

SETTLEMENT AGREEMENT
CEC et al. v. Garland et al., 22-cv-01004-SRB (D. Ariz.)

I. INTRODUCTION

This action arises under the Religious Freedom Restoration Act (“RFRA”), 42 U.S.C. §§ 2000bb *et seq.* and the Freedom of Information Act (“FOIA”), 5 U.S.C. § 522(a)(4)(B). This Settlement Agreement and Release (“Agreement”), effective as of the last date of execution below (“Effective Date”), is made by and between Plaintiffs—Church of the Eagle and the Condor (“CEC”), Joseph Tafur, Belinda Eriacho, Kewal Wright, Benjamin Sullivan, and Joseph Bellus—and Defendants—Merrick Garland, in his official capacity as Attorney General of the United States, Alejandro Mayorkas, in his official capacity as Secretary of Homeland Security, Anne Milgram, in her official capacity as Administrator of the U.S. Drug Enforcement Administration (“DEA”), and Troy Miller, in his official capacity as Acting Commissioner of U.S. Customs and Border Protection (“CBP”) (together the “Government”)—in Case No. 22-cv-1004-SRB (D. Ariz.). Plaintiffs and Defendants hereinafter are referred to collectively as the “Parties.”

II. RECITALS

Plaintiff CEC seeks to import, manufacture, distribute, and possess ayahuasca¹ for use in religious ceremonies. Ayahuasca contains dimethyltryptamine (“DMT”), a Schedule I controlled substance under the Controlled Substances Act (“CSA”), 21 U.S.C. §§ 801 *et seq.* The CSA and its regulations are enforced by DEA. CBP enforces certain federal laws and regulations related to the importation of controlled substances at the U.S. border.

The Parties have expended effort and resources in investigating and evaluating the allegations set forth in CEC’s complaint, including initial discovery.

The Parties, through their authorized representatives, and without either adjudication of CEC’s allegations and claims or admission by the Government of any alleged violation or wrongdoing, now wish to resolve and settle all disputes, obligations, and purported or actual claims or causes of action, which may exist by and between CEC and the Government, including without limitation, any disputes, obligations, claims, and/or causes of action that were or could have been asserted in or pursuant to RFRA or FOIA.

The Parties agree it is in their mutual interest to enter into this Settlement Agreement (“Agreement”). By entering into this Agreement, the parties do not intend to compromise their positions on the disputed issues or to make any concessions with respect to any of the disputed issues. Nothing in this Agreement shall be construed as an admission or concession as to any of the disputed issues in this action.

NOW, THEREFORE, in consideration of the execution of this Settlement Agreement and the releases, satisfactions, and promises made herein, it is hereby agreed upon by the Parties as follows:

¹ For purposes of this Agreement, the term “ayahuasca” is defined as a traditional Amazonian decoction with psychoactive properties made from the vine of the *Banisteriopsis caapi* and leaves of the *Psychotria viridis* bush. As relevant to this Agreement, ayahuasca can take the form of a concentrated paste or a drinkable tea.

III. GENERAL PROVISIONS

1. This Agreement shall not be construed to bar the U.S. Government, or any of its agents or agencies, departments, components, or other subparts, from exercising any of its law enforcement authority to ensure that Plaintiffs' activities fully comply with U.S. law, except to the extent specifically provided in this Agreement. Subject to the terms and conditions set forth in this Agreement, Defendants, their agencies, agents, employees, and those persons under their control will not apply or enforce against the Plaintiffs, the CSA or its implementing regulations governing the legal importation, manufacture, distribution, transportation, religious use, and possession of DMT, a Schedule I substance. Nothing in this Agreement shall restrict or limit CBP's lawful authority to inspect, sample, seize, detain, or take any other action with regard to Plaintiffs' ayahuasca, once CBP determines that such activities should be undertaken in compliance with this Agreement, for a reason other than the fact that a properly registered shipment of ayahuasca contains DMT, a Schedule I controlled substance.
2. CEC will import ayahuasca in concentrated paste form or in liquid form. Upon receipt, CEC will combine the ayahuasca paste with water to manufacture ayahuasca tea for sacramental uses. CEC will receive the imported ayahuasca and conduct all manufacturing activities at the following address: 1220 E. Medlock Drive, #210, Phoenix, AZ 85014.
3. This Agreement permits CEC to import, receive, manufacture, distribute, transport, securely store, and dispose of ayahuasca solely for CEC's religious purposes. CEC may not conduct any of these activities for non-religious purposes, including but not limited to recreational purposes. CEC may not use any DEA registrations subject to this Agreement to import, receive, manufacture, distribute, store, or use any other controlled substance.
4. DEA will waive as to CEC all fees otherwise required under its regulations implementing the CSA.
5. As set forth below, CEC will account for the ayahuasca paste and liquid they import into the U.S. until its ultimate use or disposal and will cooperate with DEA's verification efforts and procedures, as described below.
6. As set forth below, CEC will account for the ayahuasca tea they manufacture in the U.S. until its ultimate use or disposal and will cooperate with DEA's verification efforts and procedures, as described below.
7. CEC, through its designated ayahuasqueros, currently Plaintiffs Joseph Tafur and Benjamin Sullivan, will be responsible for the importation, receipt, secured storage, manufacture, distribution, disposal, and all applicable record keeping requirements of the ayahuasca as set forth in this Agreement. CEC will comply with any applicable DEA notification requirement relating to new ayahuasqueros who are designated in the future as set out by CEC's bylaws.
8. The amount of ayahuasca tea to be manufactured for each individual ceremony will be based on the number of ceremony participants. Participants gather regularly as designated by CEC. Ceremonies will be held in private residences of CEC members or other locations as determined by CEC that can ensure security of the ayahuasca and the safety of the participants. CEC ayahuasqueros will personally transport the approximate amount of ayahuasca tea needed for each ceremony.

