

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

### Permit to Move LIVE PLANT PESTS, BIOCONTROL ORGANISMS, FEDERAL NOXIOUS WEEDS, SOIL, AND BEES

#### Interstate (Movement between states) Regulated by 7 CFR 330, CFR 360, and CFR 322

APPLICATION NUMBER:	A-00272494	DATE ISSUED:	12/15/2023
PERMIT NUMBER:	526-23-349-29969	EFFECTIVE:	12/15/2023 - 12/15/2026
APPLICANT NAME: ORGANIZATION: ADDRESS:	Tammy Greer Biolog, Inc. 225 Corporate Blvd, NEWARK, Delaware, 19702	PERMITTEE NAME: ORGANIZATION: ADDRESS:	Robert Wicke Biolog, Inc. 225 Corporate Blvd., Newark, Delaware, 19702
MAILING ADDRESS:	225 Corporate Blvd, NEWARK, Delaware, 19702	MAILING ADDRESS:	225 Corporate Blvd., Newark, Delaware, 19702
PHONE:	3027374297	PHONE:	302-737-4297
ALTERNATE PHONE:		ALTERNATE PHONE:	
EMAIL:	tgreer@biolog.com	EMAIL:	rwicke@biolog.com
ALTERNATE EMAIL:		ALTERNATE EMAIL:	
APPROVED FOR HAND	CARRY: Authorized		

PORTS OF ARRIVAL/PLANT INSPECTION STATIONS:

**Destination Location** 

Name: Biolog, Inc. Facility Number: PPQ-DE-302543 Type: Laboratory Room Number: Address: 225 Corporate Blvd City, State, ZIP Code: Newark, DE 19702

#### Primary Contact Name: Robert Wicke Email: rwicke@biolog.com Alternate Email: rwicke@biolog.com Phone: 302-737-4297 Alternate Phone:

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Under the conditions specified, this permit authorizes the following:					
Regulated Article	Life Stage(s)	Intended Use	Shipment Origins	Originally Collected	Culture Designation
Various Species of Bacteria	Any	Research – Laboratory	, Alaska;Hawaii;P uerto Rico;Virgin Islands (U.S.);Continent al United States	Foreign and domestic locations	
Various Species of Fungi	Any	Research – Laboratory	, Alaska;Hawaii;P uerto Rico;Virgin Islands (U.S.);Continent al United States	Foreign and domestic locations	

# SPECIAL INSTRUCTIONS TO INSPECTORS

See permit conditions below

# PERMIT GUIDANCE

1) Importation, interstate movement, and environmental release of the listed regulated organisms that have been genetically engineered may require a different permit issued under regulations at 7 CFR part 340. Any unauthorized importation, interstate movement, or environmental release (including accidental release) of a regulated GE organism would be a violation of those regulations. Before moving genetically engineered organisms, contact APHIS Biotechnology Regulatory Services (BRS) at: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology.

If BRS does not require a permit, contact the Pest, Pathogen, and Biocontrol permit unit for further guidance at: pest.permits@usda.gov

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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)

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2) 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

3) If a human pathogen is identified, please refer to the CDC Etiologic Agent Import Permit Program at http://www.cdc.gov/od/eaipp/

4) 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.

5) 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.

6) When the regulated material includes Domestic soil You must abide by all local quarantines see: http://www.aphis.usda.gov/planthealth/pests\_and\_diseases

Of special concern for movement of soil from certain continental areas are: IMPORTED FIRE ANTS: http://www.aphis.usda.gov/plant-health/ifa;

GOLDEN NEMATODES: http://www.aphis.usda.gov/planthealth/gn;

POTATO/PALE CYST NEMATODE: http://www.aphis.usda.gov/planthealth/pcn ; PHYTOPHTHORA RAMORUM (Sudden Oak Death): http://www.aphis.usda.gov/plant-health/sod

# PERMIT CONDITIONS

USDA APHIS issues this Permit to Robert Wicke with Biolog, Inc. in Newark, Delaware. This permit authorizes the interstate movement of various species of Bacteria and Fungi associated with soil, host material and culture medium from the continental United States and its territories to Delaware for laboratory research in the APHIS approved containment facility PPQ-DE-302543.

- 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.

