

United States Department of Agriculture
Animal and Plant Health Inspection Service
4700 River Road
Riverdale, MD 20737

Permit to Receive Soil
Regulated by 7 CFR 330

This permit was generated electronically via the ePermits system.

PERMITTEE NAME:	Dora M. Ogles	PERMIT NUMBER:	P330-16-00294
COMPANY:	Microbial Insights, Inc.	APPLICATION NUMBER:	P525-160705-001
RECEIVING ADDRESS:	10515 Research Drive Knoxville, TN 37932-2536	DATE ISSUED:	10/04/2016
MAILING ADDRESS:	10515 Research Drive Knoxville, TN 37932-2536		
PHONE:	(865) 573-8188 Ext. 107	EXPIRES:	08/27/2019
FAX:	(865) 573-8133		

PORTS OF ARRIVAL/PLANT INSPECTION STATIONS: AK, Anchorage; AL, Huntsville; AL, Mobile; AZ, Douglas; AZ, Lukeville; AZ, Naco; AZ, Nogales; AZ, Phoenix; AZ, San Luis; AZ, Tucson; CA, Calexico; CA, El Segundo; CA, Fresno; CA, Long Beach; CA, Oakland; CA, Ontario; CA, Otay Mesa; CA, Port Hueneme; CA, Sacramento; CA, San Diego; CA, San Francisco; CA, San Jose; CA, San Ysidro; CA, Tecate; CO, Denver; CT, Hartford; CT, New Haven; DE, Dover; DE, Wilmington; FL, Ft. Lauderdale; FL, Ft. Myers; FL, Ft. Pierce; FL, Jacksonville; FL, Key West; FL, Miami; FL, Miami (Cargo, DHL, Fed Ex, UPS, etc.); FL, Orlando; FL, Pensacola; FL, Port Canaveral; FL, Port Everglades; FL, Sanford; FL, Tampa; FL, West Palm Beach; GA, Atlanta; GA, Savannah; GU, Agana; HI, Hilo; HI, Honolulu; HI, Kahului; HI, Kailua-Kona; HI, Lihue; ID, Eastport; IL, Chicago; IN, Indianapolis; KY, Louisville; MA, South Boston; MD, Baltimore; MD, Beltsville; ME, Bangor; ME, Calais; ME, Houlton; ME, Portland; MI, Detroit; MI, Port Huron; MI, Romulus; MI, Sault Saint Marie; MN, Duluth; MN, Grand Portage; MN, International Falls; MN, Minneapolis; MO, Kansas City; MO, St. Louis; MP, Commonwealth of the Northern Mariana Islands; MS, Gulfport; MS, Port Bienville; MT, Raymond; MT, Roosville; MT, Sweetgrass; NC, Raleigh; NC, Wilmington; ND, Dunseith; ND, Pembina; ND, Portal; NJ, Linden; NM, Albuquerque; NM, Columbus; NM, SantaTeresa; NV, Las Vegas; NY, Albany; NY, Alexandria Bay; NY, Brooklyn; NY, Buffalo; NY, Champlain, Rouses Point; NY, Jamaica; NY, Jamaica; NY, Newburgh; OH, Ashtabula; OH, Cincinnati; OH, Cleveland; OH, Columbus; OH, Toledo; OH, Wilmington; OK, Oklahoma City; OR, Portland; PA, Allentown; PA, Harrisburg; PA, Philadelphia; PA, Pittsburgh; PA, Scranton; PR, Aguadilla; PR, Carolina; PR, Fajardo; PR, Mayaguez; PR, Ponce; RI, Warwick/Providence; SC, Charleston; TN, Memphis; TN, Nashville; TX, Austin; TX, Brownsville; TX, Corpus Christi; TX, Dallas; TX, Del Rio; TX, Eagle Pass; TX, El Paso; TX, Fabens; TX, Falcon; TX, Fort Hancock; TX, Galveston; TX, Hidalgo; TX, Humble; TX, Laredo; TX, Los Indios; TX, Pharr; TX, Port Arthur; TX, Presidio; TX, Progresso; TX, Rio Grande City; TX, Roma; TX, San Antonio; TX, Victoria; UT, Salt Lake City; VA, Dulles; VA, Norfolk; VI, St. Croix; VI, St. Thomas; VT, Berlin; WA, Blaine; WA, Oroville; WA, Port Angeles; WA, SeaTac; WA, Sumas; WI, Green Bay; WI, Milwaukee

