Ralstonia Exclusion Program

Last Modified:

USDA regulates *Ralstonia solanacearum* race 3 biovar 2 (Rs R3bv2), a select agent pathogen that poses a severe threat to important U.S. agricultural commodities such as tomatoes, potatoes, and eggplants.

Rs R3bv2 was listed as a select agent in the USDA Agricultural Bioterrorism Protection Act of 2002. In 2005, APHIS amended the regulations (70 FR 61351) to establish a certification program for articles of *Pelargonium* spp. and *Solanum* spp. imported from countries where the bacterium (Rs R3bv2) is known to occur. For *Pelargonium* spp. imports, the certification program followed the Minimum Sanitation Protocol for Offshore Geranium Cutting Production.

In 2024, APHIS is implementing an updated framework for all Rs R3bv2 host commodities under the Ralstonia Exclusion Program (REP). The REP framework will be a basis for bilateral operational work plans allowing imports of Rs R3bv2 host plants under the REP from countries regulated by USDA for this select agent. The framework closes known sanitation and testing gaps in earlier protocols and clarifies roles and responsibilities of all program participants. It also provides updated standard operating procedures to execute following an Rs R3bv2 detection. The REP framework now supersedes the 2007 Minimum Sanitation Protocol for Offshore Geranium Cutting Production.

View the 2024 Ralstonia Exclusion Program Framework (769.81 KB)

General Requirements

To import into the United States Rs R3bv2 host plants from countries where the select agent is known to occur, exporters must work with their National Plant Protection Organization (NPPO) to participate in the REP. Participants may export Rs R3bv2 host plants such as *Pelargonium* spp. cuttings or tomato plantlets in growing media to the United States if they meet the following criteria:

- Consignments meet all requirements of an operational work plan between APHIS and the NPPO of the exporting country.
- REP host plants are produced in an APHIS-certified facility.
- Consignments are represented by a customs entry that was filed with APHIS CORE Message Set.

APHIS Facility Certification

APHIS must physically visit and certify all interested offshore facilities before they may participate in the program. APHIS will provide certification services to facilities that meet or exceed the minimum standards for facility construction, security, production and sanitation, pest management, scouting, diagnostic testing, training, treatments and record-keeping as described in the Ralstonia Exclusion Program Framework (769.81 KB). APHIS will work with the exporting NPPOs to coordinate certification audits once a year. Participation in the REP requires the establishment of a trust fund through a signed cooperative service agreement to cover the cost of certification services and other site visits.

For additional information please refer to the Ralstonia Exclusion Program Framework (769.81 KB), review the frequently asked questions below, or email questions to pop.rep@usda.gov.

Frequently Asked Questions

The following questions and answers provide guidance and general information about the implementation of the REP.

General Questions

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What is the Ralstonia Exclusion Program?

The Ralstonia Exclusion Program (REP) is a certification program for offshore facilities that produce *Ralstonia solanacearum* race 3 biovar 2 (Rs R3bv2) host plants for export to the United States under a systems approach. The REP intends to mitigate risks of importing propagative plant material that can host select agent Rs R3bv2 into the continental United States from countries where Rs R3bv2 is known to occur. The minimum phytosanitary measures include, but are not limited to, protocols for commodity production, packing, safeguarding, diagnostic testing, treatment, export certification, and shipping to the United States. Commodities regulated for this select agent are eligible for import when program participants comply with this framework and with an operational work plan (OWP) signed with the National Plant Protection Organization (NPPO) of the country of origin. OWP agreements with each NPPO may describe in greater detail mitigation measures necessary at specific production sites to meet REP program standards.

The select agent Rs R3bv2 (7 CFR 331.3) is a damaging pathogen of important US agricultural commodities such as tomatoes, potatoes, and eggplants. In production greenhouses, spread of this pathogen can occur through transplanting infected plants, pinching buds off plants without sanitizing, using contaminated tools between cuttings, and irrigating with sub-irrigation or ebb-and-flow systems. Growing plants in certified greenhouses under a systems approach can effectively mitigate most of the pest risk associated with these practices.

What happened to the Minimum Sanitation Protocol for Offshore Geranium Cutting Production?

The Minimum Sanitation Protocol for Offshore Geranium Cutting Production was last updated by APHIS in 2007. In updating this protocol, APHIS developed the Ralstonia Exclusion Program to incorporate sanitation protocols and program requirements for all Rs R3bv2 host plants, including Pelargonium spp. and Solanum spp., into a single framework.

Is participation mandatory to export Pelargonium spp. cuttings or tomato plantlets in growing media from Mexico to the United States?

Yes, participation in the REP is mandatory, unless imported from a country where Rs R3bv2 is known not to occur. Currently only Canada and Israel are known to be free of Rs R3bv2.

Who can participate?

Any offshore producer that meets the program requirements and is approved to participate by their NPPO may participate in the program.

What are the program's eligibility criteria?

- There must be a bilateral agreement between APHIS and the NPPO of the exporting country.
- Rs R3bv2 host plants must be produced in an APHIS-certified facility.
- Consignments must meet all the permit and import requirements stated in 7 CFR 319.37, the Plants for Planting Manual, Agricultural Commodities Import Requirements database, and relevant operational work plans.
- Consignments must be represented by a customs entry that was filed with APHIS CORE Message Set and which includes the NPPO-assigned facility code.

Are Pelargonium spp. and Geranium spp. both regulated under the program?

No. *Pelargonium* spp. and *Geranium* spp. are two separate genera of plants in the geranium family. A common name for both species is geranium. Only *Pelargonium* spp. is regulated as a host of Rs R3bv2.

What is the process of joining the program?

