

United States Department of Agriculture
Animal and Plant Health Inspection Service
Plant Protection & Quarantine
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:	Megan O'Neil	PERMIT NUMBER:	P330-20-00125
COMPANY:	National Ag Genotyping Center	APPLICATION NUMBER:	P525-200424-001
RECEIVING ADDRESS:	1605 Albrecht Blvd N Fargo, ND 58102	DATE ISSUED:	05/23/2020
MAILING ADDRESS:	1616 Albrecht Blvd N Fargo, ND 58102		
PHONE:	(701) 239-1449	EXPIRES:	05/22/2023
FAX:			

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 Jose; CA, San Ysidro; CA, South San Francisco; 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, 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, Freeport; TX, Galveston; TX, Hidalgo; TX, Humble; TX, Laredo; TX, Los Indios; TX, Pharr; TX, Port Arthur; TX, Presidio; TX, Progreso; 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

Sterilization will interfere with intended use - Your facility **MUST** be inspected and approved to receive this soil

SPECIAL INSTRUCTIONS TO INSPECTORS

See permit conditions below

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<p>THIS PERMIT HAS BEEN APPROVED ELECTRONICALLY BY THE FOLLOWING PPQ HEADQUARTER OFFICIAL VIA EPERMITS.</p>  <p>Gibbs Smith</p>	<p>DATE</p> <p>05/18/2020</p>
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**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).

Otherwise:

- 1) Confirm that the shipment under this USDA PPQ P330 permit is under bond to the point of entry.
- 2) Validate the permit in ePermits using the CBP search feature.
- 3) Confirm that the imported shipment has a valid USDA PPQ Form 550 Black/White label.
- 4) 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

- 1) Receipt or use of foreign isolates or samples from countries under sanctions requires specific permission from the U.S. Department of Treasury; please refer to <https://www.treasury.gov/resource-center/sanctions/Programs/Pages/Programs.aspx>
- 2) This permit does not authorize importation, interstate movement, possession, and/or use of strains of genetically engineered regulated materials/organisms (created by the use of recombinant DNA technology).
- 3) 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.shtml
- 4) If a human pathogen is identified, please refer to the CDC Etiologic Agent Import Permit Program at <http://www.cdc.gov/od/eaipp/>
- 5) This permit does not fulfill the requirements of other federal or state regulatory authorities. Please contact the appropriate agencies, such as 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, the APHIS Biotechnology Regulatory Services, or your State's Department of Agriculture to ensure proper permitting.
- 6) 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.

PERMIT CONDITIONS

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CHEMICAL/PHYSICAL ANALYSIS AND DNA/RNA EXTRACTION

USDA-APHIS issues this permit to Megan O'Neil with National Ag Genotyping Center in Fargo, North Dakota. The 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 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.


1. 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.

2. If an accidental release into the environment occurs, notification must be made within one business day by email to: pest.permits@usda.gov (preferred) or in writing to: APHIS, PPQ, 4700 River Rd., unit 133; Riverdale, MD 20737; or by calling 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.

3.

- This permit is issued by the United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS). It conveys APHIS regulations and requirements for the material(s) listed on this permit. It does not reduce or eliminate your legal duty and responsibility to comply with all other applicable Federal and State regulatory requirements.
- The permit number or a copy of the permit must accompany the shipment.
- You must be an individual at least 18 years old, or legal entity such as partnership, corporation, association, or joint venture.
- You are legally responsible for complying with all permit requirements and permit conditions.
- The regulated material and shipping container(s) are subject to inspection by officials of Custom and Border Protection (CBP) and APHIS. CBP or APHIS officials may require the shipment to be treated, seized, re-exported, or destroyed (in part or whole). You will be responsible for expenses.

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- If you violate any applicable laws associated with this permit, you may face substantial civil or criminal penalties. We may cancel all current permits and deny future permit applications.
- Without prior notice and during reasonable hours, authorized Federal and State Regulators must be allowed to inspect the conditions associated with the regulated materials/organisms authorized under this permit.

4. 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.

5. Further distribution of soil is not allowed without a permit from the receiving lab. 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.

6. All operations must be consistent with information submitted in association with the above listed APHIS-PPQ inspected facility and subject to the conditions below.

7. The shipment must be free from foreign matter or debris, plants and plant parts, and other macro-organisms, such as insects, cyst nematodes, mollusks and acari. Regulated material commingled with unauthorized material will be subject to re-export or destruction.

8. 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 (valid, current P330 permit in ePermits) or check with your local State Plant Health Director and/or local PPQ field office.


9. 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.