HAND CARRY: No

Under the conditions specified, this permit authorizes the following:

Quantity of Soil per Shipment and Treatment
Over 3 lbs - Your facility **MUST** be inspected and approved to receive this soil

SPECIAL INSTRUCTIONS TO INSPECTORS

See permit conditions below

Permit Number P330-16-00294

THIS PERMIT HAS BEEN APPROVED ELECTRONICALLY BY THE
FOLLOWING PPQ HEADQUARTER OFFICIAL VIA EPERMITS.


Mark A. Stull

DATE

08/27/2016

WARNING: Any alteration, forgery or unauthorized use of this Federal Form is subject to civil penalties of up to \$250,000 (7 U.S.C.s 7734(b)) or punishable by a fine of not more than \$10,000, or imprisonment of not more than 5 years, or both (18 U.S.C.s 1001)

INSTRUCTIONS TO DHS CBP INSPECTORS FOR IMPORTED SOIL SHIPMENTS ROUTED TO RECEIVING FACILITY:

For hand carry of soil, an official of CBP Agricultural Programs and Trade Liaison (APTL) would have been notified to document and facilitate the entry of the soil (See hand carry conditions below if stipulated).

THIS PERMIT DOES NOT AUTHORIZE HAND-CARRY OF THE REGULATED MATERIAL.

Otherwise:

1. Validate the permit in ePermits using the CBP search feature by logging on to:
<https://epermits.aphis.usda.gov/epermits>
2. Confirm that the shipment is being routed directly to a USDA APHIS PPQ Inspected Facility authorized to receive soil by logging on to: <https://web01.aphis.usda.gov/PPQ/AuthSoilLabs.nsf/web?openform>
3. Confirm that the imported shipment has a valid USDA PPQ Form 550 Black/White label.
4. Confirm that the carrier of the shipment imported under this USDA PPQ 525 permit is commercially bonded.
5. For questions or concerns, contact the USDA APHIS PPQ Permit Unit in Riverdale, MD, at 866-524-5421 and ask to speak with a compliance officer.

PERMIT GUIDANCE

Receipt or use of foreign isolates or samples from countries under sanctions requires specific permission from the U.S. Department of Treasury (see <http://www.treasury.gov/resource-center/sanctions/Programs/Pages/Programs.aspx> for current country/regional listings) for current country listings.

This permit does not authorize importation, interstate movement, possession, and/or use of strains of genetically engineered regulated organisms (created by the use of recombinant DNA technology).

If an animal pathogen is identified in your shipment, to ensure appropriate safeguarding, please refer to http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_anproducts.sh

tml.

If a human pathogen is identified, please see the CDC Etiologic Agent Import Permit Program at <http://www.cdc.gov/od/eaipp/>

This permit does not fulfill the requirements of other federal or state regulatory authorities. As appropriate, please contact the U.S. Environmental Protection Agency, the U.S. Fish and Wildlife Service, the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, the APHIS Veterinary Services unit, or your State's Department of Agriculture to ensure proper permitting.

If you are considering renewal of this permit, an application should be submitted at least 90 days prior to the expiration date of this permit to ensure continued coverage. Permits requiring containment facilities may take a longer period of time to process.

