



FOR INFORMATION AND ACTION

DA-2006-04

February 9, 2006

United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

1400 Independence
Avenue, SW
Washington, DC
20250

SUBJECT: Organism Permitting Review -
Findings and Recommendations

**TO: STATE AND TERRITORY AGRICULTURAL REGULATORY
OFFICIALS**

In early FY 2006, the Animal and Plant Health Inspection Service, Plant Protection and Quarantine (PPQ) concluded an evaluation of the Agency's organism permitting function. The review was designed to identify and implement improvements to this crucial PPQ activity.

As a result of its review, PPQ is updating its organism permitting system as follows:

1. Hand-Carrying of Permitted Organisms – PPQ has reestablished the policy allowing permit holders the option to hand-carry organisms into approved facilities and to do so without the need to use commercial carriers or to divert shipments to the PPQ Plant Inspection Station in Beltsville, Maryland.

Policies and procedures for hand-carrying organisms are attached to this letter. Additionally, holders of existing permits wanting to 'hand-carry' organisms should contact PPQ's permitting staff as indicated below for more details.

2. Permitting Board of Advisors – PPQ is instituting a Permitting Board of Advisors composed of Federal and State stakeholders to counsel and support the Agency in continued improvements to its permitting policies and procedures.
3. Customer Service – Communication is central to PPQ's efforts to improve its permitting activities. PPQ is establishing a Permitting Customer Service Center to help stakeholders with services ranging from permit applications and inquiries through obtaining information on policies and procedures.
4. Regulatory Reforms – The process of updating organism permit regulations was put on hold after the events of 9/11 as the Agency focused on addressing potential new threats to U.S. agriculture. PPQ is now re-engaging in a comprehensive update of its organism permitting regulations to ensure that they are based on sound science, are transparent, and have the benefit of public involvement.

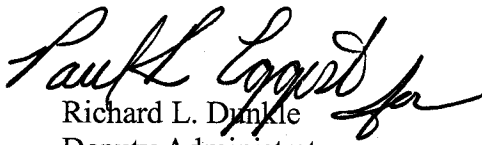
I greatly appreciate the dedication of PPQ's permitting staff in light of the tremendous challenges that they face in ensuring that organisms entering the nation do so both safely and efficiently. I also greatly value the input of our stakeholders designed to help the Agency to continuously improve on the public services that PPQ provides.



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In addition to PPQ's policies and procedures for hand-carrying organisms, highlights of PPQ's Organism Permitting Review are also attached to this letter. Please contact PPQ's permitting unit for information on organism permitting policies and procedures and for added details about this Review. The organism permitting unit can be reached toll-free at 1-877-770-5990, by e-mail at Pest.Permits@aphis.usda.gov or by visiting their web site at <http://www.aphis.usda.gov/ppq/permits>.


Richard L. Dinkie
Deputy Administrator
Plant Protection and Quarantine

Attachments:

- Policy and Procedures for Hand-Carrying Living Organisms under a USDA APHIS PPQ Permit
- PPQ Organism Permitting Review Highlights



FEB - 9 2006

United States
Department of
Agriculture

Subject: Policy and Procedures for Hand-Carrying Living Organisms under a USDA
APHIS PPQ Permit

Animal and
Plant Health
Inspection
Service

Plant Protection
and Quarantine

Plant Health
Programs

4700 River Road
Riverdale, MD
20737

A specific authorization on a valid USDA APHIS PPQ permit (PPQ Form 526) is required for persons to move any of the following living organisms in personal baggage (i.e. "hand-carry") into the United States or any of its Territories or possessions from any place outside thereof, or from any Territory or possession into any other Territory or possession or the Continental United States: plant pests, Federally listed noxious weeds, parasitic plants, bees, earthworms or biological control agents.

The following considerations apply:

