costs arising from any conduct that may have occurred prior to the date of the transaction, so long as such indemnification does not have the effect of circumventing or frustrating the enforcement purposes of this Agreement, as determined by the United States. Nothing herein shall restrict INOTIV from making changes in corporate form, so long as such changes do not have the effect of circumventing or frustrating the Plea Agreement or this Agreement.

10. INOTIV must notify the Court, the United States, and United States Probation Office as soon as reasonably practicable, in writing by both email and certified mail with return receipt, of any event (including, but not limited to, sale, merger, dissolution, etc.) that would jeopardize its ability to pay any amounts under this Agreement. In such event, the United States may immediately collect the entire fine and accrued interest from any of the INOTIV ENTITIES.

11. The parties warrant, in evaluating whether to execute this Agreement, they have (a) intended the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to INOTIV, within the meaning of 11 U.S.C. § 547(c)(1); and (b) concluded these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the parties warrant the

In re: Inotiv, Inc.

Resolution Agreement

mutual promises, covenants, and obligations set forth herein are intended to, and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which INOTIV was or became indebted to on or after the date of entry of ENVIGO's guilty pleas, within the meaning of 11 U.S.C. § 548(a)(1). INOTIV agrees its obligations under this Agreement and Section 7(a)-(e) of the Plea Agreement may not be avoided pursuant to 11 U.S.C. § 547, and INOTIV shall not argue or otherwise take the position in any such case, action, or proceeding that (1) INOTIV's obligations under this Agreement may be avoided under 11 U.S.C. § 547; (2) INOTIV was insolvent at the time this Agreement was entered into; or (3) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to INOTIV. INOTIV acknowledges the agreements in this Paragraph are provided in exchange for valuable consideration provided in this Agreement. INOTIV agrees all obligations payable under this Agreement and Section 7(a)-(e) of the Plea Agreement are not dischargeable in bankruptcy and shall be considered debt for a fine, penalty, or forfeiture payable to and for the benefit of a governmental unit pursuant to 11 U.S.C. § 523(a)(7).

12. During the probation period, INOTIV shall provide to the United States the following financial reports:

- a. statements of income, balance sheet, and cash flows for the preceding quarter within forty-five days of the end of each fiscal quarter.
- b. statements of income, balance sheet, and cash flows for the preceding fiscal year within ninety days of the end of each fiscal year.
- c. a thirteen-week cash flow forecast that shows anticipated consolidated cash receipts and disbursements for the next thirteen weeks on a consolidated basis within forty-five days of the end of each fiscal quarter.
- d. any non-public information shall remain confidential and not shared with any non-government entities and anyone receiving this information is prohibited from trading or selling NOTV shares.

13. INOTIV will not make any false or misleading statements to the United States.

14. INOTIV will fully cooperate with all investigations and prosecutions, if any, by the United States or Virginia Office of the Attorney General. INOTIV's cooperation in the investigation and prosecution of individuals and entities pursuant to this Paragraph includes, but is not limited to, using best efforts promptly to secure the attendance and testimony of any current or former officer, director, agent, or employee of all INOTIV

In re: Inotiv, Inc.

Resolution Agreement

ENTITIES at any meeting or interview or before the grand jury or at any trial or other court proceeding; and truthfully disclosing all factual information, documents, records, or other tangible evidence not protected by a valid claim of privilege or work product. INOTIV's cooperation is subject to applicable laws and regulations, including relevant data privacy and national security laws and regulations, as well as valid claims of attorney-client privilege or attorney work product doctrine. INOTIV expressly understands, to the extent there is conduct disclosed by INOTIV that is not part of the conduct covered by the Information, such conduct will not be exempt from prosecution and is not within the scope of the non-prosecution terms of this Agreement. Nothing in this Agreement shall be construed to require INOTIV to waive any attorney-client privilege or work-product protection.

15. INOTIV will execute and transmit all documents needed to effectuate the terms of this Agreement.

16. INOTIV stipulates (a) the facts and allegations set forth in the Information to which ENVIGO is pleading guilty are true and correct, (b) the United States had probable cause to bring all the counts in the Information, (c) the Information was not frivolous, vexatious or in bad faith, and (d) neither INOTIV nor ENVIGO is, in any way, a "prevailing party" with regard to the Information. INOTIV waives any claim for attorney's fees and other litigation expenses arising out of the investigation or prosecution of this matter. INOTIV further agrees that if it breaches this Agreement, the United States may use its agreement herein to the facts set forth in the Information, and those facts, as evidence against it at any subsequent trial or hearing.

17. The INOTIV ENTITIES will not, through their present or future directors, officers, employees, agents, or attorneys, (1) make any public statement or (2) make any statement or take any position in litigation in which any United States department or agency is a party, in either case, contradicting any statement or provision set forth in the Plea Agreement, this Agreement, Information, or their attachments. If the INOTIV ENTITIES makes a public statement that in whole or in part contradicts any such statement or provision, the INOTIV ENTITIES may avoid being in violation of this Agreement by promptly publicly repudiating such statement. For the purposes of this Paragraph, the term "public statement" means any statement made or authorized by any of the INOTIV ENTITIES' directors, officers, employees, agents, or attorneys and includes, but is not limited to, a statement in (1) a press release, (2) public relations material, (3) required disclosures under securities laws, or (4) any of the INOTIV ENTITIES' publicly accessible company websites. Notwithstanding the above, the INOTIV ENTITIES may avail themselves of any legal or factual arguments available in defending litigation brought by a party other than the United States. This Paragraph does not apply to any statement made by any individual in the course of any actual or

In re: Inotiv, Inc.

Resolution Agreement

contemplated criminal, regulatory, administrative, or civil case initiated by any governmental or private party against such individual.

18. If INOTIV is in compliance with all of the terms of this Agreement, the Court enters a judgment and conviction order against ENVIGO, and the Court enters an order requiring INOTIV to fully comply with this Agreement, the United States will not prosecute or seek forfeiture against INOTIV or its successors or assigns for any criminal conduct occurring prior to the date this Agreement is signed and that is based on conduct covered by the Information. However, the United States may use any information gathered during its investigation for any purpose, including, but not limited to, use in contempt proceedings and revocation proceedings. Nothing prevents the United States from pursuing any action against any individual.

19. Notwithstanding any other provision of this Agreement and during the term of the probationary period, if the United States, in its sole discretion, determines one of the INOTIV ENTITIES: (a) provided deliberately false, incomplete, or misleading information at any time in connection with this Agreement; (b) committed a felony during the term of this Agreement; or (c) failed to comply with any provision of this Agreement, (1) the United States will not be bound to their agreement not to prosecute INOTIV or the INOTIV ENTITIES for the matters covered in the Information, (2) INOTIV will not assert any claim under the United States Constitution, Rule 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, or any other rule or law, that any statements or testimony made by or on behalf of INOTIV prior or subsequent to this Agreement, or any leads derived therefrom, should be suppressed or are otherwise inadmissible, and (3) the United States may file any charges which were filed or could have been filed against INOTIV. It is understood that any prosecution not time-barred by the applicable statutes of limitations on the date INOTIV signed this Agreement may be commenced against any of the INOTIV ENTITIES, including, but not limited to, INOTIV, in the event of its knowing or intentional violation of a provision of this Agreement. Accordingly, INOTIV has executed and agrees to be bound by the Tolling Agreement included as Attachment 4. Should the United States determine that INOTIV has violated any provision of this Agreement, the United States shall provide prompt written notice to INOTIV addressed to its Chief Legal Officer, and to its outside counsel, Daniel Suleiman, Covington & Burling LLP, One CityCenter, 850 Tenth Street, NW Washington, DC 20001-4956 or to any successor INOTIV may designate, of the alleged violation and provide INOTIV with a 45-day period from the date of receipt of notice in which to make a presentation to the United States to demonstrate that no violation occurred, that any violation was unintentional or inadvertent, or, to the extent applicable, that the violation should not result in adverse action, including because the violation has been cured by INOTIV.

In re: Inotiv, Inc.

Resolution Agreement

20. INOTIV will agree to the entry of an order of the Court (attached as Attachment 5), in which INOTIV is ordered to comply with the terms of this Agreement and the Plea Agreement, and be subject to, in addition to the other remedies available in this Agreement, the jurisdiction of the Court for a proceeding that could result in contempt or any other remedy the Court deems appropriate should any of the INOTIV ENTITIES fail to comply with any term of the Agreement. For the purposes of a dispute over an alleged violation of the Agreement, a determination by the United States that one of the INOTIV ENTITIES failed to comply with a term of the Agreement shall not be binding on the Court. INOTIV agrees nothing will divest the Court of jurisdiction, including, but not limited to, any proceeding relating to bankruptcy, insolvency, reorganization, or relief of debtors.

21. INOTIV waives all rights, whether asserted directly or by a representative, to request or receive from the United States Department of Justice or the Virginia Office of the Attorney General any records pertaining to the investigation or prosecution of this case, including, without limitation, any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, the Privacy Act of 1974, 5 U.S.C. § 552a, or the Virginia Freedom of Information Act, Va. Code §§ 2.2-3700-3714.

22. Nothing in this Agreement resolves, in any way, any liability of any individual.

23. If the Court refuses to accept the Plea Agreement with the agreed-upon sentence, either party may withdraw from this Agreement by giving written notice to the other party within 10 days of the Court's rejection.

24. This Agreement, the Plea Agreement, and their attachments are the complete and only agreements between the United States and INOTIV concerning resolution of this matter. This Agreement, the Plea Agreement, and their attachments set forth the entire understanding between the parties and constitute the complete agreement between the United States and INOTIV and no other additional terms or agreements shall be entered except and unless those other terms or agreements are in writing and signed by the parties. INOTIV and the Commonwealth of Virginia have entered into a separate agreement (attached as Attachment 6).

25. INOTIV understands its Authorized Corporate Officer's signature on this Agreement constitutes a binding offer to enter into this Agreement. INOTIV understands the United States has not accepted INOTIV's offer until all of the authorized representatives of the United States have signed this Agreement and the Plea Agreement.

In re: Inotiv, Inc.

Resolution Agreement

26. INOTIV acknowledges its acceptance of this Agreement by the signature of its counsel and Authorized Corporate Officer. A copy of a resolution by INOTIV's Board of Directors authorizing its Authorized Corporate Officer to execute this Agreement and all other documents to resolve this matter on behalf of INOTIV is attached as Attachment 1.