9. CEC requires, and will continue to require, ceremony participants to undergo a health screening for issues that could preclude participation, and shall provide participants with information related to potential health issues that could be adversely affected by participation. All ceremonies will have the presence of one person trained in basic first aid and capable of responding in an emergency. CEC shall maintain medical emergency protocols to respond to any medical needs of participants.

10. DEA has agreed to grant CEC an importer registration for the importation of ayahuasca and a manufacturer bulk registration for ayahuasca tea, with the following listed exemptions from certain registration, security, and record keeping requirements under the CSA and its implementing regulations, provided that CEC agrees to the terms within this Agreement. DEA will provide CEC with the Certificates of Registration (COR) and COR numbers after the execution of this agreement and prior to the filing of the Notice of Settlement with the Court.

A. Issuance and Renewal of DEA Registration(s)

11. The registered location of CEC will maintain the DEA registration(s) applicable to the authorized handling of the Schedule I controlled substance DMT for religious purposes.

12. CEC will be authorized through its importer DEA registration to import ayahuasca paste or liquid, which contains the Schedule I controlled substance DMT as described in 21 C.F.R. §§ 1312.11 - 1312.19, with distribution as a coincident activity allowed as described in § 1301.13(e)(1)(viii).

13. CEC will advise the local DEA Field Office whenever there is a change with the country of initial exportation or with its consignor shipping the ayahuasca paste or liquid to CEC through its import DEA registration. CEC will further advise the local DEA Field Office if there is a change in the form in which it imports ayahuasca.

14. CEC will be issued a bulk manufacturer DEA registration for the receipt of the ayahuasca paste or liquid from CEC's importer DEA registration and for the manufacturing processes authorized under the terms of this Agreement, with distribution allowed as a coincident activity of both importing and manufacturing, as described in 21 C.F.R. § 1301.13(e)(1)(i) and 21 C.F.R. § 1301.13(e)(1)(viii).

15. CEC will not be required to obtain a separate distributor DEA registration for distribution activities, including distributing ayahuasca tea for sacramental use at the specific ceremonial location(s) benefiting from that exemption, provided that CEC abides by the security requirements allowed under the terms of its registrations and this Agreement. The CEC must notify and seek approval from DEA for any further distribution as coincident activities other than those set forth in this Agreement.

16. Except as set forth in this Agreement, CEC will submit DEA application(s) for registration(s) for each physical location where the ayahuasca will be imported, stored, manufactured, and distributed. CEC acknowledges that, as registrants, they must apply to modify their registration before a physical location changes. *See* 21 C.F.R. § 1301.51. CEC will also notify the local DEA Field Office of any change in location incidental to the distribution of ayahuasca as a coincident activity of a registration.

17. As part of this Agreement, CEC is not required to file an application with the DEA's "Guidance Regarding Petitions for Religious Exemption from the Controlled Substance Act Pursuant to the Religious Freedom Restoration Act."

18. In applying for a DEA registration and filling out DEA Form 225, pursuant to 21 C.F.R. § 1301.13(i), CEC may consider the word "business" on the relevant DEA application form to mean

“activities of a religious entity” involving controlled substances if the activities have been specified as such in the petition, or it is known at the signing of this Agreement that the connected application pertains to the import or manufacture and distribution of ayahuasca only for religious purposes.

19. Whenever the DEA application form asks for information pertaining to any “officer, partner, stockholder or proprietor,” CEC shall supply all names of its officers, as specified in the records of the state in which CEC is incorporated at the time of the application for registration.

20. If the import or bulk manufacture registration is set to expire, and CEC has timely submitted a renewal application that is still being processed by the DEA, CEC is allowed to continue to operate on a day-by-day basis until the registration is renewed in accordance with 21 C.F.R. § 1301.36(i), subject to the provisions of this Agreement.

21. DEA, upon receipt of a complete DEA application, will conduct the initial on-site inspection of each new location for which CEC seeks a DEA registration as soon as practicable. DEA will not deny CEC’s application(s) for DEA registration, renewal of registration(s), or import permits solely on the ground that the sacramental use of ayahuasca constitutes a basis for denial. The Defendants agree not to enforce the provisions of 21 C.F.R. §§ 1301.34(a), (b)(6), (d), (e), (f), 1301.35(b), Part 1303, and 21 C.F.R. §§ 1304.33 and 1312.13(a) against CEC for the sacramental use of ayahuasca, so long as CEC remains a DEA registrant.

22. If DEA makes, pursuant to 21 C.F.R. § 1301.15, a reasonable request for additional information that DEA needs to process CEC’s DEA application(s), CEC will provide such information. Any dispute regarding requests for additional information will be handled pursuant to the dispute resolution provisions described in this Agreement.

23. DEA will issue registration(s) for which CEC has applied within sixty (60) calendar days after receipt of a complete DEA application for registration unless justified by exceptional circumstances.

24. Except as otherwise authorized by law, DEA shall not publish and will not voluntarily disclose the address of any registered location where CEC as registrant handles ayahuasca. DEA shall not publish any notice in the Federal Register concerning any application by CEC for registration as importer or manufacturer of a Schedule I controlled substance. DEA shall ensure that no registered location of CEC appears in the National Technical Information Service (NTIS) database.