1. A new permit or an amendment to an existing permit authorizing hand-carrying will only be issued to persons transporting organisms to facilities currently approved to receive and contain them, or following an inspection of a newly proposed receiving facility by PPQ personnel and a determination that the facility is physically and operationally adequate to contain the permitted organisms.
2. An authorization to hand-carry shall only be issued to citizens or permanent United States residents with a valid Passport or Permanent Visa. Hand-carry authorizations shall not be issued to foreign nationals or individuals with temporary Visas.
3. Applications must specifically request a hand-carry option, and identify all individuals the applicant seeks to have authorized to hand-carry. Applications must include current address, telephone number, fax number, and email addresses of individuals not associated with the receiving facility who the permit holder seeks to have authorized to hand-carry.
4. An authorization to hand-carry is not transferable and cannot be assigned to other individuals or organizations not identified in the permit.
5. Requests to hand-carry are authorized based on factors including: risk of the organisms to United States agriculture and the environment, country of origin of the shipment, and source of the organisms (e.g., field collected or laboratory reared/processed).
6. An authorization to hand-carry shall be denied for good cause when the desired organisms are deemed to pose exceptional risk, when the facility's containment capabilities are likely to be exceeded, or when there is substantial risk of diversion of organisms from reaching containment. Other factors used in the determination include applicant history in complying with the terms and conditions of prior permits and information provided by the applicant supporting the need to hand-carry.
7. An authorization to hand-carry includes only the organism identified in the permit. Presence of unauthorized organisms in any packages on an individual authorized to hand-carry is a permit violation. Presence of unauthorized organism at the receiving containment facility at any time is also evidence of a permit violation.
8. Denial of a request to hand-carry shall not prejudice the issuance of a permit for receipt of the organism by other means.



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The following restrictions apply to Permit Amendments:


1. Requests to amend an existing permit must be supported in writing. Send mail requests to : USDA APHIS PPQ Pest Permit Evaluations, 4700 River Road Unit 133, Riverdale, MD 20737. Send Fax requests to: 301-734-5392.
2. Requests to amend an existing permit must be signed by the original permit holder, cite the permit number, and contain the name of all individuals the permit holder seeks to have authorized to hand-carry.
3. Requests to amend must include current address, telephone, fax number, and email addresses of individuals not associated with the receiving facility who the permit holder seeks to have authorized to hand-carry.
4. Amendments to existing permits require five to ten working days for processing as long as the receiving facility has already been evaluated for adequacy by PPQ. Requests for amendments may be processed by the Permit Unit as a separate permit application when administratively convenient.

The following conditions apply to all hand-carry authorizations:

1. Ten to twenty days prior to each hand-carry incident, the permit holder or designee must notify the PPQ Permit Compliance Officer by email (pest.permits@aphis.usda.gov) or telephone (866-524-5421) to provide specific information on the hand carrier's identity, the anticipated first port of arrival into the United States, the expected date of arrival, the time, and, if travel is by airline, the flight number. The Compliance Officer will notify Customs and Border Protection (CBP) Agriculture Inspectors at the port of entry to document and facilitate the entry of the organisms. PPQ will issue a red-and-white label authorizing hand-carrying through the specific port-of-entry. The notification must precede the date of arrival by a sufficient period of time for PPQ to issue the label and send it to the permit holder.
2. The hand carrier must indicate that living organisms are being imported under a USDA permit on the Customs Declaration form if such form is required at the port of entry.
3. At the port of entry, individuals carrying permitted organism must also present to CBP Agriculture Inspectors the following articles: U.S. Passport or Visa, a copy of the PPQ Permit authorizing hand-carrying including all applicable attachments and a valid red-and-white shipping label (PPQ Form 599) issued to that numbered permit.
4. Inspection by CBP Agriculture Inspectors must confirm that all hand carried articles are securely packaged as per the permit conditions. Upon clearance, the package will be sealed by CBP Agriculture Inspectors with CBP Agriculture Quarantine security tape (yellow) for movement to the authorized facility. In the event that a problem is detected, the CBP Agriculture Inspector may seize the package and require its movement to the nearest PPQ Inspection Station for processing or clearance. The permit holder will be responsible for all costs incidental to such forwarding.
5. After CBP Agriculture confirmation and clearance through the first port of entry into the United States, hand carried organisms must be transported directly to the containment facility authorized in the permit. The sealed package must not be opened until it arrives at the authorized facility.

6. Upon arrival at the facility, the PPQ Compliance Officer must be notified within 24 hours that the organisms arrived and that the package remained sealed until arrival. Notification may be by telephone (866-524-5421), fax (301-734-5392) or email (pest.permits@aphis.usda.gov). Unless otherwise specified in the permit, notification must be by an independent third party (e.g. containment facility director, campus biosafety officer, etc.) identified by the applicant and listed in the permit's conditions. A PPQ inspector may also visit the facility to confirm the arrival and integrity of the package and its contents.
7. Violation of any permit condition is subject to civil penalties of up to \$50,000 per violation for individuals and \$250,000 per violation for other entities. Criminal penalties may also apply.