Agreed to:

INOTIV, INC. and the INOTIV ENTITIES:

BY: <u>Andrea Castetter</u> Andrea Castetter Senior Vice President – General Counsel and Corporate Secretary, Inotiv, Inc <i>Authorized Corporate Officer for Inotiv, Inc. and the Inotiv Entities</i>	<u>June 1, 2024</u> DATE
---	-----------------------------

Counsel has fully explained to the Board of Directors of INOTIV the facts and circumstances of the prosecution and the consequences of entering into this Agreement. Counsel has reviewed this entire Agreement and documents referenced herein, and their attachments, with the client, through its Authorized Corporate Officer. INOTIV understands the terms and conditions of this Agreement, and INOTIV's decision to enter into this Agreement is knowing and voluntary. INOTIV's execution of and entry into this Agreement is done with Counsel's consent.

<u>Daniel Suleiman</u> Daniel Suleiman Christopher M. Denig Jeannie M. Perron, DVM Daniel T. Grant COVINGTON & BURLING LLP	<u>06/01/2024</u> DATE
---	---------------------------

Counsel for Inotiv, Inc. and the Inotiv Entities

In re: *Inotiv, Inc.*

Resolution Agreement

The United States Attorney's Office for the Western District of Virginia:

BY: *Christopher R. Kavanaugh* *6/3/2024*
 CHRISTOPHER R. KAVANAUGH DATE
United States Attorney
 RANDY RAMSEYER
Assistant United States Attorney
 MICHELLE WELCH
Special Assistant United States Attorney
 COREY HALL
Assistant United States Attorney
 CARRIE MACON
Assistant United States Attorney

The United States Department of Justice, Environmental Crimes Section:

BY: *Banumathi Rangarajan* *6/3/2024*
 TODD KIM DATE
Assistant Attorney General
 BANUMATHI RANGARAJAN
Senior Trial Attorney
 SARAH BROWN
Trial Attorney

TOLLING AGREEMENT

This Statute of Limitations Tolling Agreement (“Agreement”) is entered into between the INOTIV ENTITIES (collectively consisting of Inotiv, Inc., Envigo RMS, LLC, and Envigo Global Services, Inc., and all entities related to any of those entities, and all successors in interest to such entities) and the Government (collectively consisting of the United States Attorney’s Office for the Western District of Virginia, the Environmental Crimes Section of the United States Department of Justice, Environment and Natural Resources Division, and the Virginia Attorney General’s Office - Animal Law Unit).

A. This Agreement has been entered into to effect provisions of a Resolution Agreement and provide the INOTIV ENTITIES and the INOTIV ENTITIES’ counsel an opportunity to present information they believe may be relevant to the Government’s decision-making process regarding the INOTIV ENTITIES. The INOTIV ENTITIES, the INOTIV ENTITIES’ counsel, and the Government acknowledge that it is their mutual intention for this Agreement to effect a waiver and tolling of the statutes of limitations for violations of law described in paragraph B below.

B. This Agreement applies to any and all federal and state criminal offenses relating in any way to the INOTIV ENTITIES arising out of the Government’s investigation that led to the Plea Agreement to which this Agreement is attached.

C. The parties to this Agreement now agree and stipulate that the period beginning on April 1, 2024, and continuing until and including (i) 46 (forty-six) days after the completion of Envigo RMS, LLC’s and Envigo Global Services, Inc.’s probationary period or (ii) 46 (forty-six) days after the final payment is made pursuant to the Plea Agreement and Resolution Agreement, whichever is later (“Exclusion Period”), shall be forever excluded from any calculation of time for purposes of the application of any statute of limitations to any violation of law described in paragraph B above.

D. The parties to this Agreement further agree and stipulate that the Exclusion Period shall not be considered or assessed against the Government for purposes of any constitutional, statutory, or other challenge involving a claim of delay relating to any violation of law described in paragraph B above.

E. The INOTIV ENTITIES, having been advised by counsel of the potential consequences of this Agreement to the INOTIV ENTITIES’ rights under the Fifth and Sixth Amendments of the United States Constitution, the statutes of limitations, and Rule 48(b) of the Federal Rules of Criminal Procedure, expressly waive their right to raise any defense based on the failure of a grand jury, the United States, or the Commonwealth of Virginia to charge the INOTIV ENTITIES with any violation of law described in paragraph B above, during the Exclusion Period or any delay related to any trial as to such charges.

Attachment 4 to Resolution Agreement
In re: Inotiv, Inc.

Tolling Agreement

F. It is understood by the parties to this Agreement that nothing in this Agreement revives any criminal or civil charges for which the applicable statute of limitations ran prior to April 1, 2024.

G. The act of entering into this Agreement does not constitute an admission by the INOTIV ENTITIES of any wrongdoing; it has been entered into for the sole purpose of effectuating the Resolution Agreement entered into between the INOTIV ENTITIES, and for further discussions and the exchange of information with the Government. This Agreement and its contents are admissible in evidence in any proceeding solely for the purpose of establishing that the INOTIV ENTITIES voluntarily agreed to a tolling of applicable statutes of limitations. The Agreement is inadmissible for any other purpose.

H. Except as otherwise stated herein, this Agreement does not limit or affect the right or discretion of the Government or any component of the United States Department of Justice, to bring criminal charges against the INOTIV ENTITIES for violation of any law described in paragraph B above, or any other violation of law, at any time.

Agreed to:

INOTIV, INC. and the INOTIV ENTITIES:

BY:

Andrea Castetter
Andrea Castetter
Senior Vice President – General Counsel
and Corporate Secretary, Inotiv, Inc
*Authorized Corporate Officer
for Inotiv, Inc. and the Inotiv Entities*

May 29, 2024
DATE

Daniel Suleiman
Daniel Suleiman
Christopher M. Denig
Jeannie M. Perron, DVM
Daniel T. Grant
COVINGTON & BURLING LLP


05/29/2024
DATE

Counsel for Inotiv, Inc. and the Inotiv Entities

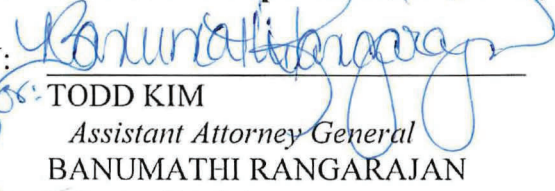
Attachment 4 to Resolution Agreement
In re: Inotiv, Inc.

Tolling Agreement

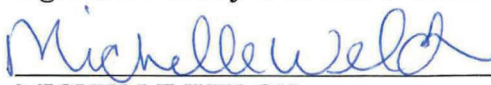
The United States Attorney's Office for the Western District of Virginia:

BY:  6/3/2024
 CHRISTOPHER R. KAVANAUGH DATE
United States Attorney
 RANDY RAMSEYER
Assistant United States Attorney
 MICHELLE WELCH
Special Assistant United States Attorney
 COREY HALL
Assistant United States Attorney
 CARRIE MACON
Assistant United States Attorney

The United States Department of Justice, Environmental Crimes Section:

BY:  6/3/2024
 TODD KIM DATE
Assistant Attorney General
 BANUMATHI RANGARAJAN
Senior Trial Attorney
 SARAH BROWN
Trial Attorney

The Virginia Attorney General's Office - Animal Law Unit:

BY:  6/3/2024
 MICHELLE WELCH DATE
Senior Assistant Attorney General
Director of the Animal Law Unit

*Attachment 5 to Resolution Agreement
In re: Inotiv, Inc.*

Order Compelling Compliance

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
LYNCHBURG DIVISION**

CLERKS OFFICE U.S. DIST. COURT
AT LYNCHBURG, VA
FILED

6/3/2024

IN RE:

INOTIV, INC.

)
)
)
)
)

Case No. 6:24MC00001

LAURA A. AUSTIN, CLERK
BY: s/ CARMEN AMOS
DEPUTY CLERK

**AGREED ORDER COMPELLING COMPLIANCE
WITH RESOLUTION AGREEMENT**

The INOTIV ENTITIES (collectively consisting of Inotiv, Inc., Envigo RMS, LLC, and Envigo Global Services, Inc., and all entities related to any of those entities) have been the subject of an investigation by the United States Attorney for the Western District of Virginia and the Environmental Crimes Section of the United States Department of Justice, Environment and Natural Resources Division (collectively referred to as the "United States"), concerning potential violations of federal criminal law. The United States and Inotiv, Inc. ("INOTIV") have entered into an agreement to resolve this matter by way of a Resolution Agreement attached as Exhibit 1. The Parties agree the Court has (a) jurisdiction over the subject matter, the United States, INOTIV, and the INOTIV ENTITIES, and the Resolution Agreement, and (b) authority to enter and enforce this order compelling INOTIV and the INOTIV ENTITIES to comply with the terms of the Resolution Agreement.

Accordingly, based on the agreement of the United States and INOTIV and for good cause shown, the INOTIV ENTITIES, including, but not limited to, INOTIV, and any

Attachment 5 to Resolution Agreement
In re: Inotiv, Inc.

Order Compelling Compliance

successors in interest are hereby ORDERED to fully comply with the terms of the Resolution Agreement.

The Court may impose any sanction it deems appropriate for any violation of a term of the Resolution Agreement and/or this Order. Also, any violation of a term of the Resolution Agreement and/or this Order by any of the INOTIV ENTITIES, including, but not limited to, INOTIV, or any successor, may be punished as contempt of court, including, but not limited to, criminal contempt, in violation of Title 18, United States Code, Section 401.

Entered this 3rd day of June, 2024.



United States District Judge

Part of Attachment B to Plea Agreement
United States v. Envigo RMS, LLC & Envigo Global Services, Inc.

Authorized Corporate Officer's Initials: AC

*Attachment 5 to Resolution Agreement
In re: Inotiv, Inc.*

Order Compelling Compliance

Agreed to:

INOTIV, INC. and INOTIV ENTITIES:

BY:

Andrea Castetter

Andrea Castetter
Senior Vice President – General Counsel
and Corporate Secretary, Inotiv, Inc
*Authorized Corporate Officer
for Inotiv, Inc. and the Inotiv Entities*

June 1, 2024

DATE

D - Suleiman

Daniel Suleiman
Christopher M. Denig
Jeannie M. Perron, DVM
Daniel T. Grant
COVINGTON & BURLING LLP

06/01/2024

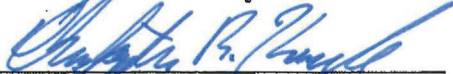
DATE

Counsel for Inotiv, Inc. and the Inotiv Entities

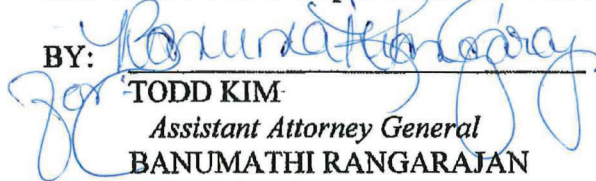
Attachment 5 to Resolution Agreement
In re: Inotiv, Inc.