B. Denial, Suspension, Or Revocation of Registration(s)

25. Consistent with this Agreement and under existing authority, DEA may seek to deny, suspend, or revoke the registration by serving upon CEC an order to show cause pursuant to 21 C.F.R. § 1301.37, and, if requested by the registrant, by holding a hearing pursuant to 21 C.F.R. § 1301.41 before an Administrative Law Judge. In the event of an imminent danger to the public health or safety, DEA may suspend the registration without prior notice and seek administrative action by issuing an Immediate Suspension Order (ISO) pursuant to 21 U.S.C. § 824(d). Nothing in this Settlement Agreement shall be construed as a waiver by Plaintiffs of any of their rights including, without limitation, their rights under RFRA, the First Amendment, and principles of equal protection.

C. Importation of the Ayahuasca

26. CEC’s registered location will maintain a DEA registration to import ayahuasca, which contains the Schedule I controlled substance DMT, in accordance with 21 C.F.R. §§ 1312.11 - 1312.19, with

distribution to CEC's manufacturer/bulk manufacturer DEA registration allowed as a coincident activity, as described in 1301.13(e)(1)(viii).

27. To facilitate Defendants' efforts to coordinate shipments, Plaintiffs have advised DEA that CEC will import ayahuasca as a concentrated paste or liquid from Peru to CEC's registered address in the U.S. through a common international carrier utilizing a tracking number. CEC initially anticipates importing up to 25 kg of ayahuasca paste per year. CEC anticipates this will be divided into several shipments of approximately 2kg to 4kg of ayahuasca paste. CEC expects to import from Ricardo Amaringo or his authorized agents, who prepare the ayahuasca and assists in the shipping process from Peru to the United States. The quantity of imported ayahuasca for Plaintiffs' religious use shall not be limited. However, CEC must notify DEA of any increase in the amount of ayahuasca it plans to import to meet its anticipated legitimate needs.

28. Unless otherwise altered by future DEA registrations or required notifications, Plaintiff Tafur (currently the CEC Point of Contact) is the only individual authorized to receive imported ayahuasca paste or liquid at CEC's registered importer location and will be listed as the importer of record or consignee on all shipments. CEC will be responsible for notifying DEA of any change in or additional CEC points of contact and for all record keeping related to the importation of ayahuasca paste and will log in the receipt of each shipment with date, time, weight, and notes regarding its quality. Each shipment will receive a batch number starting with the number one (1) for the first shipment, and sequentially thereafter.

29. CEC will submit an application as described in 21 C.F.R. § 1312.12(a) for a permit to import controlled substances on DEA Form 357 for each shipment of ayahuasca paste or liquid to be imported. DEA will not require CEC to specify in the DEA-357 the amount of the controlled substance DMT contained in each consignment, as described in 21 C.F.R. § 1312.12(b)(8). The amount of ayahuasca paste to be imported may be stated in kilograms, and the amount of liquid may be stated in liters.

30. DEA will issue a single import permit for each shipment of ayahuasca paste (*see* 21 C.F.R. § 1312.13(e)), and such issuance should occur within thirty (30) days of receipt of a complete DEA application, unless justified by exceptional circumstances. An import permit will be void and of no effect after the expiration date specified therein, and in no event will the date be more than 180 calendar days after the date the permit is issued. An importer may request through the DEA Diversion Control Division secure network application that an import permit or permit application be amended or canceled, and request a new permit. *See* 21 C.F.R. § 1312.16.

31. CEC, as an authorized importer, must furnish an official record of the declaration (available through the DEA Diversion Control Division secure network application after the Administration issues a transaction identification number) to the foreign shipper. CEC agrees to submit an official record of the declaration and/or required data concerning the import transaction to a customs officer at the port of entry in compliance with all import control requirements of agencies with import control authorities under the Act or statutory authority other than the Controlled Substances Import and Export Act. An official record of the declaration shall accompany the shipment to its final destination, which must only be the registered location of the importer (i.e., drop shipments are prohibited). *See* 21 C.F.R. § 1312.19.

32. Plaintiffs shall provide at least 72 hours of advance notice to the DEA Import/Export Section Point of Contact (defined in paragraph 78 below) of the identity of the courier and the tracking number of shipment. Plaintiffs shall promptly advise the DEA Point of Contact of any changes in the itinerary. DEA will reasonably coordinate with CBP in an effort to facilitate processing and clearance of shipments through the U.S. port of entry.

33. To facilitate Defendants' efforts to coordinate shipments, Plaintiffs have advised DEA that they intend to import CEC's sacrament through ports of entry in Los Angeles, Miami, Houston, and Atlanta. Plaintiffs' Point of Contact (currently Joseph Tafur), will inform DEA's Point of Contact of any changes in the ports of entry at least 45 days in advance of changing the port of entry in order to facilitate processing and clearance of shipments. If, through external circumstances beyond the parties' control, CEC's shipment enters through a different port of entry than those specified herein, neither party shall be considered in breach of this agreement.

34. To facilitate the movement of shipments, Plaintiffs will ensure that their authorized couriers carry with them copies of the appropriate DEA Certificate of Registration (COR) (DEA Form 223), together with a copy of the import permit (DEA Form 357) authorizing the particular shipment. The original COR must remain at the CEC registered location at all times.

35. If there are changes to the source of supply and means by which the ayahuasca will be imported to the U.S. and delivered to its final destination (i.e., foreign shipper, couriers or contract carriers), CEC shall promptly advise the local DEA Field Office of these changes and update any related information that may be required on DEA Form 357 for in-process and future import(s). DEA will reasonably work with CEC to facilitate processing and clearance of shipments through the U.S. port of entry.