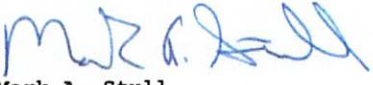
This permit authorizes the importation of soil from all foreign sources (except countries with sanctions or embargoes by U.S. State Department) only for chemical/ physical analysis in a controlled laboratory environment at the named facility on the permit.

All soil residues must be dry-heated, incinerated or autoclaved.

Dry Heat Treatment: use one of the following schedules:

110- 120.5 degrees C (230-249 F) for 16 hours

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121-154 degrees C (250-309 F) for 2 hours
154.4 - 192.5 degrees C (310-379 F) for 30 minutes
193-220 degrees C (380-429 F) for 4 minutes
221-232 degrees C (430-450) for 2 minutes

Time starts when the entire sample reaches the required temperature, and a suitable temperature probe must be used for verification.

Autoclaving Waste

- Waste must be autoclaved at 121 degrees Centigrade (250 degrees Fahrenheit) for a minimum of 30 minutes.
- Autoclave tape or other indicators must be placed on each load prior to treatment. The autoclave tape or other indicator on each container must be checked to verify color change before disposal.
- The autoclave must be professionally calibrated annually and a written record must be maintained.
- Every 3 months, you must use a commercially available biological indicator kit that uses bacterial spores (e.g. *Geobacillus* species) that are rendered unviable at 121 degrees C. You must follow the manufacturer's instructions. If any growth is observed, you must have the autoclave serviced and retested.

Incineration:

With the exception of metal and glass containers, all regulated and associated material must be reduced completely to ash at the end of the incineration cycle.

PERMIT CONDITIONS

This permit authorizes the importation of soil from all foreign sources (except countries with sanctions or embargoes by U.S. State Department), and interstate/ domestic movement of soil from Hawaii, the contiguous U.S., the continental U.S., and all U.S. territories for chemical/ physical analysis including the isolation and/or culture of Deoxyribonucleic Acid (DNA) or Ribonucleic Acid (RNA) in a controlled laboratory environment at the named facility on the permit.

- This permit is issued only for the named permit holder at the address(s) identified on this permit. This permit cannot be transferred or assigned.
- The permit holder verifies United States residency by initialing and accepting these permit conditions. If you are not a United States resident, it is unlawful for you to initial or accept these permit conditions because a USDA 525 soil Permit can only be issued to United States residents.
- The permit holder is solely responsible for ensuring compliance with all statutory requirements and specifically listed permit conditions. Failure to comply with the terms and conditions of this permit is cause for the following: (a) cancellation of this permit, (b) cancellation of other permits issued to the permit holder, (c) seizure and/or destruction of regulated organisms, (d) denial of future permit applications by this permit holder, (e) liability for civil penalties, and (f) criminal prosecution under provisions in the Plant Protection Act.
- Any alteration, forgery, unauthorized use of this permit and/or associated Federal Forms are subject to civil and criminal penalties including fines and imprisonment.
- This permit must not be used for the movement or use of plant pathogens listed in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. If any organism listed as a Select Agent is identified from materials associated with this research, the permit holder is required to notify APHIS, Agricultural Select Agent Program (ASAP) within one business day by phone at 301-851-3300, and within seven (7) days submit APHIS/CDC Form 4 (Report of Identification of a Select Agent or Toxin in a Clinical or Diagnostic Laboratory) to APHIS, ASAP; 4700 River Rd, Unit 2, Riverdale, MD 20737 (see instructions at: http://www.aphis.usda.gov/programs/ag_selectagent/index.shtml). Failure to comply with this requirement is a violation of the Agricultural Bioterrorism Protection Act of 2002.