Order Compelling Compliance

The United States Attorney's Office for the Western District of Virginia:

BY:  6/3/2024
 CHRISTOPHER R. KAVANAUGH DATE
United States Attorney
 RANDY RAMSEYER
Assistant United States Attorney
 MICHELLE WELCH
Special Assistant United States Attorney
 COREY HALL
Assistant United States Attorney
 CARRIE MACON
Assistant United States Attorney

The United States Department of Justice, Environmental Crimes Section:

BY:  6/3/2024
 TODD KIM DATE
Assistant Attorney General
 BANUMATHI RANGARAJAN
Senior Trial Attorney
 SARAH BROWN
Trial Attorney

Attachment 6 to Resolution Agreement
In re: Inotiv, Inc.

Virginia Agreement



COMMONWEALTH of VIRGINIA
Office of the Attorney General

Jason S. Miyares
Attorney General

202 North 9th Street
Richmond, Virginia 23219
804-786-2071
FAX 804-786-1991
Virginia Relay Services
800-828-1120

The Commonwealth of Virginia (“Commonwealth”) has been fully apprised of the Plea Agreement and Resolution Agreement reached between Envigo RMS, LLC, Envigo Global Services, Inc., Inotiv, Inc., and all entities related to Inotiv, Inc., and all successors in interest to such entities (collectively “INOTIV ENTITIES”) and the United States. The Commonwealth is aware of the comprehensive resolution which includes, among other terms, the payment of sizable sums, and the agreement by the INOTIV ENTITIES to improve their facilities and personnel and to comply with 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.

Accordingly, the Commonwealth and the INOTIV ENTITIES hereby agree as follows:

1. The INOTIV ENTITIES shall fully comply with all terms of the Plea Agreement and Resolution Agreement reached with the United States.
2. The INOTIV ENTITIES waive any statute of limitations defense to any charges brought by the Commonwealth related to the Envigo dog breeding facility located in Cumberland County, Virginia (“Cumberland Facility”), as reflected in the Tolling Agreement.
3. The Commonwealth agrees if the INOTIV ENTITIES fully comply with every provision of the Plea Agreement and Resolution Agreement reached with the United States, it will not bring any charges against the INOTIV ENTITIES related to conduct covered by the Information.
4. Nothing prevents the Commonwealth from pursuing any action against any individual, including but not limited to any criminal, civil, administrative, or forfeiture proceeding.

Part of Attachment B to Plea Agreement
United States v. Envigo RMS, LLC & Envigo Global Services, Inc.

Authorized Corporate Officer's Initials: AC

Attachment 6 to Resolution Agreement
In re: Inotiv, Inc.

Virginia Agreement

The INOTIV ENTITIES understand if they fail to comply with any provision in the Plea Agreement or Resolution Agreement, the Commonwealth will be free to bring any charges related to the Cumberland Facility.

Agreed to:

INOTIV, INC. and the INOTIV ENTITIES

BY: Andrea Castetter
Andrea Castetter
Senior Vice President – General Counsel
and Corporate Secretary, Inotiv, Inc.
*Authorized Corporate Officer
for Inotiv, Inc. and the Inotiv Entities*

May 29, 2024
DATE

Counsel has fully explained to the Board of Directors of Inotiv, Inc, the facts and circumstances of the case and the consequences of entering into this agreement. Inotiv, Inc. and the INOTIV ENTITIES understand the terms and conditions of this agreement, and the INOTIV ENTITIES’ decision to enter into this agreement is knowing and voluntary. The INOTIV ENTITIES’ execution of and entry into this agreement is done with Counsel’s consent.

D. / S. —
Daniel Suleiman
Christopher M. Denig
Jeannie M. Perron, DVM
Daniel T. Grant
COVINGTON & BURLING LLP

05/29/2024
DATE

Counsel for Inotiv, Inc. and the Inotiv Entities

COMMONWEALTH OF VIRGINIA

BY: Michelle Welch
MICHELLE WELCH
*Senior Assistant Attorney General
Director of the Animal Law Unit*

6/3/2024
DATE

*Part of Attachment B to Plea Agreement
United States v. Envigo RMS, LLC & Envigo Global Services, Inc.*

Authorized Corporate Officer's Initials: AC

Attachment 3 to Resolution Agreement
In re: Inotiv, Inc.

Information

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
LYNCHBURG DIVISION

CLERKS OFFICE U.S. DIST. COURT
AT LYNCHBURG, VA
FILED

6/3/2024

LAURA A. AUSTIN, CLERK
BY: s/ CARMEN AMOS
DEPUTY CLERK

UNITED STATES OF AMERICA)	
)	Case No. 6:24CR16
v.)	
)	Violations: 18 U.S.C. § 371
)	7 U.S.C. § 2149(d)
ENVIGO RMS, LLC)	33 U.S.C. §§ 1311, 1319(c)(2)(A)
ENVIGO GLOBAL SERVICES, INC.)	

INFORMATION

The United States Attorney and the Assistant Attorney General for the Environment and Natural Resources Division of the United States Department of Justice charge that:

COUNT ONE

I. INTRODUCTORY STATEMENT

1. ENVIGO RMS, LLC (“ENVIGO RMS”) and other persons conspired, in violation of 18 U.S.C. § 371, to knowingly violate the Animal Welfare Act, 7 U.S.C. § 2131 *et seq.* and the standards, rules, and regulations promulgated thereunder (hereinafter collectively referred to as the “AWA”), by failing to provide, among other things, adequate veterinary care, adequate staffing, and safe and sanitary living conditions for the dogs housed at ENVIGO RMS’s dog breeding facility located in Cumberland County, Virginia (“Cumberland Facility”). Despite being on notice since at least July 2021 that the conditions at the Cumberland Facility fell below the AWA’s minimum standards,

Attachment C to Plea Agreement
United States v. Envigo RMS, LLC & Envigo Global Services, Inc.

ENVIGO failed to take the necessary steps to ensure that the Cumberland Facility complied with the AWA.

2. In addition, ENVIGO GLOBAL SERVICES INC. (collectively, with ENVIGO RMS, “ENVIGO”) and other persons conspired, in violation of 18 U.S.C. § 371, to violate the Clean Water Act (“CWA”), 33 U.S.C. § 1251 *et seq.*, by failing to properly operate and maintain the wastewater treatment plant at the Cumberland Facility. ENVIGO’s failure to properly repair, operate, and maintain its wastewater treatment plant resulted in exceedances of effluent limits, unauthorized discharges, and unsanitary conditions.

II. OVERVIEW AND BACKGROUND

DEFENDANTS AND CORPORATE STRUCTURE

3. ENVIGO RMS, a Delaware limited liability company, was a wholly owned subsidiary of Envigo RMS Holding Corp., an Indiana corporation. Envigo RMS Holding Corp. was formed on April 9, 2019, in anticipation of the acquisition of animal breeding facilities held by another business entity, hereinafter referred to as Corporation A, which included the Cumberland Facility.

4. ENVIGO RMS, headquartered in Indianapolis, Indiana, conducted business in the pharmaceutical and biotechnology industries. On June 3, 2019, ENVIGO RMS registered to transact business in the Commonwealth of Virginia as a foreign limited liability corporation.

5. Envigo RMS Holding Corp., through restructuring acquired Corporation B, a foreign for-profit corporation formed in Pennsylvania, with a principal place of business in Denver, Pennsylvania. On August 1, 2019, Corporation B was renamed ENVIGO GLOBAL SERVICES, INC. On August 8, 2019, ENVIGO GLOBAL SERVICES, INC. filed an assumed business name filing with the Indiana Secretary of State that it would conduct business under the name of Envigo Research Products, Inc. Hereinafter, both ENVIGO GLOBAL SERVICES, INC. and Envigo Research Products, Inc. will be collectively referred to as “EGSI.”

6. Among other things, ENVIGO bred, exported, and sold research-quality animals for medical and scientific research purposes at the Cumberland Facility located within the Western District of Virginia. EGSI owned the Cumberland Facility and paid the salaries of the employees, including attending veterinarians, that worked at the Cumberland Facility. ENVIGO RMS at times paid the salaries of attending veterinarians. ENVIGO held the regulatory licenses and/or the permits necessary for the business to operate.

7. Commercial animal dealers, like ENVIGO, are regulated and licensed by the United States Department of Agriculture (“USDA”), Animal and Plant Health Inspection Service (“APHIS”). APHIS issues a Class A license to dealers who sell animals that are bred and raised at the dealer’s facility in a closed or stable colony.

8. ENVIGO RMS applied to APHIS for a Class A license around June 2019. By signing the application form, ENVIGO RMS acknowledged that it had reviewed and

agreed to comply with the AWA. APHIS issued Class A dealer license 32-A-0774 to ENVIGO RMS. The license covered the Cumberland Facility.

9. On September 21, 2021, Inotiv, Inc., a pharmaceutical development company, agreed to purchase ENVIGO. The purchase was completed on November 5, 2021. The Cumberland Facility remained an approved site under ENVIGO RMS's AWA license 32-A-0774.

10. As a licensed animal dealer, ENVIGO's facilities were subject to ongoing inspection by APHIS to ensure it operated in compliance with the AWA. APHIS concluded each inspection with the issuance of an inspection report documenting any violations found, the severity of those violations, and a date by which ENVIGO needed to correct those violations.