36. Each imported batch and container shall remain sealed and unopened from its arrival at a U.S. port of entry until its receipt at the registered import location. CEC shall take reasonable steps to ensure that the seal is tamper-resistant and tamper-evident.

37. In the event that a shipment of ayahuasca paste or liquid has been denied release by a customs officer at the U.S. port of entry for any reason, CEC must report as described in 21 C.F.R. § 1312.12(e), within five (5) business days of the denial, that the shipment was denied and the reason for denial.

38. Notwithstanding 21 C.F.R. § 1312.15, if a consignment of ayahuasca is detained by CBP because the amount consigned is significantly greater than the amount authorized by the import permit, DEA will work with CEC to remedy the discrepancy through the issuance of an amended import permit to facilitate the prompt clearance by CBP of the shipment upon CEC's provision to DEA of a satisfactory non-diversionary explanation as to the discrepancy. Such shipments may be detained by CBP pending a satisfactory, non-diversionary explanation by CEC as to the discrepancy. Non-compliant shipments for which no explanation is provided are subject to seizure. Plaintiffs have explained that the consigned volume of ayahuasca in liquid form may be as much as 5% greater than or less than the volume specified in the permit due to (1) the thermal contraction of ayahuasca, which is packaged at high temperatures but arrives at Port of Entry at ambient temperatures over which Plaintiffs have no control and (2) there are variable rates of precipitation of inactive dissolved solids at the bottom of containers of ayahuasca.

39. All goods, conveyances, and persons are subject to search upon entry into the U.S. from a foreign country upon the demand of any CBP official. *See* 19 U.S.C. §§ 482, 1433, 1459, 1461, 1582; 8 U.S.C. § 1357; 19 C.F.R. Part 162; 8 C.F.R. Part 235.

40. DEA reserves the right to spot sample any consignment of imported ayahuasca once it has arrived at the registered location for the purpose of confirming that the consignment is in fact ayahuasca which contains no controlled substance other than DMT.

- a. DEA will notify CEC of DEA's intent to obtain a sample, which shall be taken when a sealed container, which, per above, is secured with a tamper-resistant and tamper-evident seal, is received by the registered importer at the registered location.

- b. When requested by DEA to do so, CEC's authorized individual will extract a reasonable amount of unadulterated sample of ayahuasca under the observation of DEA personnel. The authorized individual will place the sample in a container, to be provided by DEA, which will be shipped directly to a DEA forensics laboratory for testing.
- c. DEA will not return fully used portions of the sample to CEC. Storage and/or disposal of fully used samples will be solely within the discretion of DEA.

D. Manufacture of the Ayahuasca

41. Manufacturing processes include but are not limited to the production of ayahuasca batches for ceremonial use, and any related repackaging and relabeling of ayahuasca in containers.

42. CEC must account for the amount of imported ayahuasca liquid or ayahuasca paste containing the Schedule I controlled substance DMT being used to manufacture ayahuasca tea. To account for the amount of ayahuasca liquid or ayahuasca paste used in the manufacturing of ayahuasca tea, CEC must use DEA Form 222 (U.S. Official Order Forms – Schedules I and II), in accordance with and as required by the provisions under 21 C.F.R. Part 1305. The order forms will be completed as follows:

- a. CEC, on behalf of the manufacturer DEA registration (referred in the DEA Form 222 as the Purchaser) shall prepare and execute a DEA Form 222, make a copy of the original DEA Form 222 for its records and then submit the original for the importer DEA registration's records. The copy retained within the manufacturer registration's records may be in paper or electronic form.
- b. CEC, on behalf of the importer DEA registration (referred in the DEA Form 222 as the Supplier) shall complete its portion of the order form in accordance with 21 C.F.R. Part 1305, fill the order for the manufacturer registration which ordered the ayahuasca and retain the original DEA Form 222 for the supplier's files in accordance with 21 C.F.R. § 1305.17(c). The importer registration shall, in accordance with 21 C.F.R. § 1305.13(d), simultaneously make and submit a copy of the original DEA Form 222 to DEA at the close of the month during which the order is filled, either by mail to the Registration Section, or by email to DEA.Orderforms@usdoj.gov.
- c. CEC, on behalf of the manufacturer DEA registration must, at the receipt of the ayahuasca, record on its copy of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser (manufacturer registration). All executed DEA 222 order forms will be kept at the registered location for a minimum of two years. The distribution of manufactured ayahuasca, as an authorized coincident activity of the manufacturer DEA registration pursuant to 21 C.F.R. § 1301.13(e)(1)(i), will not require the use of DEA Forms 222 since DEA agrees in this Settlement Agreement to exempt CEC from separately registering with DEA as a distributor for the distribution of sacramental ayahuasca.

43. If a bulk manufacturing registration is granted to CEC, Plaintiffs Joseph Tafur and Benjamin Sullivan, the two currently authorized ayahuasqueros at CEC, are the only individuals authorized to manufacture under that registration and they are only authorized to manufacture at CEC's registered address. The CEC will notify the DEA of any additional or subsequent authorized ayahuasqueros. CEC

will log the date, time, and weight of the ayahuasca paste, or volume of the ayahuasca liquid that is removed from the storage refrigerator for manufacturing purposes.