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- 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.
- 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.
- 2. The permit holder must:
  - maintain a valid PPQ526 permit so long as the regulated materials/organisms are alive or viable,
  - not assign or transfer this permit to other persons without APHIS PPQ authorization,
  - maintain an official permanent work assignment, residence, or affiliation at the address on this permit,
  - notify the Pest Permit Staff as soon as possible 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 materials/organisms,
  - adequately mitigate environmental impacts resulting from unauthorized release of regulated materials/organisms and notify the Pest Permit staff immediately if one occurs,
  - notify the Pest Permit Staff if the facility is damaged/destroyed or if you wish to decommission the facility,
  - destroy all regulated materials/organisms prior to departure from the organization unless other arrangements are confirmed by the Pest Permit Staff.

Notifications to the Pest Permit Staff must be made via 866-524-5421 or pest.permits@usda.gov within one business day of the event triggering a notification.

3. This permit does not authorize movement or use of organisms 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, Agriculture Select Agent Services (AgSAS) immediately by phone at 301-851-3300 option 3, and within seven (7) days submit APHIS/CDC Form 4A (Report of Identification of a Select Agent or Toxin in a Clinical or Diagnostic Laboratory) to APHIS, AgSAS; 4700 River Rd, Unit 2, Riverdale, MD 20737 (see instructions at: https://www.selectagents.gov/forms/form4.htm). Failure to comply with this requirement is a violation of the Agricultural Bioterrorism Protection Act of 2002. For a complete list of Select Agents please visit:

https://www.selectagents.gov/selectagentsandtoxinslist.html Select agents include: Peronosclerospora philippinensis (Peronosclerospora sacchari), Coniothyrium glycines (formerly Phoma glycinicola and Pyrenochaeta glycines), Ralstonia solanacearum, Rathayibacter toxicus, Sclerophthora rayssiae, Synchytrium endobioticum, Xanthomonas oryzae, Bacillus anthracis, Brucella abortus, Brucella melitensis, Brucella suis, Burkholderia mallei, and Burkholderia pseudomallei. For applicants

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applying for a permit for Ralstonia solanacearum non-race 3 biovar 2, an exclusion letter will need to be submitted along with the application

- 4. All persons working with the listed regulated materials/organisms must be informed of these permit conditions. Anyone working with these materials/organisms must agree to adhere to and sign/initial these conditions before beginning work. These signed conditions do not need to be submitted to USDA/APHIS but must be readily accessible and made available to Federal and State regulators upon request. Note: these conditions may be copied and stored electronically for electronic signature and initialing provided that the permit number, authorized materials/organisms and life stages, release locations if applicable, and authorization statement all appear on the document with the permit number. Signing these conditions only indicates that the permit.
- 5. Field collected infected host material may include, but is not necessarily limited to, plants, plant parts, and soil.
- 6. All packages for transport must minimally consist of both inner/primary and outer/secondary packages securely sealed so that both are effective barriers to escape or unauthorized dissemination of the listed materials/organisms. The inner/primary package(s) will contain all regulated materials/organisms and must be cushioned and sealed in such a way that it remains sealed during shock, impact, and pressure changes that may occur. The outer/secondary shipping container must be rigid and strong enough to withstand typical shipping conditions (dropping, stacking, impact from other freight, etc.) without opening.
- 7. Upon receipt all samples potentially containing mobile arthropod contaminants must be placed in a refrigerator for at least 4 hours prior to opening the package. Following this initial processing, living arthropod contaminants must be devitalized.
- 8. IF INFECTED HOST MATERIAL INCLUDES SOIL THEN THE FOLLOWING APPLIES:
  - Adequate protective clothing must be worn when working with soil and infected/infested samples so that movement of plant pests out of the facilities on hands, clothing, and shoes does not occur.
  - The laboratory floor must be uniform (i.e., no cracks/defects) and made of materials that can be cleaned. The floor must be maintained free of soil and infected/infested material.
  - Work benches must be uniform (i.e., no crack/defects) and made of materials that can be cleaned. When not working with the regulated material, the benches must be cleaned and maintained free of soil and infected/infested material.
  - Any sink that drains water that may contain live plant pests/pathogens harbored by infested soil samples must be equipped with traps that allow collection of waste water. The waste water must be treated according to the devitalization and waste disposal condition in this permit before final disposal.
- 9. All packages must be opened within the APHIS approved facility identified above. Whenever possible packages must be opened within a Class II or III biosafety cabinet, otherwise packages must be opened within an area dedicated for this purpose within this facility.
- 10 Plant inoculations are not authorized under this permit.
- 11 Measures to control potential insect vectors (e.g. black lights, yellow sticky boards, insecticides) must be in place.

