

Chapter 3

Petition and Permitting

APHIS Permitting Process

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Introduction

APHIS has authority to regulate the importation and interstate movement and release of plant pests noxious weeds and biological control organisms under the Plant Protection Act of 2000. APHIS regulates the movement of these organisms in order to prevent the dissemination of plant pests or noxious weeds. These regulations may be found in the Code of Federal Regulations Chapter 7 Part 330 (see <http://www.aphis.usda.gov/regulations/index.shtml>)

Permitting Process section of the Petition and Permitting chapter provides information about APHIS' role in each step of the review process for authorizing first-time release of non-indigenous organisms used as the documentation flow of petitions, and the approval process for weed biological control agents of weeds.

Permitting Process for Weed Biological Control Agents

The Plant Protection Act of 2000 (7 U.S.C. 7701 *et seq.*) provides the Secretary of Agriculture with the authority to regulate “any enemy, antagonist, or competitor used to control a plant pest or noxious weed”. However, other legislation such as the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*), the Endangered Species Act (ESA) (16 U.S.C. 1531 *et seq.*), and Executive Orders 13112 (64FR 6183) for Invasive Species and EO 12898 “Federal Actions to Address Environmental Justice in Minority Populations and Low-income Populations,” may affect the decision to release a non-indigenous weed biological control agent into the environment. Because the issuance of a permit is a federal action, it is therefore the responsibility of APHIS to meet any requirement of these Acts and Executive Orders. TAG-BCAW petitioners may refer to the following pages that describe the content of and flow of documents used by APHIS to meet the requirements of these Acts and Executive Orders. An understanding of the various documents APHIS prepares and or reviews conducted should help to clarify this process.

Step 1: Early Input

Researchers should submit a proposed test plant list to the Technical Advisory Group (TAG-BCAW) whether or not a candidate biological control agent has yet been identified. The TAG-BCAW an interagency group, was established to advise weed biological control researchers and provide the APHIS-PPQ Pest Permitting Branch with a recommendation on the proposed federal action, issuance of a permit authorizing release to the environment. At this early stage of the review process, TAG-BCAW makes recommendations on the target weed choices and comments on the proposed test plant list for host specificity testing.

Both TAG-BCAW reviewers and researchers should review federal and state lists of threatened and endangered species prior to host specificity testing. All federally listed threatened and endangered species must be considered when designing the test plant list. Candidate species and species proposed for listing should also be considered because they may be listed at any time. Web sites to obtain information on listed species include http://ecos.fws.gov/tess_public/ or <http://ecos.fws.gov/ecos/indexPublic.do>. Even though a U.S. Fish and Wildlife Service (USFWS) representative participates on the TAG-BCAW review panel, this **does not** substitute for the ESA consultation process.

Petitioners are encouraged to contact the Regional Offices and local Field Offices of the USFWS in the areas where the target weed is located prior

to and during the host testing phase in order to obtain advice and guidance regarding any threatened, endangered, proposed and candidate species. The USFWS can also provide guidance regarding obtaining seeds or samples of these plants, or related species that can serve as surrogates for these species.

Step 2 Obtaining Permits from APHIS

Permits are required from APHIS for any of the following situations:

1. **Importation** of live biological control organisms into the United States and its Territories (see Step 2-1; **Importation Permits**);
2. **Interstate movement** of live biological control organisms (includes movement between any state, territory and the District of Columbia) (See Step 2-2; **Interstate Movement Permits**);
3. **Retaining live biological control organisms in containment facilities after expiration of a permit** (see Step 2-3 **Continued Curation Permits**);
4. **The movement of any live biological control organism from the confines of a containment facility to any other containment facility, or for environmental release** (see Step 2-4; **Removal From Containment**).