44. The ayahuasquero(s) will prepare the ayahuasca tea for ceremonial use according to CEC's practices by adding hot water to the ayahuasca paste. This process will occur under the constant supervision of at least one ayahuasquero. Plaintiffs estimate the amount of ayahuasca tea needed per ceremony to be about 30 to 45 ml on average per participant. After preparing the ceremonial tea, the ayahuasquero will note the resulting amount of liquid in milliliters, and transfer it to a secure bottle. The log will record the volume in milliliters, the time and date produced, and any notes about quality.

45. If in liquid form, in the event it becomes necessary to decant stored ayahuasca, clear off mold and any harmful contaminants or impurities, or boil the ayahuasca to render the ayahuasca suitable for use, CEC shall measure the volume of ayahuasca before and after boiling and maintain a written record of all such processing of ayahuasca, memorializing any incidental change of volume.

46. If ayahuasca originating from one batch is mixed with ayahuasca originating from a different batch, the resulting mix shall be stored in containers labeled with the unique identifiers of any and all originating batches and the precise volume taken from each. If ayahuasca must be boiled again, some loss of volume may occur due to evaporation; hence, a written record of the total volume after boiling should also be recorded for accuracy of records.

47. All manufacturing activities, including processing, packaging, and labeling, shall be conducted at the location registered for said activities by an authorized person. All ayahuasca being processed, packaged, or labeled, shall be securely locked at the end of the activity [21 C.F.R. § 1301.73].

48. This Agreement only grants CEC the authorization to manufacture ayahuasca from the concentrated ayahuasca paste or liquid that it has imported. If Plaintiffs decide to manufacture ayahuasca from plants grown in the United States, Plaintiffs will apply to DEA for registration as a bulk manufacturer. Plaintiffs will determine the amount of ayahuasca to be imported or manufactured solely for their religious use.

49. CEC must advise the local DEA Field Office of any intended changes to its manufacturing processes that are inconsistent with this Settlement Agreement.

E. Distribution of the Ayahuasca

50. DEA agrees to exempt CEC from separately registering with DEA as a distributor. DEA considers the transportation and distribution of sacramental ayahuasca tea at CEC's ceremonial location(s) to be a coincident activity of the DEA manufacturer registration, as described in 21 C.F.R. § 1301.13(e)(1)(i). This incidental transportation and distribution are permitted solely for the CEC's religious exercise under RFRA. Consequently, CEC's ceremonial location(s) in the State in which it is registered to manufacture ayahuasca under RFRA do not need a separate DEA registration as long as CEC does not store or manufacture ayahuasca at the ceremonial location(s).

51. Plaintiffs Tafur and Sullivan, are the only individuals currently authorized to transport the ceremonial tea to the designated ceremony site(s). The ceremony locations will be at the residence of members of CEC or at other locations determined to ensure the security of the ayahuasca and the safety of participants, and such locations shall be determined by CEC. CEC accepts sole responsibility for compliance with all applicable federal, state, and local laws in determining ceremony locations.

52. CEC may designate any individual(s) of its choice to handle ayahuasca tea when conducting religious ceremonies and performing religious functions. CEC's protocols require, and CEC will continue to require, ceremony participants consuming ayahuasca tea to undergo a health screening. CEC has developed an Emergency Response Plan in case of any medical or psychiatric needs. All ceremonies will have the presence of one person trained in basic first aid and capable of responding in an emergency. CEC will mitigate risks of ceremony participants leaving the premises while under the influence of ayahuasca.

53. For transportation and distribution incidental to the manufacture of ayahuasca for religious ceremonies, DEA agrees not to enforce the DEA regulations applicable to distributors, except as provided by this Agreement. CEC will maintain records of the dates of each delivery or distribution event, the form of the controlled substance (liquid, paste, etc.), the approximate number of persons provided with ayahuasca doses, and the approximate amount of controlled substances (ounces, pounds, liters, gallons, etc.) delivered or distributed at each ceremony or other event where the ayahuasca will be utilized for religious purposes. CEC's authorized staff/members will provide to the DEA the initials of the ayahuasquero(s) who provided the ayahuasca to participants of the ceremony. CEC's records will also identify the ayahuasca manufactured batch(es) and container(s) from which the consumed ayahuasca is taken. CEC shall not be required to report the names or addresses of individual members or non-member ceremonial participants.

F. Quota

54. To adhere to its quota obligations and the requirements set forth under the Single Convention on Narcotic Drugs, DEA may account for the total amount of the controlled substance, exempted under RFRA, authorized to be imported and/or manufactured by CEC to meet all anticipated legitimate needs. In any quota proceeding, DEA will not seek to limit the quantity of ayahuasca necessary for Plaintiffs' religious use.

G. Inspection

55. DEA may inspect any location that CEC seeks to register as an import or manufacture location. *See* 21 C.F.R. § 1301.31. CEC agrees to cooperate with any such lawful inspections, and the inspection of the proposed registered location should be limited to the area used to handle all activities related to the importation or manufacture of ayahuasca. DEA agrees to avoid any burden to ayahuasqueros, and not to extend to or seek inspection of, other areas of the property as long as CEC restricts any movement of ayahuasca to those designated areas.