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- 12 Records must be kept of all organisms maintained under this permit. Minimally the record will consist of the name of the organism identified to the lowest taxon possible, the country, or US state/territory, where each isolate was collected, the date the isolate was received, and the date and how the organism was devitalized. These records must be made available to Federal and State regulators upon request.
- 13 When not working with the regulated materials/organisms, you must store and/or maintain them within the APHIS approved containment facility identified above. All stored regulated materials/organisms must be kept in a locked area with access limited to authorized personnel.
- 14 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: 4700 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. A list of all persons with access to the containment facility must be maintained and available upon request by Federal or State Regulatory Officials. All persons working with the regulated material/organism(s) must be trained on, and implement the permit conditions, and all APHIS approved SOPs governing the facility listed above.
- 15 Modifications to the containment facility or any changes that affect the containment of the regulated materials/organisms must be approved by APHIS prior to making changes. Please contact the Pest Permit Staff (email: pest.permits@usda.gov; phone: 866-524-5421; address: 4700 River Rd., Unit 133, Riverdale, MD 20737; Fax: 301-734-8700).
- 16 DEVITALIZATION AND WASTE DISPOSAL All regulated materials/organisms and all items coming in direct contact or exposed to the regulated materials/organisms must be sterilized/sanitized/decontaminated prior to removal from the authorized containment facility. This includes all items from shipping, culturing, care, and maintenance of these regulated materials/organisms. This requirement includes but is not necessarily limited to: packaging directly exposed to the regulated materials/organisms, substrates (culture media, soil, plant materials (food materials or host plants)), leftover/unused/unneeded live cultures, and dead specimens/cultures unless specified otherwise in the permit. Prior to disposal or reuse, you must treat all contaminated and all potentially contaminated materials by one of the following methods, either alone or in combination: 1) autoclaved (see protocol below), 2) disposed of off-site by a facility holding a valid PPQ compliance agreement (organisms and/or contaminated waste must be stored in sealed containers prior to pick up by this company), 3) incinerated, 4) immersed in a minimum of a final concentration of 0.525 percent sodium hypochlorite (for example; 1 part fresh household bleach to 9 parts water) for at least 20 minutes, or 5) immersed in 70 percent alcohol for at least 30 minutes. Treated waste will be double bagged prior to disposal. Other sterilization methods are only allowed with prior written agreement from the USDA/APHIS PPQ Pest Permit Staff. If using an autoclave the following protocol must be used: a. Waste must be autoclaved at 121 Celsius (250 Fahrenheit) for a minimum of 30 minutes at 15 psi. 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 calibrated according to the manufacturer's instructions annually and a commercially available biological indicator kit that uses bacterial spores of Geobacillus stearothermophilus that are rendered unviable at 121 Celsius (250 Fahrenheit) must be used every three months. OR The autoclave must be calibrated according to the manufacturer's instructions every

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two years and a commercially available biological indicator kit that uses bacterial spores of Geobacillus stearothermophilus that are rendered unviable at 121 Celsius (250 Fahrenheit) must be used every two weeks. d. A written record of the calibration and the biological indicator tests must be maintained. You must follow the manufacturer's instructions for the Geobacillus sterothermophilus and if any growth is observed, you must have the autoclave serviced and retested before it is used again for the regulated articles/organisms listed on this permit.

- 17 As an alternative to the DEVITALIZATION AND WASTE DISPOSAL requirements listed above, devitalization/destruction of organisms and infected material may be conducted off site by a facility holding a valid PPQ compliance agreement prior to disposal. Vendor may or may not be in the same state. All organisms, contaminants and/or packaging materials must be in sealed containers during transport to this waste management facility in order to prevent any unauthorized dissemination of the regulated articles.
- 18 There is to be no further movement or distribution of the listed regulated materials/organisms within the United States and its territories unless the recipient holds, or is named as a responsible party on a valid PPQ526 permit for receipt of such materials/organisms.

#### END OF PERMIT CONDITIONS

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