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6. If a regulated organism is received in this shipment, the permit holder must take all prudent measures to contain the organism(s) and notify the permit unit within one business day by calling 866-524-5421 or by e-mail to pest.permits@aphis.usda.gov. The permit holder must immediately notify the permit unit of the destruction of regulated organisms received under this permit, as above. Similarly, the permit holder must immediately notify the permit unit if facilities are destroyed or decommissioned for any reason.
7. You as the permit holder are responsible for maintaining a valid permit for as long as the soil is in your possession. APHIS does not issue extensions or renewals of existing permits; the permit holder must submit a new permit application at least three months prior to the expiration of this permit, and obtain a new permit to continue uninterrupted authorization for the soil approved under this permit.
8. If an accidental release into the environment occurs, notification must be made within one business day to APHIS, PPQ, 4700 River Rd., unit 133; Riverdale, MD 20737; 866-524-5421. A written report of the incident must be submitted identifying: (a) the name of the permit holder (responsible person), (b) the permit number, (c) the country or State of origin of the soil, (d) the nature of the release, and (e) measures already taken to contain, reduce or limit the effects of the accidentally released soil. Any plans prepared to contain, reduce or limit the effects of the accidentally released soil may be submitted as developed.
9. Without prior notice and during reasonable hours, authorized PPQ and/or State regulatory officials shall be allowed to inspect the conditions associated with the regulated soil authorized under this permit.
10. The permit holder must maintain an official permanent work assignment at the address identified on this permit. If the permit holder ceases assignment/affiliation at the address identified on this permit, or personnel circumstances change in any way, then a compliance officer must be notified at the PPQ permit unit immediately (that is, within one business day) by either (a) email to pest.permits@aphis.usda.gov, (b) fax to 301-734-4300 or 8700/5392, or (c) conventional mail to USDA PPQ Permit Unit, 4700 River Road, Riverdale, MD 20737. Should the permit holder depart from the organization/facility, the permit holder must either (a) request cancellation of this permit and comply with all permit-specific termination conditions, (b) apply for and receive a permit to move the soil to a new facility, or (c) relinquish control of the regulated soil to a qualified individual who obtained a permit for the continued use of this regulated soil prior to this permit holder's departure.
11. A copy of this permit must accompany all shipments authorized under this permit.
12. CBP-AI and PPQ have the authority to order and approve treatment, re-exportation or destruction of a shipment, a portion of a shipment or any other material associated with the shipment (i.e. pallets, packaging, and means of conveyance). If an official of CBP-AI or PPQ determines that the shipment requires treatment as a condition of entry, is contaminated with a quarantine plant pest or pests, is commingled with prohibited plant material or the required documentation is incomplete or missing, then that official may order and approve treatment, re-exportation or destruction of a shipment, a portion of a shipment or any other material associated with the shipment (i.e. pallets, packaging, means of conveyance).
13. All solid wood packing material (SWPM) accompanying the shipment must be in compliance with ISPM 15 treatment regulations and IPPC stamp requirements and enforcement. Noncompliant shipments will be treated, re-exported or destroyed at the consignee's expense.
14. All costs and arrangements for safeguarding and transportation of the cargo are the responsibility of the importer, broker or other parties associated with the shipment.
15. All operations must be consistent with information submitted in association with the above listed APHIS-PPQ inspected facility and subject to the conditions below.
16. Soil must be shipped in a securely closed, watertight container (primary container, test tube, vial, etc.) which must be enclosed in a second, durable watertight container (secondary container).
17. The shipment must be free from foreign matter or debris, plants and plant parts including noxious weeds and infestations by other macroorganisms such as insects, Cyst nematodes, mollusks and acari. Authorized material found to be commingled with unauthorized material will be subject to the same action (i.e. re-export, destruction) as unauthorized material.
18. The imported article can be released without treatment at the port of entry to the permittee's address listed on the permit or label or to an authorized user only if the final destination is an approved facility listed at <https://web01.aphis.usda.gov/PPQ/AuthSoilLabs.nsf/web?openform>.

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19. The soil must not be used in field research or release into the environment before sterilization.

The soil must not be used for isolation or culture of organisms, or for extracting and concentrating organisms from the soil.

The soil must not be used as a growing medium.