To coordinate implementation with Customs and Border Protection, these policies and procedures become effective on March 1, 2006. However, current permit holders and applicants may request authorizations to hand-carry immediately. These policies and procedures do not apply to the hand-carrying of living organisms transiting the United States and its Territories or possessions.


Richard L. Dunkle
Deputy Administrator
Plant Protection and Quarantine

PPQ Organism Permitting Review Highlights

Background:

PPQ's permitting function is an indispensable and highly valued component of APHIS' agricultural safeguarding system. It is complex, handles a tremendous volume of requests annually, and is managed and staffed by dedicated people.

In early FY 2006, PPQ completed a review of its organism permitting function, designed to seek improvements in permitting policies, procedures, and communications. The review resulted in findings and recommendations, including those highlighted below:

Review Findings and Recommendations:

1. Permitted Organism Hand-Carry Policy:

Issue: To better account for and track organisms entering and transiting the United States in the aftermath of the events of 9/11, PPQ instituted a policy requiring that such organisms only move by commercial (bonded) carriers. PPQ also required further inspection of some shipments at its Plant Inspection Station in Beltsville, Maryland.

Finding: Though many organisms routinely benefit from commercial shipments, certain types of organisms are especially vulnerable to the delays inherent in the process. Additionally, improved Federal label and tracking procedures could allow stakeholders to return to the option to hand-carry permitted organisms when desired.

Recommendation:

PPQ reestablished the policy allowing permit holders an option to hand-carry organisms into approved facilities, to do so without the need to use commercial carriers, or to divert shipments to the PPQ Plant Inspection Station in Maryland.

2. Permitting Board of Advisors:

Issue: PPQ's permitting activities significantly impact American agriculture; affecting safety as well as research and commerce.

Finding: Balanced and sustained improvements to PPQ's permitting processes are best accomplished with the help of a diverse Board of Advisors entrusted with providing both insights and support to this important function.

Recommendation:

PPQ is instituting a Permitting Board of Advisors composed of Federal and State stakeholders to counsel and support the Agency in continued improvements to its permitting policies and procedures. This Board, composed of 8-10 members, will report to PPQ's Executive Director for Plant Health Programs.

3. Customer Service and Communication:

Issue: A significant number of suggestions on improvements to PPQ's permitting function deal with the issues of customer service and communication.

Finding: Many of PPQ's permitting policies, procedures, and protocols are complex. There has been a significant increase in permit applications, coupled with the need for rigorous review to ensure organism safety. This has resulted in some concerns raised by stakeholders. These include delays in permit application processing, heightened need for procedural assistance, increased stakeholder requests to troubleshoot problems, and a desire for more frequent stakeholder permitting communication and issues updates.

Recommendations:

PPQ is establishing a Permitting Customer Service Center to help stakeholders with services ranging from permit applications and inquiries through obtaining information on policies and procedures. Additionally, to better improve services PPQ is also looking at other process improvements; including workload prioritization based on risk and seeking to improve its internal and external collaborative networks in support of its permitting function.

4. Regulatory Reforms:

Issue: Regulations governing the movement of organisms have not been substantially modified since the passage of the Plant Protection Act in 2000. The events of 9/11 further compelled the Agency to focus on addressing an unprecedented new threat; the possibility that its permitting system could be used for purposes of agro-terrorism.

Finding: The need for the Agency to respond quickly in the aftermath of the events of 9/11 coupled with subsequent delays to updated regulations has resulted in some imperfect or unclear policies and procedures. These include permitting requirements that are not well understood by stakeholders, clearly based on sound science and risk, transparent, and facilitative of safety as well as efficiency.

Recommendation:

PPQ is re-engaging in the process of comprehensively updating its organism permitting Regulations; Title 7 CFR 330, Sections 200-212.

Concluding Remarks:

In addition to (1) reestablishing a permitted organism hand-carry option, (2) instituting a Board of Advisors, (3) establishing a Customer Service Center, and (4) re-engaging in regulatory reforms, PPQ shall also seek additional opportunities for improvements to its organism permitting policies, procedures, safety, and services.

Please contact PPQ's organism permitting unit for more information on the Agency's policies and procedures, and for added details on the status of recommendations and actions mentioned in this document. The organism permitting unit can be reached toll-free at 1-877-770-5990 or by e-mail at Pest.Permits@aphis.usda.gov.

Regular updates to organism permitting policies may also be found on PPQ's permitting website at: <http://www.aphis.usda.gov/ppq/permits>.