56. DEA has the authority to enter registered premises and conduct administrative inspections and audits thereof at reasonable times and in a reasonable manner. *See* 21 C.F.R. § 1316.03. If representatives of the DEA arrive at a registered location unannounced and an authorized person is not present, the DEA representatives will promptly attempt to notify an authorized person of their intent to inspect the location, and the authorized person will make every reasonable effort to ensure that DEA representatives are able to inspect the location promptly. 21 C.F.R. § 1316.08. DEA will not conduct administrative inspections during CEC-authorized religious ceremonies. DEA acknowledges that the registered locations where CEC handles ayahuasca are not businesses with regular business hours, and, accordingly, that it might be necessary to make arrangements before the inspection to ensure that an authorized person, as defined by paragraph 7 of this Agreement, is available at the time the DEA seeks to conduct an inspection. If DEA personnel arrive at a registered location unannounced and an authorized person is not present, the DEA representatives will promptly attempt to notify an authorized person of their intent to inspect the location, and the authorized person will make every reasonable effort to ensure that DEA personnel are able to inspect the location promptly. DEA personnel may only enter a registered location to conduct an

administrative inspection pursuant to 21 C.F.R. § 1316.03 when an authorized person is present at the location.

57. CEC will provide the local DEA Field Office with general information about the locations and dates of their ceremonies. CEC will notify DEA in writing of any significant changes to this information.

58. During administrative inspections, DEA personnel may take a physical inventory of all ayahuasca on the premises. CEC's authorized individuals at each location will assist in the physical inventory by handling the containers of ayahuasca so that their labels can be read by DEA personnel without the need for DEA personnel physically to touch the containers.

59. If DEA seeks to inspect an item or items as described in 21 C.F.R. § 1316.03(f) and, and if CEC objects on any basis, then CEC may package the item or items in a container in the presence of DEA personnel; DEA personnel will affix a seal to the container. DEA may then submit an application for an administrative inspection warrant to a United States District Judge or Magistrate Judge as described in 21 C.F.R. § 1316.09. CEC agrees that the seal will remain unbroken and that the container will not be opened until a determination is made by a court of competent jurisdiction whether the item(s) can lawfully be inspected by DEA.

H. Record Keeping

60. CEC will be responsible for all record keeping related to its inventory of ayahuasca in any authorized form. CEC's registered location shall establish and maintain on a current basis a complete and accurate written record of its importation, receipt, manufacture, distribution, and disposal of ayahuasca in accordance with 21 C.F.R. § 1304.21 *et seq.* Once a registration has been granted, in addition to an initial physical inventory, each CEC's registered location shall take a physical inventory of all ayahuasca at least once every two years.

61. CEC shall maintain separate inventory records of all ayahuasca for a minimum of two years. Each inventory will be a physical count of all ayahuasca on hand on the date the inventory is taken, and CEC will maintain the inventory in readily retrievable form at the registered location. Each inventory will include all information listed in 21 C.F.R. § 1304.11.

62. All distribution of ayahuasca from a DEA registration to another DEA registration, shall be documented on a DEA Form 222, Official Order Form, as described in 21 C.F.R. § 1305.

63. CEC shall assign a unique identifier to each batch and container of ayahuasca that is received through international shipment. The DEA import permit number shall also appear on each container. Each container being imported into the U.S. shall bear a sufficiently prominent label with clear and sufficiently large symbols to enable DEA personnel to read from arm's-length distance the DEA permit number, point of origin (city, state/province, and country), batch identifier, end location, quantity, and date shipped. To facilitate maintenance of a chain of custody, the unique identifier shall follow the imported ayahuasca and shall be used in CEC's records until its ultimate use or disposal and shall also appear on any container into which imported ayahuasca from a particular batch or consignment may be decanted or repackaged.

64. CEC shall maintain records of their distribution of ayahuasca, listing the date distributed; general location; the number of participants in the religious ceremony or event who received ayahuasca; the total amount of ayahuasca consumed during the ceremony or event; and the dispenser's initials. These records will also identify the batch(es) and container(s) from which the consumed ayahuasca is taken. *See* 21 C.F.R. § 1304.24(a).

65. All required records shall be in readily retrievable form and available for inspection upon request by DEA for a minimum of two years. *See* 21 C.F.R. §§ 1304.04, 1304.11, 1304.21-1304.22, 1305.

I. Security

66. CEC acknowledges its obligation to provide effective controls and procedures to guard against theft and diversion. CEC will store the ayahuasca at CEC's registered address. The residence is equipped with a door with a deadbolt lock. The ayahuasca will be secured inside a locked refrigerator. CEC ayahuasqueros will be the only ones with access to the storage area. Plaintiffs will maintain at the current CEC central import and storage location a 24-hour alarm system through which a report of any unauthorized access to the location will be immediately transmitted to a protection company with a duty to respond or to the appropriate local law enforcement agency. Defendants acknowledge that CEC is not required to install and maintain such alarm systems at its other non-registered locations.

67. CEC shall designate in writing any authorized individual(s) who will have access to the ayahuasca at each registered location. CEC shall provide written notification of the names (including aliases and maiden names, where applicable), last four digits of their social security numbers and dates of birth of each authorized individual to the DEA Point of Contact, and to the local DEA Diversion Program Manager.

68. DEA may conduct appropriate inquiries to ascertain whether an authorized individual has been convicted of a felony relating to controlled substances. If DEA discovers that an authorized individual has been convicted of such a felony, DEA will promptly so advise the CEC Point of Contact. The parties will discuss whether, based on all the facts and circumstances of the particular case, in light of CEC's religious concerns and DEA's security concerns, the authorized individual should have access to or custody of the locked safe(s) or refrigerator(s) used solely for the purpose of storing ayahuasca, or be permitted to handle ayahuasca outside the context of religious ceremonies.

69. Whenever anyone, other than an authorized individual, or an authorized official or agent of the U.S. government, is present in the room in which ayahuasca is stored at a registered location, that person shall be accompanied at all times by an authorized individual.

