United States Department of Agriculture

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, Noxious Weeds, and Soil

Importation

Regulated by 7 CFR 330

This permit was generated electronically via the ePermits system

PERMITTEE NAME:	Mr. Steven Koike	**PERMIT NUMBER:**	P526P-21-05435
ORGANIZATION:	TriCal Diagnostics	**APPLICATION NUMBER:**	P526-210809-074
ADDRESS:	8770 Highway 25 Hollister, CA 95023	**DATE ISSUED:**	09/20/2021
		EXPIRES:	09/20/2024
MAILING ADDRESS:	8100 Arroyo Circle Gilroy, CA 95020	**FACILITY NUMBER:**	4742
		HAND CARRY:	No
PHONE:	4086126729	**FACILITY ACCOUNT:**	TriCal Diagnostics
ALT. PHONE:		**RESEARCH CENTER:**	
EMAIL:	SKoike@trical.com	**FACILITY NAME:**	
FAX:		**FACILITY ADDRESS:**	8770 Highway 25 Hollister, California 95023
		FACILITY GPS:	
		MAIL ADDRESS:	8770 Highway 25 Hollister, California 95023
		FACILITY CONTACT:	Mr. Steven Koike
		PHONE:	408-612-6729
		ALT. PHONE:	
		FAX:	
		EMAIL:	SKoike@trical.com

DESTINATION: 8770 Highway 25, Hollister, CA 95023
DESIGNATED PORTS: CA, El Segundo; CA, South San Francisco; FL, Miami (Cargo, DHL, Fed Ex, UPS, etc); GA, Atlanta; NJ, Linden; NY, Jamaica; TX, Humble; WA, SeaTac

Under the conditions specified, this permit authorizes the following:

Regulated Article	Life Stage(s)	Intended Use	Shipment Origins	Originally Collected	Culture Designation
Bacteria	Any	Diagnostic Labs	New Zealand, Asia, Australia, Caribbean Islands (except Puerto Rico and US Virgin Islands), Central America, Europe, North America (except USA), South America	Originally Collected from Foreign Locations	
Fungi	Any	Diagnostic Labs	New Zealand, Asia, Australia, Caribbean Islands (except Puerto Rico and US Virgin Islands), Central America, Europe, North America (except USA), South America	Originally Collected from Foreign Locations	
Nematodes	Any	Diagnostic Labs	New Zealand, Asia, Australia, Caribbean Islands (except Puerto Rico and US Virgin Islands), Central America, Europe, North America (except USA), South America	Originally Collected from Foreign Locations	

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Virus	Any	Diagnostic Labs	New Zealand, Asia, Australia, Caribbean Islands (except Puerto Rico and US Virgin Islands), Central America, Europe, North America (except USA), South America	Originally Collected from Foreign Locations

SPECIAL INSTRUCTIONS TO INSPECTORS

See permit conditions below

This permit does not authorize hand-carry or movement of the regulated materials/organisms via passenger baggage into the United States.

DHS CBP INSPECTORS - SHIPMENT BY BONDED CARRIER
1) Confirm that the carrier of the shipment imported under this USDA PPQ 526 permit is commercially bonded.
2) Confirm that the imported shipment has a valid USDA PPQ Form 599 Red/White label attached to the exterior for routing to a USDA APHIS PPQ Inspection Station or other "Designated Port" as stated on the Permit. A valid label will have the permit number, expiration date, label number, and address of a USDA APHIS PPQ Plant Inspection Station/Designated Port. PLEASE NOTE: In the event of a shipment of bulk container with discrete units, a single PPQ Form 599 Red/White label may be used.
3) Validate the permit in ePermits using the CBP search feature.
4) If a valid PPQ Form 599 Red/White label is not attached to the exterior of the package or the label has been covered or is otherwise not legible, then forward to the nearest USDA APHIS PPQ Plant Inspection Station.
5) If the address on the airway bill does not match the address on the PPQ Form 599 Red/White label then forward the package to the nearest USDA APHIS PPQ Plant Inspection Station/designated port shown on the PPQ Form 599 label. All costs associated with rerouting misaddressed packages will be assumed by the permit holder.