ENVIGO'S CUMBERLAND, VIRGINIA FACILITY

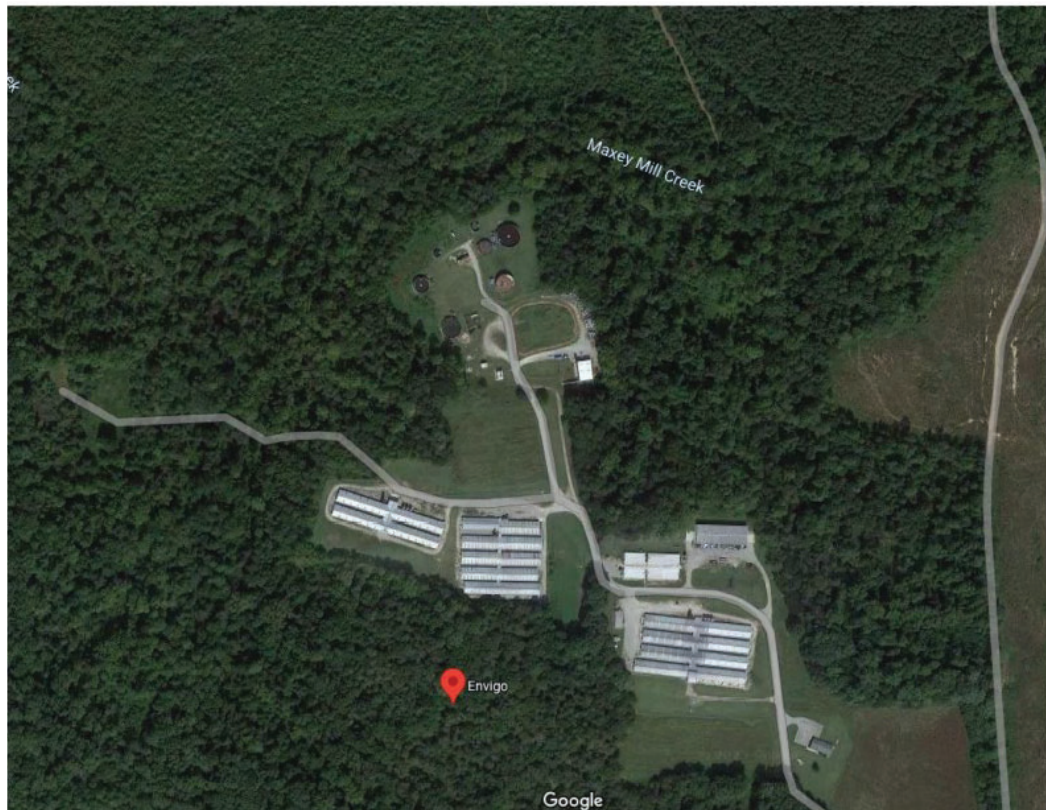
11. The Cumberland Facility, which is located at 482 Frenchs Store Road, Cumberland, Virginia, is identified as Site 005 on the inspection reports prepared by APHIS for license 32-A-0774.

12. The Cumberland Facility is a large multi-building commercial animal breeding facility that housed upwards of 5,000 dogs at any given time. In 2019, the Cumberland Facility shipped 4,795 beagles to purchasers, amounting to approximately \$4,716,686 in sales. In 2020, the Cumberland Facility shipped 4,085 beagles to purchasers, amounting to approximately \$4,442,030 in sales. In 2021, the Cumberland Facility shipped 4,675 beagles to purchasers, amounting to approximately \$5,044,888 in sales. Between

January 2022 and May 2022, the Cumberland Facility shipped 1,439 beagles to purchasers, amounting to approximately \$1,625,648 in sales. ENVIGO kept an average of 4,874 dogs per month on site in 2019, 5,378 dogs per month on site in 2020, and 5,134 dogs per month on site in 2021.

13. The Cumberland Facility consisted of multiple large kennel buildings, office buildings, storage facilities, medical facilities, maintenance facilities, an incinerator, and a wastewater treatment plant, as depicted in Photograph 1 below.

Photograph 1. Aerial photograph of the Cumberland Facility (Source: Google Maps).



14. The Cumberland Facility's onsite employees included a site director, manager of operations, administrative and maintenance personnel, animal technicians, and an attending veterinarian. ENVIGO's "Executive Leadership Team" was offsite, primarily

in the United States. The Executive Leadership Team consisted of the Chief Executive Officer, Chief Finance Officer, Chief Operating Officer (“COO”), Senior Vice President of Veterinary Services (“SVP-VS”), Senior Vice President of Human Resources, and the Senior Vice President of Commercial. ENVIGO’s SVP-VS and Chief Finance Officer were in the United Kingdom.

III. ANIMAL WELFARE ACT

15. 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. 7 U.S.C. § 2131 *et seq.*; 9 C.F.R. §§ 2.1-3.20.

16. The AWA is administered by the Secretary of Agriculture or his representative. 7 U.S.C. § 2151. 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.

17. The Secretary has promulgated regulations and standards to govern the humane handling, care, treatment, and transportation by dealers, which includes the minimum requirements for adequate veterinary care and housing. 7 U.S.C. § 2143(a)(1), (a)(2)(A); 9 C.F.R. §§ 3.1, 3.20. Dealers must comply in all respects with these regulations and standards. 7 U.S.C. § 2149(d); 9 C.F.R. §§ 2.1-3.20.

18. When construing or enforcing the provisions of the AWA, 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.

19. 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”).

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

21. 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).

22. The Secretary will issue a license to a dealer upon application, provided that no such license will be issued until the dealer has demonstrated that his facilities comply with the standards promulgated by the Secretary pursuant to 7 U.S.C. § 2143. 7 U.S.C. § 2133.

23. By signing the application form, the applicant acknowledges that it has reviewed the AWA and agrees to so comply. 9 C.F.R. § 2.2.

24. The AWA requires the Secretary to make investigations and inspections as necessary to determine whether any dealer has violated any provision of the AWA. 7 U.S.C. § 2146(a).

25. Animal Care is a program under APHIS, which, as relevant here, is tasked with conducting the inspections to ensure compliance with promulgated regulations and standards, and ultimately, ensuring the humane treatment of animals covered by the AWA.

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

27. During an inspection, inspectors must document critical and direct violations of the AWA. A critical noncompliance is one that has a serious or severe adverse effect on the health and well-being of the animals. 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.

28. The AWA further mandates that the Animal Care inspector shall have access to the place of business and the facilities, animals, and records. 7 U.S.C. § 2146(a); 9 C.F.R. § 2.126.

IV. FACTUAL BACKGROUND

INSPECTION HISTORY OF THE CUMBERLAND FACILITY

29. Between July 2021 and May 2022, ENVIGO amassed over 60 citations at the Cumberland Facility for non-compliance with the AWA. More than half of those citations were deemed critical or direct, the most serious types of citation.

30. The first inspection by APHIS of the Cumberland Facility following ENVIGO's acquisition of the site took place in August 2019. It was a focused inspection and included no citation. APHIS did not inspect the Cumberland Facility in 2020. The next APHIS inspection of the Cumberland Facility was in July 2021. During the routine inspection, APHIS documented violations of 18 different provisions of the AWA, of which 10 of the violations were deemed to be direct or critical.

31. APHIS conducted subsequent inspections of the Cumberland Facility over the next several months. At each inspection APHIS documented violations, many of which were direct and critical. APHIS also cited ENVIGO for multiple repeat violations, including noncompliant items APHIS identified as early as the July 2021 inspection. By the March 2022 inspection, ENVIGO had been on notice that it needed to correct its violations for eight months. ENVIGO had undertaken a series of actions to address the non-compliant items identified by APHIS. The actions were insufficient; APHIS cited ENVIGO for five violations of the AWA at the March inspection. All were repeat violations, and two were direct violations. On May 3, 2022, during the course of a focused inspection, APHIS cited ENVIGO for one repeat violation.

32. On May 18, 2022, the USDA Office of Inspector General and other law enforcement began executing a multi-day federal search warrant at the Cumberland Facility. While on site, law enforcement and experts assisting in the execution of the warrant determined that serious and adverse conditions continued to exist at the Cumberland Facility.

33. Pursuant to the warrant, 445 beagles from the Cumberland Facility were seized after they were found to be in acute distress by two licensed veterinarians. 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.

34. On May 19, 2022, the United States filed a civil Complaint for Declaratory and Injunctive Relief and an Emergency Motion for Temporary Restraining Order against ENVIGO RMS in the United States District Court for the Western District of Virginia. On May 21, 2022, the Honorable District Judge Norman K. Moon granted the government's motion and issued a Temporary Restraining Order. On June 17, 2022, the Court granted a preliminary injunction.

35. By September 6, 2022, and pursuant to a consent agreement, ENVIGO transferred all the remaining beagles out of the Cumberland Facility, ending commercial operation at the Cumberland Facility.

36. ENVIGO ceased operations at the Cumberland Facility as of January 24, 2024.

INADEQUATE VETERINARY CARE

37. ENVIGO and its predecessor hired and retained an inadequate attending veterinarian, hereinafter “AV,” from May 2018 through April 2022, and failed to establish and maintain a program of adequate veterinary care at the Cumberland Facility, all in violation of the AWA. *See* 9 C.F.R. § 2.40(a) (Each dealer must employ an “attending veterinarian,” who must “provide adequate veterinary care to [the dealer’s] animals in compliance with [the AWA].” 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.”). Additionally, 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 AWA requires the program of veterinary care to include specific requirements to ensure the humane treatment of animals. *See, e.g.*, 9 C.F.R. § 2.40(b) (requirements for physical examinations, vaccines, and preventative care); 9 C.F.R. § 2.40(b)(2) (treatment of diseases and injuries, availability of off-hours care); 9 C.F.R. § 2.40(b)(3) (daily observation and communication between veterinarian and staff); 9 C.F.R. § 2.40(b)(4) & (5) (anesthesia, euthanasia, and procedural requirements).

38. ENVIGO RMS’s predecessor, Corporation A, conducted an interview process for an attending veterinarian at the Cumberland Facility in 2018. The hiring process was led by Corporation A employees who became ENVIGO employees after the 2019 business acquisition. AV was interviewed and ultimately selected as part of that process.

Attachment 3 to Resolution Agreement
In re: Inotiv, Inc.

Information

During AV's interview process, Corporation A's site supervisor expressed concerns over the selection of AV. Even so, Corporation A hired AV. After ENVIGO RMS acquired the Cumberland Facility on June 3, 2019, ENVIGO continued to employ AV despite continued employee complaints about AV's adequacy as a surgeon and as a supervisor of technicians, a communication breakdown between AV and employees, and AV's failure to show up for work. Repeated complaints by site supervisors and requests to remove AV as the attending veterinarian were denied or ignored by the Vice President of North American Operations ("VP-NOA") and members of the Executive Leadership Team, including the COO and the SVP-VS, who was AV's direct supervisor.

39. The SVP-VS was aware of a multitude of ongoing concerns with AV's adequacy as a veterinarian. Shortly after AV was hired, and continuing until she eventually resigned from her position, the SVP-VS received numerous requests to remove AV as the attending veterinarian. Rather than terminate AV, the SVP-VS and other members of the Executive Leadership Team worked to provide AV additional resources and support, and SVP-VS met with AV, other members of the Executive Leadership Team, and site supervisors to monitor AV's performance. Nonetheless, although the SVP-VS was AV's direct supervisor and was aware of concerns regarding the adequacy of AV's performance for years, he never terminated or recommended termination of AV.

40. For example, in February 2021, the Cumberland Facility site supervisor observed AV mishandle the surgeries of five dogs. Immediately thereafter, the site

Attachment C to Plea Agreement
United States v. Envigo RMS, LLC & Envigo Global Services, Inc.

supervisor provided the COO, SVP-VS, and Senior Human Resource Business Partner with a log of concerns regarding AV's abilities.

41. Shortly thereafter, and after further investigation, the Senior Human Resources Business Partner recommended to the COO, VP-NOA, and SVP-VS that AV be terminated. The COO, VP-NOA, and the Senior Vice President of Human Resources decided to retain AV despite this recommendation.