70. DEA will conduct a preregistration inspection of any location at which a DEA registration is sought. In evaluating the overall security system and the needs of each registrant, DEA will consider the factors enumerated under 21 C.F.R. § 1301.71(b) to safeguard properly the ayahuasca under the control of each registrant. The local DEA Field Office and CEC's representative at each location within the field office's jurisdiction will engage in discussions to attempt to arrive at a mutually agreeable security plan based on the security needs of each specific location and commensurate with the quantity stored.

71. DEA agrees to enforce only the specific physical security measures described in 21 C.F.R. § 1301.72(a) and (d) as set forth in this Agreement. CEC will maintain, at CEC's expense, at the registered storage location the security system specified in paragraph 66 of this Agreement. In the event it becomes necessary to modify the security settings to ensure effective controls, CEC shall notify the local DEA Field Office. Any modification in the storage area that has not been approved by the Administration, shall not necessarily be deemed to comply substantially with the standards set forth in §§ 1301.72 and 1301.73.

72. CEC agrees to transport manufactured ayahuasca tea to the ceremonial place for the purpose of religious exercise in a secured lockbox out of plain view in a locked vehicle. For security during any incidental transport, CEC ayahuasqueros agree to keep the ayahuasca in a lockbox and will not leave it unsupervised. CEC will not designate anyone other than an authorized person to transport ayahuasca.

CEC will not be required to install and maintain physical security measures described in 21 C.F.R. § 1301.72 (a) through (d) at incidental locations (i.e., ceremonial places) that do not store the controlled substance(s), but CEC shall maintain adequate controls at incidental location(s) to prevent diversion as set forth in this Agreement.

73. When importing ayahuasca paste or liquid, CEC is responsible for selecting couriers or contract carriers that provide adequate security to guard against in-transit loss, as described in 21 C.F.R. § 1301.74(e).

74. CEC will immediately advise the local DEA Field Office of any diversion, theft, or significant loss of ayahuasca, including in-transit losses by their agent or the common or contract carrier after a shipment has been released by CBP at the port of entry. Written notification must be made within one business day of discovery of the diversion, theft, or loss. A completed and accurate DEA Form 106, Report of Theft or Loss of Controlled Substances, shall also be filed through the DEA Diversion Control Division secure network application within 45 calendar days after discovery of the theft or loss. *See* 21 C.F.R. 1301.74(c). In the event there is any diversion, theft, or significant loss of ayahuasca from a registered location, DEA will discuss with CEC what, if any, additional security measures are reasonably necessary to prevent future theft.

J. Disposal

75. CEC acknowledges that any transported ayahuasca sacrament will be entirely consumed on ceremonial premises, disposed of, or returned to storage.

76. When CEC determines that it is necessary to make final disposition of ayahuasca, the registrant shall advise the Special Agent in Charge (“SAC”) of the area by submitting a DEA Form 41, listing the amount to be disposed of, identifying the batch and container from which it was taken, stating the date, time, and place at which CEC proposes to dispose of the Ayahuasca, and identifying the individuals who will take part in the ayahuasca disposal.

77. The SAC and/or designee shall have the discretionary authority to observe the disposal of ayahuasca. Nothing herein should be construed as DEA approving or endorsing the disposal method selected by CEC. Nothing in this Agreement shall require CEC to dispose ayahuasca in a manner that violates the religious tenets of CEC, provided that CEC accepts sole responsibility for compliance with all applicable federal, state, and local laws, implicated by the disposal of ayahuasca.

IV. POINTS OF CONTACT

78. Direct written communications to DEA’s headquarters elements who are referred to in this Agreement should be directed to the email (preferred) and postal addresses below:

| DEA Point of Contact | Email Address | Postal Address |
|----------------------|---------------|---|
| Regulatory Section | DRG@dea.gov | Drug Enforcement Administration Regulatory Section/DRG Attention: RFRA 8701 Morrissette Drive Springfield, VA 22152 |

| | | |
|--|-------------------------------|--|
| Import/Export Section | ODGI@dea.gov | Drug Enforcement Administration Regulatory Section Attention: Import/Export (DRI) 8701 Morrissette Drive Springfield, VA 22152 |
| Registration and Program Support Section | DRRO@dea.gov | Drug Enforcement Administration Registration Section Attention: RFRA 8701 Morrissette Drive Springfield, VA 22152 |
| DEA Local Field Office | Phoenixdiversiongroup@dea.gov | DEA Phoenix Divisional Office Attn: Diversion Group 3439 East University Drive Phoenix, Arizona 85034 |

V. NON-LIABILITY OF THE U.S. GOVERNMENT

79. The United States assumes no liability with respect to third party claims arising out of the performance of any religious practices by CEC, including but not limited to the quantity or quality of any sacrament distributed and ingested. The sole remedy for damages by third parties will be against CEC and not the United States.

VI. DURATION, AMENDMENT, AND EFFECT

80. Execution: This Agreement may be executed in counterparts, each of which constitutes an original, and all of which constitute one and the same agreement. Copies or facsimiles of signatures will constitute acceptable, binding signatures for purposes of this Agreement. This Agreement is effective and becomes binding upon the date of the last signature below. Each person who signs this Agreement in a representative capacity warrants that he or she is fully authorized to do so. The government signatories represent that they are signing this Agreement in their official capacities.