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

11. The Permit holder must comply with all the items listed below. In cases where notification is required, the notification must be made to the Pest Permit staff at 866-524-5421 or pest.permits@usda.gov within one business day of the event triggering a notification. You must also notify the PPQ State Plant Health Director in your State. Access the list of SPHDs at https://www.aphis.usda.gov/aphis/ourfocus/planthealth/ppq-program-overview/ct_sphd.

- maintain a valid PPQ 330 permit so long as any portion of the regulated soil remains

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untreated,

- not assign or transfer this permit to other persons without prior APHIS PPQ authorization,
- maintain an official permanent work assignment or affiliation at the address on this permit,
- notify the Pest Permit Staff of any change in the permit holder's work assignment, residence, or affiliation,
- notify the Pest Permit Staff of the receipt of unauthorized and/or misdirected shipments of regulated soil,
- adequately mitigate environmental impacts resulting from unauthorized or accidental release of the regulated soil,
- notify the Pest Permit Staff if the facility or equipment is damaged/destroyed or if you wish to decommission the facility,
- devitalize/sterilize all regulated soil prior to departure from the organization unless other arrangements are confirmed by the Pest Permit Staff,
- notify the Pest Permit Staff if you intend to let your permit expire and you will no longer receive or work with the regulated soil.

12. For soil that originates in Hawaii and Puerto Rico, a copy of this permit or permit number and the shipment must be presented to APHIS-PPQ for inspection and clearance prior to departure. For soil that originates in the U.S. Virgin Islands, a copy of this permit or the permit number and the shipment must be presented to DHS-CBP for inspection and clearance prior to departure.

Following inspection, soil shipments from Hawaii, Puerto Rico, and the U.S. Virgin Islands are authorized to enter at any arrival point on the mainland U.S.

13. Upon arrival at the APHIS approved facility, the regulated soil must be stored in two levels of secured containment until transferred or sterilized. As long as regulated soil is present, the containment and all other affected areas of the facility must be restricted to access by authorized personnel only. All containers and storage areas will be labeled: 'USDA-Regulated Soil'. The secured containment area must store only regulated material or, if the area also houses unregulated material, the regulated material must be clearly segregated from the unregulated material as well as being appropriately labeled.


14. 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.

15. Prior to disposal, all regulated soil must be sterilized by one of the following method:

Autoclave:

- Autoclave at a minimum of 121 Celsius (250 Fahrenheit) for a minimum of 30 minutes at a minimum of 15 psi.
- Place autoclave tape or other indicators on each load prior to treatment. Check the autoclave tape or other indicator on each container to verify color change before disposal.
- Calibrate annually according to the manufacturer's instructions and maintain written records.

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- Use a commercially available biological indicator kit every 3 months, containing bacterial spores (e.g. *Geobacillus stearothermophilus* species) that are rendered unviable at 121 Celsius (250 Fahrenheit). Follow the manufacturer's instructions. Service and retest the autoclave if any growth is observed.

Dry Heat:

Use the following minimum combined temperature and time ranges:

- 110 - 120.5 Celsius (230 - 249 Fahrenheit) for 16 hours
- 121 - 154 Celsius (250 - 309 Fahrenheit) for 2 hours
- 154.4 - 192.5 Celsius (310 - 379 Fahrenheit) for 30 minutes
- 193 - 220 Celsius (380 - 429 Fahrenheit) for 4 minutes
- 221 - 232 Celsius (430 - 450 Fahrenheit) for 2 minutes

Time starts when the entire sample reaches the required temperature. Use a suitable temperature probe or currently calibrated thermometer for verification. The soil must be spread evenly throughout the chamber and not exceed 6 inches in depth.

Hydroclave:

- Hydroclave at a minimum temperature of 121 Celsius (250 Fahrenheit) for a minimum of 30 minutes, or at a minimum of 132 Celsius (267 Fahrenheit) for a minimum of 15 minutes.
- Observe the temperature sensor to ensure that the hydroclave maintains its required temperature.
- Calibrate hydroclave annually according to the manufacturer's instructions and maintain written records.

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.


Other:

No other sterilization methods are allowed without prior review and approval from the USDA-APHIS-PPQ Pest Permit Staff.

16. Unless other disposal arrangements have been approved in advance by USDA-APHIS-PPQ Pest Permit Staff, all items coming in direct contact with, or exposed to, the regulated soil -- including but not limited to glassware, countertops, equipment, waste material, effluent, and shipping materials -- must be sterilized/sanitized/decontaminated prior to removal from the APHIS approved facility, and prior to the expiration of this permit.

Use any of the following, either alone or in combination: 1) immersed in a minimum of a final concentration of 0.525 percent sodium hypochlorite for at least 20 minutes, 2) immersed in 70

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percent alcohol or ethanol for at least 10 minutes, 3) flamed with ethanol, 4) treated with quaternary ammonium compounds per manufacturer's specifications, or 5) one of the soil sterilization methods above.