42. Although the site supervisor also recommended hiring a new veterinarian to replace AV, the COO refused to fire AV claiming it was hard to find a veterinarian for the Cumberland Facility.

43. Staff rejection of AV's authority paired with AV's inadequate veterinary skills led to multiple additional improper and inadequate veterinary practices at the Cumberland Facility, including, but not limited to: ENVIGO employees on multiple occasions failed to follow euthanasia practices and instead used euthanasia methods causing pain and suffering to dogs; and ENVIGO employees on multiple occasions withheld anesthesia from conscious dogs before performing intracardiac injection euthanasia.

44. AV also failed to ensure healthy dogs left the Cumberland Facility when fulfilling orders to ENVIGO's clients. At times, AV failed to perform adequate head to toe health checks of the dogs before shipment. In some instances, dead and sick animals were received by clients. Clients complained to ENVIGO that the dogs they received in

shipments were unhealthy. The Executive Leadership Team knew of these issues but continued to employ AV and allowed the dogs to be shipped.

45. AV's lack of oversight at the Cumberland Facility also involved the falsification of records. ENVIGO employees knowingly falsely signified they recorded temperatures for refrigerated medications for several months when they had not.

46. ENVIGO refused to terminate AV even though members of the Executive Leadership Team knew AV was not providing adequate veterinary care to the dogs at the Cumberland Facility, which contributed to 445 animals classified in acute distress and needing immediate medical attention by two licensed veterinarians during the May 2022 federal search warrant.

47. AV resigned from her position as attending veterinarian at the Cumberland Facility in April 2022.

FAILURE TO PROVIDE POTABLE WATER TO DOGS

48. The AWA mandates that potable water – that is, water suitable for drinking – must be continuously available to dogs unless restricted by the attending veterinarian. 9 C.F.R. §§ 3.10(a), 3.1(d). ENVIGO failed to abide by the AWA's requirement to provide potable water at the Cumberland Facility.

49. ENVIGO knew the water provided to the dogs at the Cumberland Facility was not suitable for drinking and provided bottled water and water coolers for its employees. At other times, ENVIGO posted a "Boil Water" notice for its employees at the

facility. Notwithstanding, and in violation of the AWA, ENVIGO continued to provide the non-potable water to the dogs at the facility.

50. The AWA also mandates that potable water be used for cleaning and other husbandry requirements. 9 C.F.R. § 3.1(d). ENVIGO violated this requirement, and several other sanitation-related restrictions, by using the contaminated well water to power wash kennels, creating an increased risk of disease.

INADEQUATE HOUSING AND PRIMARY ENCLOSURES

51. ENVIGO violated several provisions of the AWA at the Cumberland Facility by failing to ensure that the primary enclosures at the facility provided the required flooring space to each dog and were constructed and maintained in a manner to protect dogs from injury. *See, e.g.*, 9 C.F.R. § 3.6(a)(2)(ii), (c)(1)(i).

52. The AWA required ENVIGO to provide each dog, nursing mom, and puppy, a minimum amount of floor space. 9 C.F.R. § 3.6(c)(1)(i), (ii). ENVIGO failed to house dogs, including nursing mothers and their puppies, in kennels with the required floor space.

53. In July 2021, APHIS found 62 nursing mothers and their 393 puppies housed in enclosures at the Cumberland Facility that failed to provide the minimum amount of floor space required by the AWA.

54. At the Cumberland Facility, 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. 9 C.F.R. § 3.6(c)(1)(i). APHIS inspectors found additional overcrowded enclosures in another building containing 15 enclosures with four-

to-five-month-old beagles. APHIS inspectors determined that enclosures in another room measured a total of 39.7 square feet. However, some of those 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 square feet. Yet, ENVIGO co-housed up to 11 dogs in each enclosure, which would require at least 58.9 feet of space.

55. Four months after APHIS advised ENVIGO of the negative impacts to dogs without the minimum amount of floor space (distress, discomfort, crowding, poor sanitation, increased trauma, and mortality), ENVIGO again violated an overcrowding regulation at the Cumberland Facility. In November 2021, APHIS found ENVIGO failed to provide a total of 742 dogs and weaned puppies with the minimum space mandated by the AWA. Six months later, in May 2022, ENVIGO still failed to provide dogs with the minimum space required at the Cumberland Facility.

56. The AWA requires primary enclosures be structurally sound and maintained in good repair to protect animals from injury and to contain the animals. 9 C.F.R. § 3.6(a). At the Cumberland Facility, ENVIGO failed to protect the dogs from injury (9 C.F.R. § 3.6(a)(2)(ii)) and have flooring that protected the dogs' feet and legs from injury and did not allow the dogs' feet to pass through openings in the floor (9 C.F.R. § 3.6(a)(2)(x)).

57. ENVIGO failed to prevent injury to dogs caused by the Cumberland Facility's flooring since at least the July 2021 APHIS inspection. APHIS notified ENVIGO that the kennel flooring was especially dangerous due to the gaps in the slatted floor that trapped the paws of dogs and puppies as young as six-to-seven weeks old. APHIS

inspectors at the Cumberland Facility observed dogs whose feet or toes were stuck in the slat flooring, or whose legs or feet had fallen through the flooring. On multiple occasions, these dogs required assistance to free their limbs.

58. The problem increased after the July 2021 APHIS inspection when ENVIGO implemented daily rough hosing of the kennels at the Cumberland Facility. This practice led to slippery flooring that increased the frequency of dogs' limbs getting stuck or falling through the flooring. Although ENVIGO knew the flooring presented a constant risk to the dogs, it failed to correct the problem. APHIS cited ENVIGO for its inadequate flooring at every inspection conducted between July 2021 and May 2022. As late as May 3, 2022, APHIS found two dogs stuck in the flooring. One of the dogs required a couple of minutes of manipulation before ENVIGO employees could free her foot. The dogs at the Cumberland Facility spent each day on the noncompliant flooring until they were seized during the May 2022 federal search warrant or surrendered afterward.

59. ENVIGO also failed to protect the dogs at the Cumberland Facility from injury by using a kennel system that allowed dogs to have their body parts bitten or pulled through the kennel walls by dogs in neighboring kennels. Dog enclosures must be constructed and maintained so that they keep other animals from entering the enclosure. 9 C.F.R. § 3.6(a)(2)(iv). This violation stemmed from other noncompliant activity at the facility: failing to maintain kennels in good repair to prevent gaps and loose kennel walls and failing to maintain overcrowding and compatible groups of dogs which can lead to aggressive disposition, fighting, injury, and death. *See* 9 C.F.R. §§ 3.1(a), 3.7.

60. ENVIGO's failure to maintain kennels in good repair at the Cumberland Facility included using flooring that was not cut to the same size and shape as the kennel walls, resulting in large gaps in between the floor and fencing. This problem resulted in dogs falling or stepping into the gaps, resulting in injury to some dogs.

61. At times, ENVIGO housed dogs in kennels with various other structural damages that created hazards and resulted in injuries to dogs at the Cumberland Facility. ENVIGO kept dogs in kennels with damaged access doors, damaged door frames, exposed gaps, rust, metal flashing, sharp points and edges, broken chain link, and unsecured walls and flooring. ENVIGO also used numerous broken waterers and feeders in the kennels.

SANITATION

62. The AWA requires primary enclosures and food and water receptacles to be cleaned and sanitized. 9 C.F.R. § 3.11. ENVIGO was required to clean the primary enclosures at the Cumberland Facility daily to remove excreta and food waste, and to reduce disease hazards, insects, pests, and odors. 9 C.F.R. § 3.11(a). ENVIGO was also required to remove dogs from the primary enclosures when employees used water to clean the enclosures, unless the dogs would not be wetted in the cleaning process. 9 C.F.R. § 3.11(a).

63. Until the July 2021 APHIS inspection, ENVIGO employees at the Cumberland Facility engaged in a practice of cleaning kennels once every two weeks. ENVIGO employees allowed feces to accumulate in the pens and troughs below. ENVIGO

failed to remove waste to the point that mold grew on piles of feces inside the troughs below the kennels.

64. ENVIGO eventually installed black mats on top of the noncompliant flooring in some kennels at the Cumberland Facility, but the mats were not porous and allowed urine and feces to pool. Because the mats were not cleaned often enough, the dogs had to stand, sleep, or lie in their urine and feces. Pursuant to the AWA, the surface of housing facilities must be constructed to allow them “to be readily cleaned and sanitized, or removed or replaced when worn or soiled.” 9 C.F.R. § 3.1(c)(1).

65. In May 2022, many dogs were observed with painful and inflamed paws because of regular contact with dirty flooring at the Cumberland Facility. The AWA mandates housing facilities must have floors cleaned to ensure that all animals can avoid contact with excreta. 9 C.F.R. § 3.1(c)(3).

66. When ENVIGO employees cleaned the kennels at the Cumberland Facility, they sprayed the kennels without first removing the dogs, or without drying the kennels before replacing the dogs. The enclosures were located opposite from a heat source, had no solid resting surface or bedding, and no functioning heat lamps. Even after APHIS notified ENVIGO of the heat source issue, ENVIGO failed to immediately resolve the problem and several puppies were found shivering in their enclosure days later.

67. ENVIGO failed to sanitize some of the primary enclosure food and water receptacles at the Cumberland Facility. 9 C.F.R. § 3.11(b). Some automatic waterers inside the kennels were coated with a black mold-like substance, rust-colored debris, and grime.

Some feeders were inadequately and infrequently sanitized, resulting in unpalatable food for the dogs. APHIS notified ENVIGO of these issues as early as November 2021, but these conditions continued as late as May 2022. In March 2022, APHIS inspectors noted that grime was still present and had built up on several feeders.

CONTAMINATED FEED AND DEPRIVATION OF FOOD

68. The AWA required ENVIGO to provide the dogs at the Cumberland Facility food that was uncontaminated, wholesome, palatable, and of sufficient quantity and nutritive value to maintain the normal condition and weight of the dogs. 9 C.F.R. § 3.9(a). ENVIGO was also required to store supplies of food to minimize contamination by excreta, pests, and water. 9 C.F.R. § 3.9(b). ENVIGO must have ensured that the food was not molding, and that the surfaces in the kennels in contact with the animals were “impervious to moisture.” 9 C.F.R. §§ 3.9(b), 3.2(d).

69. At times, ENVIGO fed some dogs at the Cumberland Facility food that was wet or contaminated with maggots, moldy, and interspersed with live insects. Additionally, the food receptacles were not kept in a manner to minimize contamination; they were not impervious to water and their placement allowed water and feces on the kennel floors to be sprayed back into the feeders. APHIS notified ENVIGO of the food contamination issues as early as July 2021, but these issues remained unresolved for months, and were observed again in March and May 2022.