The REP framework outlines requirements to become an approved participating facility. Please refer to Section 4.4 *Requirements for Approved Facilities*.

- Interested offshore producers must send an official request to APHIS through the NPPO expressing their interest in participating in the REP.
- The NPPO of the country of export must approve the facility to participate in the REP prior to notifying APHIS of their readiness for an initial certification audit.
- The NPPO must sign a Cooperative Service Agreement (CSA) between APHIS and the NPPO-designated cooperator.
- The facility must work with the NPPO-designated cooperator to reimburse APHIS for certification and inspection services using a trust fund established under the CSA agreement.

I also participate in the Offshore Greenhouse Certification Program (OGPC). Is my consignment eligible for the OGCP if I commingle Pelargonium spp. cuttings and OGCP approved plant taxa in the same consignment?

No, *Pelargonium* spp. cuttings cannot be shipped in the same consignment with OGCP approved plant taxa if an importer wishes to benefit from reduced inspection rates associated with the OCGP program. For example, if you are importing a consignment with *Pelargonium* spp. (not approved for the OGCP), and *Mandevilla sp*. (approved for the OGCP) that cargo will not be eligible for OGCP and will be inspected at the full rate at the port of entry.

Where can I find information about Ralstonia solanacearum?

There is information on the APHIS website about *Ralstonia solanacearum,* including symptoms and pest status.

Where can I find additional information about the REP?

- Visit ACIR for specific import requirements for *Pelargonium* spp. cuttings and tomato plantlets in growing media from Mexico.
- View the ACIR List of facilities approved to ship under this program.
- Send questions or requests for more information in an email to pop.rep@usda.gov.

Diagnostic Testing

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Where can I obtain a copy of the APHIS work instruction for diagnostic water testing?

Please email APHIS-PPQCPHSTBeltsvilleSampleDiagnostics@usda.gov to request a copy of the work instruction for methods for concentrating and detecting Ralstonia solanacearum in irrigation water using a filter funnel system. Please include the title of the work instruction in the subject line of the email: WI-B-T-1-112.

The work instruction is titled “Sample processing and molecular detection of Ralstonia solanacearum (Rs) in irrigation water using a Filter funnel and real time PCR.”

Information for National Plant Protection Organizations

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When are commodities regulated for this select agent eligible for import?

Commodities regulated for this select agent are eligible for import when program participants comply with this framework and with an OWP signed with the NPPO of

the exporting country of origin. OWP agreements with each NPPO may describe in greater detail mitigation measures necessary at specific production sites to meet REP program standards.

Information for Participating Offshore Producers

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When is the annual facility certification audit?

Facility certification takes place during the active plant production and harvesting period.

What will be evaluated during the annual certification audit?

The lead auditor will evaluate the facility against criteria from the REP framework, associated operational work plans and an audit checklist.

Who performs the annual facility certification audit?

A certified APHIS auditor in collaboration with an NPPO representative and, if available, a local APHIS staff. In some circumstances, two or more certified auditors might be needed to complete the audit.

What is included in the cost of a certification audit or site visit?

The cost of certification and inspection services includes the salary, benefits, overtime (if applicable), travel, accommodations, and overhead for the auditor(s). If

APHIS audits several facilities in one trip the travel costs can be divided among the facilities visited.

Are there any application fees?

No, there are no application fees to participate in the program.

Do importers need to register?

No, importers do not need to register with APHIS. However, they must register with the NPPO of the exporting country.

How long is the certification valid for?

The certification is valid for 1 year. To maintain certification, a full system certification audit is required every year for production facilities and a maximum of every third year for elite facilities.

If corrective action requests (CAR) are issued during the audit, the facility cannot be certified until all CARs are closed.

How long is the certification process?

The certification process can take up to 12 months from planning the site visit to the final certification decision. APHIS will notify the facility of the certification audit outcome by an official letter to the NPPO.

Information for Brokers

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What information is required in the APHIS Core message set for the program?

- The NPPO-assigned facility number or code
- Producer name

Who should I contact for questions about the APHIS Automated Commercial Environment?

Please contact ace.itds@usda.gov.

Deviation Requests

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What is the process for requesting a deviation from the REP framework requirements?

The deviation request process allows an REP participant to propose an alternative way to meet an REP requirement for APHIS evaluation. A deviation could include a change from the stated process in the framework, or a request for a new chemical or treatment. Follow the guidance below to request a deviation from the framework.

Process to Request Deviations from the REP Framework

1. The Producer must communicate with the NPPO of the exporting country about their deviation request, and identify the associated section and paragraph number in the REP.
2. The Producer must propose an alternative mitigation practice in detail and show how the alternative meets the safeguarding goals.
3. The NPPO must assess if the alternative mitigation is acceptable.
4. The NPPO must submit a formal letter to APHIS with the following information:

    1. A request for APHIS to assess a deviation to the REP framework for the place of production.
    2. Identification of the associated sections and paragraph numbers in the REP framework.
    3. An explanation of the reason, purpose, or need for the deviation.
    4. A detailed description of the proposed deviation.
    5. A proposed implementation plan for the deviation.
    6. Scientific evidence (i.e. peer-reviewed journals) or experimental data from the production site and any other information that supports the proposed mitigation measures for the deviation.
5. APHIS will acknowledge receipt and begin evaluation the deviation request package.
6. After receiving the deviation request package from the NPPO, APHIS may request more information. Once the deviation request package is complete, evaluation may take a minimum of 60 days.
7. If approved, APHIS will send official correspondence to the NPPO and will notify the requesting place of production via email.
8. An approval for a deviation request could be temporary and is not guaranteed.

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