APHIS PPQ INSPECTORS at PIS - High-Risk Microbial
Follow the instructions in the Plant Inspection Station Manual for High-Risk Microbial, Unknown Organisms (Diagnostics) Red and White Labeled Packages (must be opened in a biosafety cabinet; see procedures for handling on page 3-7-40). For questions or concerns, contact the USDA APHIS PPQ Pest Permit Branch in Riverdale, MD, at 301-851-2046, toll free 866-524-5421.

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) Importation, interstate movement, or 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)

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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
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

USDA-APHIS issues this permit to Mr. Steven Koike of TriCal Diagnostics in Gilroy, California. This permit authorizes the importation of host material infected with the listed regulated organisms from the listed locations to California for diagnostic work in the APHIS approved facility #4742.

1.
- 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.
- 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.

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- 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,

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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 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 person working under this permit has read them; the permit holder is the sole responsible party under this permit.
5. This permit does not authorize hand-carry or movement of the regulated materials/organisms via passenger baggage into the United States.
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. After PPQ issues this 526 permit, you will need to request Red/White labels (PPQ Form 599) at least 5 days in advance of your shipping date. If you applied for your permit online using ePermits, you may request the labels using the My Shipments/Labels feature. Otherwise, send your request to Redandwhitelabelrequest@usda.gov. All email requests must come from the permit holder or designee. If requested by the designee, the permit holder must be copied on all requests. Specify the approved port as listed on the permit and the total number of labels needed. You may request additional labels the same way.
   Packages without labels on the exterior may be refused entry.

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Review label instructions at:
https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/permits/plant-pests/or ganisms-shipping-requirements

You are responsible for instructing your shipper to carefully follow these instructions. You are responsible for each import shipping label issued under this permit.

8. Upon receipt all samples potentially containing mobile arthropod life stages must be placed in a refrigerator for at least 4 hours prior to opening the package. Following this initial processing all live, mobile arthropods must be placed in sealed containers for subsequent devitalization.
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. This authorization is strictly for diagnostic activities in a controlled environment only. Plant inoculations are authorized in the laboratory or growth chamber only as necessary to confirm a diagnosis.
11. Vector transmission is not permitted under this authorization. Only mechanical inoculation of plants is permitted.
12. Measures to control potential insect vectors (e.g. black lights, yellow sticky boards, insecticides) must be in place.
13. Placement of organisms into a culture collection or any other research with these organisms is not authorized under this permit. Separate 526 permits are required for these activities.
14.
    - 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 used for processing infested soil, infested growing media, and infected plant materials must be equipped with traps that allow collection of waste water.
    - All waste water from sink traps or other sources that potentially contains live pests or pathogens must be treated according to the devitalization and waste disposal condition in this permit before final disposal.

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15. Diagnostic samples must be maintained within the APHIS approved facility identified above. All stored samples must be kept in a locked area with access restricted to authorized personnel.
16. A record of all plant pathogens and pests identified in the regulated material must be maintained at the APHIS approved containment facility identified above. These records must be available to Federal and State regulators upon request.
17. The permit holder or authorized individual must notify APHIS Plant Protection and Quarantine (PPQ) Pests Pathogens and Biocontrol Permit Branch (PPBP) within 10 working days of the confirmation that an organism is identified as (a) a species new to science, (b) an organism not known to occur in the United States, or (c) a pest managed by an APHIS program (https://www.aphis.usda.gov/aphis/ourfocus/planthealth/plant-pest-and-disease-programs/pests-an d-diseases). Include the permit number, the origins and dates of receipt of the samples, and the identified organism. The notification must be sent to USDA/APHIS/PPQ/RPM/PPB, 4700 River Rd., Unit 133, Riverdale, MD 20737, faxed to 301-734-8700 or emailed to Pest.Permits@usda.gov , as Word, Excel or pdf documents. Notifications must also be sent to the State Plant Health Director (SPHD) and State Plant Regulatory Official (SPRO) of the destination state within 10 working days. See https://www.aphis.usda.gov/aphis/ourfocus/planthealth/ppq-program-overview/ct_sphd and https://nationalplantboard.org/membership/ for contact information.
18. 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.
19. 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).
20. • 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

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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 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.

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21. 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.
22. 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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