20. Further intrastate distribution of soil is not allowed without prior approval from Federal officials [State Plant Health Director or designee] (or from Federal officials with State concurrence): Access the website at <http://www.aphis.usda.gov/ppq/sphd/> for a list of State Plant Health Offices. Access the website at <http://nationalplantboard.org/member/index.html> for a list of State Plant Regulatory Officials.

21. Further distribution of soil across state lines is not allowed without a permit from the receiving State. While in storage, all soil must be kept locked (e.g. in freezer, cabinet) in the approved lab with access limited to authorized personnel or they will be in a restricted access building that requires a key card entry and access is restricted to authorized personnel only; or it must be in locked room restricted to authorized personnel only.

22. The soil must be handled as quarantined material until sterilized. This will include keeping the soil enclosed in containers when not in use and labeling all containers and/or storage areas: "Quarantine Soil- Sterilize Before Disposal"

23. All packing material, media, substrate, and shipping containers must be sterilized or destroyed as approved and prescribed by the permit conditions after removing the soil.

24. All unconsumed soil, containers and effluent must be autoclaved, incinerated or properly sterilized by the permittee at the conclusion of the project as approved and prescribed by the permit conditions.

25. Any water residues (effluent) from the processing of soil samples must be treated by an approved sterilization procedure such as hydroclave or autoclave.

26. All soil residues must be dry-heated, incinerated or autoclaved.

Dry Heat Treatment: use one of the following schedules:

- 110- 120.5 degrees C (230-249 F) for 16 hours
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- b. Autoclave tape or other indicators must be placed on each load prior to treatment. The autoclave tape or other indicator on each container must be checked to verify color change before disposal.
- c. The autoclave must be professionally calibrated annually and a written record must be maintained.
- d. Every 3 months, you must use a commercially available biological indicator kit that uses bacterial spores (e.g. *Geobacillus* species) that are rendered unviable at 121 degrees C. You must follow the manufacturers instructions. If any growth is observed, you must have the autoclave serviced and retested.

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27. Equipment and supplies used to conduct operations or that have contacted the soil must be decontaminated using one of the following methods:

- (a) Material can be soaked in a fresh bleach solution of 10 percent (1:10) for at least 30 minutes. (1:10 is a convention that means 1 in 10 or 1 part 9 parts = 10 parts total, which is a 10 percent solution)
- (b) Material can be soaked in 70 percent ethanol
- (c) Flamed with ethanol
- (d) Treated with quaternary ammonium compounds.

Note also that autoclaving, hydroclave, incineration, and dry heat sterilization are also acceptable sterilization/decontamination methods.

28. Upon issuance of this permit (i.e., a signed PPQ 525), you will need to request the PPQ Form 550 Black/White labels at least 5 days in advance. If you applied online using ePermits, you may request the labels using the My Shipments/Labels feature. Otherwise, send your request to BlackWhiteGreenYellowlabelrequest@aphis.usda.gov. All email requests must come from the permit holder or appointee, if requested by the appointee the permit holder must be Ccd on all requests. Specify the approved port as listed on the permit and the total number of labels needed in multiples of four. You may request additional labels the same way. We will send you the labels by email as a pdf.

A label must be attached with clear tape to the exterior of each package being imported under this permit. The labels will include detailed shipping instructions. You are responsible for instructing your shipper to carefully follow these instructions. You are responsible for each import shipping label issued under this permit.

All labels must be printed in color. Failure to do so may result in refused entry or destruction of your package.

Enclose the following supplemental information in each shipment:

- Permittee Name
- Permit number
- Label number

Underlying packaging/wrapping must carry the address, billing, and any other information required to direct the shipment to its final destination (i.e., the permit holder's address; N.B., USDA APHIS does not defray any additional shipping costs incurred for transiting the shipment through an inspection station as the initial US destination).

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END OF PERMIT CONDITIONS

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