70. The AWA mandates that dogs must be fed at least once each day, except as otherwise might be required to provide adequate veterinary care. 9 C.F.R. § 3.9(a).

ENVIGO withheld food from nursing mothers at the Cumberland Facility for multi-day periods and maintained this practice for several years. ENVIGO withheld food from mothers by turning the feeder attached to the enclosure around so it was inaccessible to the mother but remained in a position where she could see and smell the food. ENVIGO employees engaging in this practice signed forms falsely indicating the mothers had been fed on days when they had not.

71. After APHIS inspectors, the Cumberland Facility’s manager of operations, and AV instructed employees at the Cumberland Facility to cease the practice of withholding food, employees nevertheless agreed amongst themselves to continue the practice and did so for months. Those ENVIGO employees continued to falsely log that they checked the mother dogs’ feed each day and ensured they had food, when in fact, they had not.

HVAC AND SHELTER VIOLATIONS

72. The AWA mandates that the sheltered part of sheltered housing facilities must be “sufficiently heated and cooled when necessary” to protect the dogs from temperature or humidity extremes. 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). Additionally, the ambient air temperature “must not rise above 85 degrees Fahrenheit for more than 4 consecutive hours” when dogs are present. 9 C.F.R. § 3.2(a). Animals must be 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).

73. ENVIGO maintained inadequate cooling mechanisms at the Cumberland Facility. In July 2021, APHIS inspectors observed hundreds of dogs housed in areas that had temperatures above 85 degrees Fahrenheit for at least 5 hours. Some of the affected dogs were currently receiving medical treatment. Two months later in September 2021, temperatures again exceeded 85 degrees Fahrenheit.

74. For years, the Cumberland Facility did not have adequate cooling mechanisms in its kennels. In early May 2022, to prepare for the summer months, ENVIGO scheduled an air conditioning contractor to address the inadequate cooling mechanisms, and a contractor arrived during execution of the May 2022 federal search warrant. That action, however, was also inadequate and did not resolve the high temperatures in the kennels.

75. The winter months resulted in additional temperature-related violations at the Cumberland Facility. In November 2021, APHIS inspectors cited the facility for failing to maintain certain enclosure flaps allowing indoor and outdoor access for the dogs. Until ENVIGO fixed the flaps, the flaps were damaged or missing resulting in element exposure, including freezing temperatures, to the dogs.

PESTS

76. The AWA required ENVIGO to maintain a program for the control of pests “so as to promote the health and well-being of the animals and reduce contamination by

pests in animal areas.” 9 C.F.R. § 3.11(d). Pests were present throughout the buildings at the Cumberland Facility, including in dog food. The facility’s dog feeders contained ants, flies, worms, and black beetles. Large feed bins at the facility contained cockroaches and flies.

77. ENVIGO had a longstanding issue with pest control at the Cumberland Facility. APHIS notified the Cumberland Facility about its pest problems as early as August 2017. Years passed without resolution of the facility’s pest issues and although ENVIGO employees notified members of the Executive Leadership Team of pest issues, ENVIGO treated the pervasive pest problem at the Cumberland Facility as an accepted characteristic of the facility rather than a violation of the AWA.

RECORDS

78. The AWA required ENVIGO to maintain records “which fully and correctly” disclose certain information about the dogs under their control. 9 C.F.R. § 2.75(a)(1). The AWA particularly required ENVIGO to maintain records about the disposition of dogs (sale, death, euthanasia, donation). 9 C.F.R. § 2.75(a)(1)(i)–(ix).

79. The AWA required ENVIGO to 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). ENVIGO’s medical records were required to include identified problems with a dog, the date, and a description of the problem, examination findings, test results, a plan for treatment and care,

treatment procedures performed, vaccines and treatments administered, recommended testing, and the dates and findings of all screening. 9 C.F.R. § 3.13(b).

80. The AWA required ENVIGO to make, keep, and retain records pertaining to the purchase, sale, transportation, identification, and previous ownership of each dog, which fully and correctly disclosed information about 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).

81. ENVIGO failed to maintain and keep adequate records at the Cumberland Facility. The facility kept incomplete or missing euthanasia records, incomplete or vague mortality records, and missing disposition records for several dogs. Moreover, on several occasions ENVIGO employees falsely indicated necropsies were performed on deceased dogs when they were not.

82. ENVIGO lacked sufficient dental records for the dog colony at the Cumberland Facility. The facility's vaccination record-keeping system resulted in inaccurate vaccination data for certain dogs. Medical records for certain dogs at the facility were incomplete; certain records lacked exam findings, descriptions of observed issues, and test results. Certain records also lacked descriptions of symptoms, diagnostic testing, treatment plans, and causes of death. Certain euthanasia records lacked information about the route of administration used by employees to administer euthanasia drugs.

EMPLOYEES

83. ENVIGO fell short of the requirements in the AWA by failing to maintain a sufficient employee-to-dog ratio at the Cumberland Facility and by allowing a system of inadequate veterinary care to persist at the facility. 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 the facility is “certain” has the knowledge, background, and experience in proper husbandry and care of dogs to supervise others. 9 C.F.R. § 3.12.

84. ENVIGO was responsible for providing care to over 5,000 dogs at the Cumberland Facility. In July 2021, it employed merely 39 individuals to care for thousands of animals (128:1 dog/employee ratio, assuming all 39 employees were responsible for animal care and husbandry, which they were not). ENVIGO’s inadequate work force resulted in deficient daily observations of dogs. Several dogs were found in need of critical care by APHIS inspectors as early as July 2021 at the Cumberland Facility, and by the May 2022 federal search warrant, 445 animals were classified as being in acute distress and needing immediate medical attention. ENVIGO failed to remedy its employee shortage at the Cumberland Facility months after being on notice of its inadequacy. ENVIGO’s low staff levels at the facility led to various other violations of the AWA including inadequate veterinary care and sanitation practices.

ENVIGO EXECUTIVE LEADERSHIP TEAM KNEW OF THE AWA
VIOLATIONS AT THE CUMBERLAND FACILITY

85. From at least July 2021, members of ENVIGO’s Executive Leadership Team knew the Cumberland Facility was operating in violation of the AWA. ENVIGO’s COO visited the facility firsthand, and for months, discussed the facility’s violations, including “deplorable” conditions at the facility, with other ENVIGO employees. The COO, VP-NOA, and SVP-VS took inadequate steps to bring the Cumberland Facility into full compliance with the AWA. In February 2022, seven months after being on notice of the issues at the Cumberland Facility, ENVIGO’s VP-NOA described the conditions as “worse than I had seen” in July 2021.

86. ENVIGO employees estimated a total cost of \$8,000,000 for the improvements it deemed necessary to come into compliance with the AWA. Although requests for capital expenditures were made to improve the Cumberland Facility, members of the Executive Leadership Team delayed or declined such requests. Improvements that were made were insufficient.

V. THE CONSPIRACY TO VIOLATE THE AWA

87. Beginning on or about January 1, 2020, and continuing up through and including May 18, 2022, within the Western District of Virginia and elsewhere, ENVIGO RMS, defendant herein, along with other persons both known and unknown to the United States, conspired to commit offenses against the United States, that is, to knowingly violate the provisions of the Animal Welfare Act, in violation of 7 U.S.C. § 2149(d).

PURPOSE OF THE CONSPIRACY

88. It was the purpose of the conspiracy for ENVIGO and its coconspirators to unlawfully enrich themselves by, among other things, avoiding (1) millions of dollars in infrastructure upgrades, and (2) the hiring of the requisite trained and competent human resources necessary to bring the Cumberland Facility into compliance with the AWA.

MANNER AND MEANS OF THE CONSPIRACY

89. The manner and means by which ENVIGO and its coconspirators, sought to accomplish the objects and purposes of the conspiracy included, among others, the following:

- a. The conspirators concealed non-compliant features of the Cumberland Facility and its operations and procedures from APHIS during inspections.
- b. The conspirators established a business culture that prioritized convenience and profits over compliance with the AWA and the humane treatment of animals.
- c. The conspirators retained an inadequate attending veterinarian.
- d. The conspirators failed to hire sufficient and adequate staff, which exacerbated its AWA violations.
- e. The conspirators operated and maintained the Cumberland Facility wastewater treatment plant in violation of their permit and implemented interim measures rather than permanent infrastructure and operational

solutions, resulting in adverse impact to the health and welfare of the dogs housed therein.

OVERT ACTS

90. In furtherance of the conspiracy, and to affect the objects thereof, at least one of the following overt acts, among others, were committed by at least one of the conspirators in the Western District of Virginia:

Inadequate Veterinarian Care

- a. On or about February 11, 2021, ENVIGO and its coconspirator, AV, failed to provide adequate veterinarian care at the Cumberland Facility while operating on five beagles.
- b. On or about February 16, 2021, after being informed that AV operated on dogs improperly, performed botched surgeries, failed to have necessary supplies for surgical procedures, misplaced medical records, mislabeled blood draw vials, failed to ensure healthy dogs were shipped from the Cumberland Facility, had poor attendance, and ignored weekend calls regarding veterinary issues, the conspirators failed to stop the inadequate care of the animals housed at the Cumberland Facility.
- c. Between February 2021 and May 2021, and despite repeated warnings that coconspirator AV was not providing dogs at the Cumberland Facility with adequate veterinary care, the conspirators repeatedly refused to terminate AV.

Increased Risk of Death by Hypothermia

- d. On or about July 7, 2021, at the Cumberland Facility, an unindicted coconspirator washed dog kennels with a hose without first removing the dogs inside.
- e. On or about July 8, 2021, at the Cumberland Facility, an unindicted coconspirator washed dog kennels with a hose without first removing the dogs inside.
- f. On or about July 27, 2021, at the Cumberland Facility, two unindicted coconspirators washed dog kennels with a hose without first removing the dogs inside.
- g. On or about October 26, 2021, at the Cumberland Facility, an unindicted coconspirator washed dog kennels with a hose without first removing the dogs inside.

Improperly Withholding Food from Nursing Mothers

- h. Starting on or about August 2021 and continuing until at least October 2021, an unindicted coconspirator withheld food from nursing mother dogs for at least two-day periods at the Cumberland Facility against the direction of the Cumberland Facility's manager of operations and APHIS.
- i. On or about August 13, 2021, that same unindicted coconspirator advised other ENVIGO employees to withhold food from nursing mother dogs at the Cumberland Facility.

- j. On or about October 25, 2021, that same unindicted coconspirator falsely told APHIS inspectors nursing mother dogs were being fed every day at the Cumberland Facility when in fact they were not.