81. Automatic Renewal: This Agreement is effective for a one-year initial term from its effective date, subject to automatic renewal for additional one-year terms upon DEA’s approval of CEC’s application for renewal of its import registration and manufacture registration of DMT unless, on or before 60 days before the expiration of the current term, either party provides written email notice of its intention not to renew. The DEA may not refuse to renew for any reason other than upon a showing of diversion by CEC or upon a showing of a particularized risk to public health and safety. In accordance with 21 C.F.R. § 1301.13(e)(3), DEA will send CEC a renewal notification via email approximately 60 calendar days prior to their registration expiration date.

If, at the time the initial term or a renewal is set to expire, CEC has submitted a renewal application that is still being processed by the DEA at the end of a one-year term, CEC is allowed to continue to operate on a day-by-day basis until the registration is renewed in accordance with 21 C.F.R. § 1301.36(i), and the term set to expire will be automatically extended until the registration is renewed.

82. Severability: If any one or more of the provisions contained herein shall, for any reason, be held to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provision of this Agreement, but this Agreement shall be construed as if such invalid, illegal, or unenforceable provision had never been contained herein.

83. Modification: This Agreement constitutes the full and complete Agreement between the Parties. No other promises or agreements will be binding unless placed in writing and signed by both parties to the Agreement. All material representations, understandings, and promises of the parties are contained in this Agreement, and each of the parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement. Subject to the terms of this Agreement, this Agreement may be revised at any time with, and only with, the mutual written consent of the parties. Modifications to the Agreement will become effective on the date of the last signature of the authorized representatives of each party.

VII. ADDITIONAL TERMS AND CONDITIONS

84. Compliance with State and Local Laws: Any importation, manufacturing, distribution, transportation, or disposal, must be lawful in the state and locality where such action takes place. Such action also must follow all applicable state and local laws, statutes, and regulations, and be otherwise permitted by all applicable state and local regulatory and law enforcement agencies.

85. Good Faith: The terms and provisions of this Agreement shall be executed in good faith.

86. Venue & Jurisdiction: The parties agree that any dispute arising between and among the parties to this Agreement shall be resolved pursuant to the dispute resolution procedures specified in Article IX of this Agreement. If such procedures do not resolve the dispute, the Parties agree that jurisdiction is retained by and venue is proper in the United States District Court for the District of Arizona for its resolution.

87. Nothing in this Agreement shall be construed to prevent Defendants from taking actions or issuing rulemakings authorized by U.S. law (including the Administrative Procedure Act).

VIII. ATTORNEYS' FEES

88. Once this Settlement Agreement is signed by the Parties, the Parties will file a Notice of Settlement with the Court. After filing the Notice of Settlement, the parties have 60 days to negotiate attorneys' fees and costs. If, after 60 days, the Parties have not come to an agreement on attorneys' fees and costs, that issue will be submitted to the Court on a motion by Plaintiffs. Should such a Motion be necessary, nothing in this Agreement shall preclude either party from attaching this Settlement Agreement to the Motion.

89. Neither this Agreement nor the payment of attorneys' fees, costs, and expenses hereunder is an admission by Defendants of the truth of any allegation or the validity of any claim asserted in this action, or of Defendants' liability therein. The provision of attorneys' fees, expenses, and costs in this Settlement Agreement is by the agreement of the parties and is not intended to serve as precedent, nor may it be cited as such, in this or any case.

90. Compliance with all applicable federal, state, and local tax requirements shall be the sole responsibility of Plaintiffs and their attorneys, contractors, or experts.

IX. RESOLUTION OF DISPUTES ARISING OUT OF THIS AGREEMENT

91. Subject to paragraph 25 of this Agreement and the Religious Freedom Restoration Act, disputes between the Parties concerning any alleged breach of this Agreement shall be subject to the following dispute resolution procedures.

- a. The Parties shall make good faith efforts to resolve informally any alleged breach of this Agreement. If informal efforts to resolve the alleged breach are unsuccessful, the aggrieved Party shall provide written notice of the alleged breach and that Party's intent, if any, to initiate the dispute resolution procedure of this Agreement. The notice shall include a recitation of the material-facts and circumstances giving rise to the dispute, including the particular provisions of the Agreement alleged to have been breached.
- b. If the dispute is not resolved by the Parties within thirty (30) days after such notice is given, such dispute shall be submitted to mediation before a mutually agreed-upon neutral mediator. The Parties shall each bear their own costs and attorneys' fees incurred in connection with such mediation.
- c. If the dispute is not resolved by the Parties through mediation, either Party may apply to the U.S. District Court for relief, which shall retain jurisdiction solely for this purpose.

X. RELEASE, DISCHARGE, AND DISMISSAL OF PLAINTIFFS' CLAIMS

92. Upon the execution of this Settlement Agreement, and receipt of the agreed upon payment described in paragraph 88, Plaintiffs hereby release and forever discharge Defendants and their successors, the United States of America, and any department, agency, or establishment of the United States, and any officers, employees, agents, successors, or assigns of such department, agency, or establishment, from any and all past or present claims for attorneys' fees, costs, or litigation expenses in connection with this litigation.

93. This Agreement contains the entire agreement between the parties hereto, and Plaintiffs acknowledge that no promise or representation not contained in this Agreement has been made to them, and further acknowledge that this Agreement contains the entire understanding between the parties, and it contains all terms and conditions pertaining to the compromise and settlement of the disputes referenced herein.

94. Within fifteen (15) days of the receipt of the payment described in paragraph 88, Plaintiffs shall dismiss this case with prejudice pursuant to Fed. R. Civ. P. 41(a) by filing a Stipulation of Dismissal with Prejudice.

95. The undersigned represent that they are fully authorized to enter into this Agreement.

Date: April 12, 2024

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