17. Upon issuance of this permit (i.e., a signed PPQ 330), you will need to request the PPQ Form 550 Black/White labels at least 5 business days in advance of shipping date. If you applied online using ePermits, you may request the labels using the My Shipments/Labels feature. Otherwise, send your request to BlackWhiteGreenYellowlabelrequest@usda.gov. All email requests must come from the permit holder or appointee and if requested by the appointee, they must Cc the permit holder on all requests. Specify the permit number and the total number of labels needed. You may request additional labels the same way. We will send you the labels by email as a pdf.

However, the PPQ Form 550 Black/White label is not required on shipments of soil that originate in Hawaii, Puerto Rico, and the U.S. Virgin Islands.

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.

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).

18. Further distribution or movement of the regulated soil is not allowed without prior approval from the PPQ State Plant Health Director in your State. Access the list of SPHDs at <https://www.aphis.usda.gov/aphis/ourfocus/planthealth/ppq-program-overview/sphd>. For such movements, you must follow the packaging standards described in these permit conditions.

19. Certain domestic mainland soil is regulated under 7 CFR 301. This permit does NOT authorize the movement of such soil. For further information on the movement of domestic mainland soil visit:

https://www.aphis.usda.gov/plant_health/permits/organism/soil/downloads/Fed-SoilRegs.pdf and https://ecfr.io/Title-07/cfr301_main.

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20. Standard Operating Procedures (SOPs) must be filed with, and approved by, the APHIS PPQ Pest Permit Staff at: email: pest.permits@usda.gov; phone: 866-524-5421; fax: 301-734-8700; address: River Road, Unit 133, Riverdale, MD 20737. All contact information must be kept current and the SOPs must be dated. If requirements in the permit conditions are more restrictive than the SOPs, permit conditions take precedence. APHIS PPQ must approve any changes to the SOPs before implementation. At a minimum, the SOP should describe how you will maintain compliance with USDA APHIS-PPQ regulations. It must include how you plan to do the following: handle/process, store, safeguard, transport, treat, and dispose of the regulated soil, effluent, and anything else coming into contact with the regulated soil. The SOP must also contain instructions regarding the cleanup of potential spillage of regulated soil and must be posted in areas where soil is stored or processed. The SOP may be required at the time of inspection.

21. All packages must minimally consist of an inner (primary) and outer (secondary) container securely sealed so that both prevent unauthorized loss of the regulated soil. The primary package(s) must be sealed and adequately cushioned to withstand shock, impact, and pressure changes that may occur. The secondary container must be strong enough to withstand typical shipping conditions (dropping, stacking, impact from other freight, etc.) without opening.

22. The permit holder must keep records of all shipments received and samples processed under this permit. These records must be retained for a period of three (3) years after disposal, or after transfer of the regulated soil to another APHIS approved facility. If soil is transferred between soil approved facilities, the identity of the regulated soil samples must be maintained for traceability.

The records must include:


- Date of arrival of each shipment,
- Origin of the regulated soil
- Total weight of regulated soil in each shipment
- Date and weight of disposed or transferred regulated soil

Training records on each employee must be maintained for a period of three (3) years following the departure of that employee from the APHIS approved facility.

A list of all persons with access to the APHIS approved facility must be maintained. All records retained under this permit must be made available to Federal and State regulators upon request.

23. All employees working with the regulated soil must also complete annual training. The training must cover the requirements on this permit and the Standard Operating Procedures submitted to APHIS-PPQ. Both a copy of the permit and the SOPs must be available at all times for the facility staff to consult.

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24. Modifications to the facility or any procedural changes that affect the handling of the regulated soil must be approved by APHIS prior to making changes. Please contact the Pest Permit Staff (email: pest.permits@usda.gov (preferred) or by phone: 866-524-5421; or in writing to: 4700 River Road, Unit 133, Riverdale, MD 20737; fax: 301-734-8700).

25. The permit holder is responsible for the activities of those individuals working with the regulated soil. Everyone handling the regulated soil must read, agree to, and initial these conditions before beginning work. These initialed conditions do not need to be submitted to APHIS-PPQ but must be readily accessible in the event of an inspection and presented upon request.

26. Unless the regulated soil is hand carried, it must be shipped by bonded carrier to the point of entry. Further movement must be made through a recognized commercial carrier to the APHIS approved facility.


27. The regulated soil must not be used in field research or released into the environment before sterilization.

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

The regulated soil must not be used as a growing medium.

END OF PERMIT CONDITIONS

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