Falsifying Required Records

- k. In or around May 2021, two unindicted coconspirators falsified a log sheet used to record the temperature of the refrigerators in the Cumberland Facility's whelping building, knowing such conduct was in violation of the AWA.
- l. On or about August 18, 2021, an unindicted coconspirator falsely indicated on a mortality record that a necropsy was performed at the Cumberland Facility on a deceased dog when in fact one was not, knowing such conduct was in violation of the AWA.
- m. On or about October 25, 2021, an unindicted coconspirator falsely indicated on feeding forms that nursing mothers had been fed every day at the Cumberland Facility when in fact they had not.

Improper Euthanasia Techniques

- n. On or about April 25, 2021, an unindicted coconspirator did not sedate a dog before euthanizing it at the Cumberland Facility.
- o. On or about June 1, 2021, an unindicted coconspirator instructed an ENVIGO employee not to sedate a dog before euthanizing it at the Cumberland Facility.

- p. On or about August 25, 2021, an unindicted coconspirator euthanized dogs and disposed of them without first verifying they were deceased at the Cumberland Facility.

Sanitation & Drinking Water

- q. On or about August 12, 2019, the conspirators provided non-potable drinking water to the dogs at the Cumberland Facility.
- r. On or about June 3, 2021, the conspirators provided drinking water contaminated with excessive levels of nitrates to the dogs at the Cumberland Facility, knowing the water was non-potable.
- s. In or around December 2021, the conspirators pumped water contaminated with fecal matter to the Cumberland Facility's kennels for ENVIGO employees to use to flush the troughs below the dog kennels.

All in violation of Title 18, United States Code, Section 371.

COUNT TWO

1. Paragraphs 1 to 14 of Count One are incorporated by reference as if fully set forth herein.

I. CLEAN WATER ACT

2. The CWA was enacted to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters." 33 U.S.C. § 1251(a).
3. The CWA prohibits the discharge of any pollutant into waters of the United States except in compliance with a permit issued pursuant to the CWA under the National

Pollutant Discharge Elimination System (“NPDES”) or by the United States Environmental Protection Agency (“EPA”) or by a state with an approved permit program. 33 U.S.C. §§ 1311(a), 1342.

4. Under the NPDES permit program, persons, or entities who wish to discharge one or more pollutants must apply for a permit from the proper state or federal agency. *See* 40 C.F.R. § 122.21. A “permit” is “an authorization, license, or equivalent control document issued by EPA or an ‘approved State’ to implement the requirements of [the CWA].” 40 C.F.R. § 122.2.

5. States can seek approval from the EPA to administer and enforce a CWA NPDES permit program. 33 U.S.C. § 1342(b). EPA’s approval of a state program does not affect the United States’ ability to enforce the Act’s provisions. 33 U.S.C. § 1342(i). Therefore, violations of the CWA fall within the jurisdiction of the EPA even if the program is delegated to a state. EPA approved Virginia’s NPDES program on March 31, 1975.

6. The CWA defines “discharge of a pollutant” as the “addition of any pollutant to navigable waters from any point source.” 33 U.S.C. § 1362(12). The term “pollutant” includes a wide range of materials, including solid waste, industrial waste, sewage, and sewage sludge. 33 U.S.C. § 1362(6).

7. A “point source” is a “confined and discrete conveyance, including but not limited to any pipe, ditch, channel, tunnel, conduit [. . .] from which pollutants are or may

be discharged.” 33 U.S.C. § 1362(14). Outfalls conveying wastewater and stormwater to surface waters are point sources.

8. “Navigable waters” are defined in the CWA as “waters of the United States.” 33 U.S.C. § 1362(7). “Waters of the United States” include rivers and streams which are “[c]urrently used, or were used in the past, or may be susceptible to use in interstate or foreign commerce [. . .] [and the] [t]ributaries of such waters[.]” 40 C.F.R. § 120.2(a). Maxey Mill Creek, Deep Creek, and the James River are waters of the United States.

9. NPDES permits typically contain, among other things, effluent limitations; water quality standards; monitoring and reporting requirements; standard conditions applicable to all permits; and special conditions where appropriate. *See* 33 U.S.C. § 1342; 40 C.F.R. §§ 122.41–122.50.

II. FACTUAL BACKGROUND

THE CUMBERLAND FACILITY’S CWA PERMITS

10. On September 8, 2015, Virginia’s Department of Environmental Quality (VDEQ) issued CWA NPDES Permit No. VA0088382 (“Permit I”) to Corporation B for the Cumberland Facility, with an expiration date of September 7, 2020. Permit I set forth certain requirements and prohibitions, including the following:

- a. Effluent limits: Permit I set effluent limits for, among other things, Total Kjeldahl Nitrogen, *E. Coli*, Carbonaceous Biochemical Oxygen Demand, and Total Suspended Solids.
- b. Foam discharges: Permit I prohibited the discharge of “visible foam in other than trace amounts.”

- c. Operation and Maintenance Manual Requirement: Permit I required the permit holder to “maintain a current Operations and Maintenance (“O&M”) Manual for the treatment works.” The O&M Manual must set forth “the practice and procedures, which will be followed to ensure compliance with the requirements of [the] permit.” Permit I mandated that “[t]he permittee shall operate the treatment works in accordance with the O&M Manual.”
- d. Unauthorized Discharges: Unless authorized by Permit I, discharges of “sewage, industrial wastes, other wastes, or any noxious or deleterious substances” were prohibited.
- e. Reporting requirements: Permit I required unauthorized discharges to be reported, immediately upon discovery of the discharge, but in no case later than 24 hours after said discovery with a written report submitted within five days of discovery of the unauthorized discharge. There were also reporting requirements for non-compliance.
- f. Duty to comply: Permit I required compliance with all its conditions.
- g. Proper Operation and Maintenance: Permit I required the permittee to operate and maintain the facilities to achieve compliance with its terms.
- h. Licensed Operator Requirement: Permit I required the permittee to employ or contract at least one Class 3 licensed wastewater works operator for the facility.
- i. Duty to Mitigate: Permit I required the permittee to take all reasonable steps to minimize and prevent any discharge or sludge use or disposal in violation of the permit which had a reasonable likelihood of adversely affecting human health or the environment.

11. Permit I made clear that “[i]t shall not be a defense for a permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of the permit.”

12. When EGSI acquired Corporation B and the Cumberland Facility in 2019, Permit I was transferred and placed in EGSI’s name as the permittee. EGSI subsequently submitted a renewal application before the expiration deadline. In its 2021 renewal

application, EGSI estimated that it generated approximately 11.16 dry metric tons (or 24,597 pounds) of sludge per year at the Cumberland Facility.

13. On March 1, 2021, VDEQ issued Permit No. VA0088382 (“Permit II”) to EGSI. Permit II authorized the discharge into Maxey Mill Creek. Permit II, which expires on February 28, 2026, contained similar prohibitions and requirements as Permit I.

14. Both Permit I and Permit II established discharge limits for, among other things, *E. coli*, Total Kjeldahl Nitrogen (“TKN”), and total suspended solids (“TSS”).

15. Maxey Mill Creek, which bordered the Cumberland Facility, was a Section 10 navigable in fact water of the United States, located in the subbasin of the Middle James River. *See* Photograph 2 below.

Photograph 2. Aerial photograph of the Cumberland Facility’s wastewater treatment plant and Maxey Mill Creek. (Source: Google Maps).



THE CUMBERLAND FACILITY'S
WASTEWATER TREATMENT PLANT

16. The Cumberland Facility produced sludge from dog and human waste that was treated onsite at the facility's wastewater treatment plant. The wastewater treatment plant functioned to treat the wastewater so the facility could ultimately discharge the effluent into Maxey Mill Creek in accordance with EGSI's VPDES permits (Permit I and Permit II) and recycle greywater to flush troughs.

17. The Cumberland Facility wastewater treatment plant, which was originally constructed in 1995 with later upgrades in approximately 2001 and 2007, included two sequencing batch reactors ("SBRs"), two digesters, a sand filter, drying beds, an equalization tank ("EQ tank") (which held greywater), an effluent holding tank, and a chlorine contact tank. *See, e.g.*, Photograph 3 below.

Photograph 3. Marked Aerial photograph of the Cumberland Facility's wastewater treatment plant and Maxey Mill Creek. (Source: Google Maps, modified).



18. ENVIGO housed its dog colony at the Cumberland Facility in kennels inside multiple buildings. A trough system ran underneath all the kennels to collect the dogs' waste. A mechanical pit cleaner under the kennels collected the waste. Each kennel building had a pencil tank containing gray water which was used to flush the waste into a drain. The waste slurry was then gravity fed from the drain through an underground piping system to the Cumberland Facility wastewater treatment plant. In addition to the waste from the animal operations, human waste was piped to the wastewater treatment plant.

19. Once the waste slurry reached the Cumberland Facility wastewater treatment plant, it was held in an underground piping system before going to either SBR 3 or SBR 4 to begin the treatment process. SBR 3 and SBR 4 were tanks that broke down the waste by separating solids from liquids to achieve biological removal of biochemical oxygen demand ("BoD") and ammonia. SBR 3 and SBR 4 had a total combined treatment capacity of around 90,000 gallons per day. SBR 3 and SBR 4 could be operated in a sequence set by a computer and timer system, or alternatively, manually operated.

20. The SBR timer setting ensured the waste had enough time to react in the SBR 3 or SBR 4 before moving to the next step in the treatment process. During the SBR process, the waste filled, reacted, aerated, mixed, and settled. After the waste settled, the waste that settled to the bottom was sent into one of the digesters and the gray water on top was decanted.

21. The Cumberland Facility wastewater treatment plant digesters held and further broke down the sludge from the bottom of SBR 3 and SBR 4 through an aeration

treatment process. For several years before August 2020, ENVIGO used only one of its digesters (“Digester No. 2”) because the other digester (“Digester No. 1”) was not working.

22. The Cumberland Facility wastewater treatment plant decanter was set to a certain level and treated effluent was decanted to either the EQ tank or into the effluent holding tank. If the greywater went into the EQ tank, it was pumped back to the pencil tanks for reuse. If the greywater went to the effluent holding tank, it then passed through the sand filters and into the chlorine contact tank. At the chlorine contact tank, chlorine was added to the greywater and after at least thirty minutes of contact time, it was discharged into Maxey Mill Creek via the permitted outfall.

23. EGSI employed a licensed wastewater treatment plant operator to manage the Cumberland Facility wastewater treatment plant, take the necessary samples, and ensure compliance with Permit I and Permit II effluent limits as well as the maintenance of the equipment.

24. Permit I and Permit II required the licensed wastewater treatment plant operator at the Cumberland Facility to sample the wastewater treatment plant effluent prior to discharge into Maxey Mill Creek. However, the wastewater treatment plant operator sampled the effluent for chlorine, pH, dissolved oxygen, and temperature at a manhole after he began the discharge process.

25. EGSI hired Environmental System Service (“ESS”) to conduct additional wastewater testing at the Cumberland Facility, including testing for nitrates and *E. coli*, to ensure the effluent complied with the limits pursuant to Permit I and Permit II. ESS also

prepared discharge monitoring reports for EGSI based on the testing it performed. EGSI, as the permit holder, ultimately bore the responsibility for reviewing, executing, and submitting the reports to VDEQ.

26. Along with discharging into Maxey Mill Creek, ENVIGO disposed of waste by land applying sludge on fields around the Cumberland Facility. ENVIGO land applied sludge on the Cumberland Facility property and on private property. ENVIGO was supposed to, but did not always, test the nutrient content of the sludge before land applying. ENVIGO land applied its sludge several days a month before August 2020.

27. Beginning no later than 2020, VDEQ no longer permitted EGSI to land apply its sludge because it contained excessive levels of contaminants.

28. Sometime in January 2020, the exact date unknown, the Cumberland Facility wastewater treatment plant operator notified managers at the Cumberland Facility of problems with waste management and requested help dealing with the waste.

29. In 2021, the pump for Digester No. 1 failed and a backup pump was used. In 2022, the blower in SBR 4 failed. The repair for the blower took several weeks and the Cumberland Facility could not use SBR 4 at all during that time.

30. Beginning in at least May 2021, the Cumberland Facility site director and manager of operations repeatedly requested capital expenditures from the Executive Leadership Team for improvements to the Cumberland Facility wastewater treatment plant. ENVIGO did not provide funds in response to those requests.

31. By July 2021, APHIS required ENVIGO to change its sanitation practice from sanitizing the kennels only once every two weeks to every day, increasing the amount of water it used. In July 2021, the licensed operator at the Cumberland Facility made clear to managers at the Cumberland Facility that daily cleaning would be impossible, stating: “It will be absolutely impossible to clean all 80 troughs in 1 day. The plant can’t process all that. It is operating now with about 85 percent solids in the SBR. Should be around 50.” Per the O&M Manual, to function properly, the sludge percentage in SBR 3 and SBR 4 was recommended to be 30-50% of the volume.

32. At the same time, ENVIGO did not reduce the number of dogs onsite at the Cumberland Facility. The increase in wastewater taxed the old, worn-out system, resulting in violations of Permit I and Permit II, including violations of the O&M Manual.

33. As the volume of waste and water usage at the Cumberland Facility increased, along with the inability to either land apply or dispose of the sludge and a corresponding failure to follow the O&M Manual, the Cumberland Facility wastewater treatment plant no longer functioned as designed and could not properly treat the wastewater to ensure discharges in compliance with the permit limits.

34. In late December 2021, ENVIGO began hauling some of its waste from the Cumberland Facility to a municipal wastewater treatment plant to provide additional capacity for the wastewater treatment plant. The municipal wastewater treatment plant required ENVIGO to sample its waste for compliance with the facility’s pH, temperature, and nutrient requirements. At one point, the municipal wastewater treatment plant

temporarily suspended the Cumberland Facility's ability to haul waste to the municipal plant.

35. In November 2021, ENVIGO contacted an engineering firm to draft a proposal for an upgrade to the wastewater treatment plant. In June 2022, and following two site visits, one of which took place in December 2021, the engineering firm provided a proposal to ENVIGO that estimated the required upgrades to the wastewater treatment plant would cost approximately \$6,000,000. The engineering firm identified multiple necessary upgrades, including a new sludge dewatering facility, new chlorine contact tank and water pump station, new digester, and a new SBR. ENVIGO did not contract for the improvements and continued to use the failing system, without any reduction in the number of animals onsite at the Cumberland Facility until Summer of 2022. By a July 1, 2022, Transfer Plan, ENVIGO transferred ownership and physical custody of approximately 4,000 dogs to the Humane Society of the United States for placement into permanent homes. The transfer began on July 21, 2022, and all dogs were removed from the facility by September of 2022.

36. Members of the Executive Leadership Team knew of the problems with the wastewater treatment plant and failed to take corrective action, thereby allowing the continued violations of discharge prohibitions and O&M requirements of Permit II.

III. THE CONSPIRACY TO KNOWINGLY VIOLATE THE CWA

37. Beginning no later than January 1, 2020, and continuing up through and including September 30, 2022, within the Western District of Virginia and elsewhere,

ENVIGO GLOBAL SERVICES, INC., defendant herein, along with other persons, both known and unknown to the United States, conspired to commit offenses against the United States, that is: (1) to knowingly discharge pollutants from a point source into a water of the United States in violation of a permit issued pursuant to 33 U.S.C. § 1342, in violation of the CWA, 33 U.S.C. §§ 1311, 1319(c)(2)(A); and (2) to knowingly violate conditions of a permit issued pursuant to 33 U.S.C. § 1342, in violation of the CWA, 33 U.S.C. §§ 1311, 1319(c)(2)(A).

PURPOSE OF THE CONSPIRACY

38. It was the purpose of the conspiracy for the coconspirators to unlawfully enrich themselves by, among other things, (1) avoiding costs to properly dispose of wastewater and sludge as well as millions of dollars in infrastructure upgrades necessary to bring the Cumberland Facility into compliance with the CWA; and (2) continuing to breed and sell animals despite the Cumberland Facility's inability to manage the waste generated.

MANNER AND MEANS OF THE CONSPIRACY

39. The manner and means by which ENVIGO and its coconspirators sought to accomplish the objects and purposes of the conspiracy included, among others, the following:

- a. The conspirators did not record when more than trace amounts of foam were visible at the outfall.

- b. When the wastewater treatment plant equipment began to fail, the conspirators implemented a rotation of cleaning troughs, as opposed to daily flushing, allowed feces to accumulate in the troughs instead of sending the waste to the wastewater treatment plant, and started to store the sludge in various tanks in the wastewater treatment plant.
- c. The conspirators discharged effluent into the Maxey Mill Creek knowing that such effluent would exceed the Cumberland Facility's applicable limits pursuant to Permit I and Permit II.
- d. The conspirators did not test the sludge at the Cumberland Facility to avoid having to report exceedances of phosphorus and other contaminants in the sludge before it was land applied.
- e. Notwithstanding known issues, *e.g.*, foam being discharged at times and the feces in the post-equalization decant tank, the Cumberland Facility licensed operator did not test the effluent until after it was being discharged into the Maxey Mill Creek.

OVERT ACTS

40. In furtherance of the conspiracy, and to affect the objects thereof, at least one of the following overt acts, among others, were committed by at least one of the coconspirators in the Western District of Virginia:

Discharges in Violation of Permits I and II

- a. In June 2020, an unindicted coconspirator discharged approximately 65,000 gallons of effluent from the Cumberland Facility into the Maxey Mill Creek. Sampling revealed that the discharge for TKN was 31% over the monthly-average Permit I limit.
- b. In August 2020, the same unindicted coconspirator discharged approximately 82,000 gallons of effluent from the Cumberland Facility into the Maxey Mill Creek. Sampling revealed that the discharge for TKN was 47% over the monthly-average Permit I limit.
- c. In January 2021, the same unindicted coconspirator discharged approximately 167,000 gallons of effluent from the Cumberland Facility into the Maxey Mill Creek. Sampling revealed that the discharge for TKN was 10% over the monthly-average Permit I limit.
- d. In May 2021, the same unindicted coconspirator discharged approximately 53,000 gallons of effluent from the Cumberland Facility into the Maxey Mill Creek. Sampling revealed that the discharge for TKN was 53% over the

monthly-average Permit II limit. Sampling revealed other effluent violations as well.

- e. In September 2021, the same unindicted coconspirator discharged approximately 58,000 gallons of effluent from the Cumberland Facility into the Maxey Mill Creek. Sampling revealed that the discharge for TKN was 67% over the monthly-average Permit II limit.
- f. In November 2021, the same unindicted coconspirator discharged approximately 42,000 gallons of effluent from the Cumberland Facility into the Maxey Mill Creek. Sampling revealed that the discharge for TKN was 157% over the monthly-average Permit II limit and 95% over the weekly-average Permit II limit. In addition, TSS was 75% over the Permit II limit.
- g. On multiple occasions, including in March 2021 and April 2021, the conspirators failed to report the discharge of visible foam leaving the Cumberland Facility through its wastewater treatment plant outfall into Maxey Mill Creek.

Photograph 4. Foam present at the wastewater treatment plant Outfall into Maxey Mill Creek on March 30, 2021. (Source: Environmental Consulting Firm)



O&M Manual Violations

- h. In August 2020, and in violation of the O&M Manual, the conspirators began storing sludge in Digester No. 1 as the volume of sludge increased and the Cumberland Facility had no ability to land apply or haul the sludge offsite. With no external relief for the system, the conspirators continued to move the sludge into different tanks in the Cumberland Facility wastewater treatment plant, even though the tanks were not intended to store sludge.
- i. The conspirators allowed the sludge to collect in the sludge tank and by July 2021, allowed the volume in an SBR to exceed 85%.

- j. On multiple occasions, the conspirators decanted wastewater from an SBR to the effluent holding tank and recycled it as part of the greywater system. The high volumes of sludge caused wastewater outside of compliance levels for BoD, nitrates, and TSS to be sent to the effluent tank, in violation of the O&M Manual. As a result, water the color of “chocolate milk” passed through the greywater system and was used to clean the troughs below the kennels. *See, e.g.*, Photograph 5 below.

Photograph 5. The Cumberland Facility wastewater treatment plant’s “greywater” post-equalization decant tank on December 7, 2021. The “greywater” was used to clean troughs under the kennels. (Source: Third-party engineering firm).




All in violation of Title 18, United States Code, Section 371.

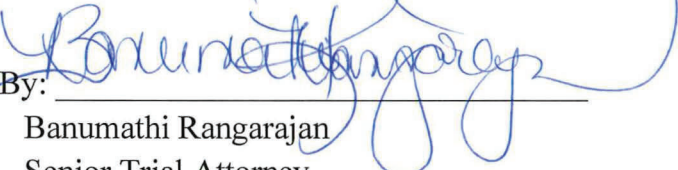
Attachment 3 to Resolution Agreement
In re: Inotiv, Inc.


Information


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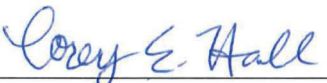
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Attachment C to Plea Agreement
United States v. Envigo RMS, LLC & Envigo Global Services, Inc.