ALL conditions of any permit, including all authorizations and restrictions, remain binding as long as the permit is valid and prior to expiry. Revocation or expiration of any permit requiring containment for the regulated organisms requires devitalization/destruction of all organisms regulated by that permit, or a new permit for the organisms. Guidance and step by step instructions for obtaining each of these types of **PPQ 526 Permits** can be found at

http://www.aphis.usda.gov/plant_health/permits/organism/index.shtml

Step 2 -1: Importation Permits:

This type of permit is needed every time live biological control organisms are imported into the United States and its Territories. These permits will require an USDA APHIS inspected containment facility as the destination, unless the organisms being imported are species having certain exemptions under APHIS regulations 7 CFR 330.200 *et seq.* ,

see also:

http://www.aphis.usda.gov/plant_health/permits/organism/index.shtml

Instructions and other information regarding applying for an Importation permit may be found at

http://www.aphis.usda.gov/plant_health/permits/organism/plant_pest_howtoapply.shtml

Additional information concerning **Containment facilities** can be found at

http://www.aphis.usda.gov/plant_health/permits/organism/containment_facility_inspections.shtml

Step 2 -2: Interstate movement Permits:

This type of permit is needed every time live weed biological control organisms are moved across state lines between any State of the United States and its Territories. Permits are required regardless of the use (research , release, etc.). There may be **exceptions** to the requirement for an interstate movement permit for certain biological control organisms. Additional information, including the list of such organisms can be found at

http://www.aphis.usda.gov/plant_health/permits/organism/index.shtml

Step 2 -3: Continued curation Permits:

These permits are required in order to retain live regulated organisms in containment beyond the expiration of any permit that requires containment. When continued movement is involved, colonies/cultures of organisms may be kept under the new importation or interstate permit when it is renewed.

Additional information can be found at

http://www.aphis.usda.gov/plant_health/permits/organism/index.shtml

Step 2 -4: Permits for Removal from Containment:

These permits are required in order to move any live regulated organism from the confines of an APHIS inspected containment for any reason, including movement between containment

facilities regardless of their relative location (in addition to such movements which may be described and permitted in the existing permit). If movement between specific containment facilities is already described and permitted in an existing permit importation, interstate or continued curation permit, then an additional permit is not required for such movement. .

A permit is required to remove a weed biological control organism from containment and enables release into the environment after the APHIS approval following the processes described in Steps 3 and 4 below. It must be kept in mind, that any removal from containment without safeguards (i.e., escape proof packaging while moving to another containment facility, or a physically separate part of a containment facility) constitutes “release” into the environment.

Step 3 APHIS Responses to the Recommendation Letter from the TAG-BCAW Chair

After receiving the TAG-BCAW recommendation, APHIS reviews the recommendation, including reviewers’ comments and any information and references cited by reviewers, and any additional information available to APHIS in order to determine if APHIS will support release of the biological control agent. The decision by APHIS to support – or not support - release may or may not agree with the TAG-BCAW recommendation to release (or not release), based on all the information APHIS considers. However, historically the TAG-BCAW recommendation and the subsequent APHIS decision regarding release frequently coincide..

Soon after receipt of the Recommendation letter from the TAG-BCAW Chair, APHIS typically will write a letter to inform the Petitioner of the APHIS decision regarding support of the request to release the biological control agent, with a copy to the TAG-BCAW Executive Secretary . In the cases where APHIS supports the request to release, APHIS may still request that the Petitioner provide additional information or clarification, which will be used to support and enhance the environmental compliance documents in the following steps.

This additional information or clarification is usually in response to questions or concerns raised by the reviewers or other parties which are often received even with a TAG_BCAW recommendation for release. .

When APHIS supports a request for release , then APHIS will invite the Petitioner to submit an application for removal from containment and environmental release of the agent ref. Step 2.4 above. NOTE: an application may be submitted by any individual in accordance with APHIS regulations (7 CFR 330.201 – 203), and may be from a party not the petitioner/researcher, but who is proposing to colonize, increase, or distribute the agent. Upon receipt of the application, APHIS will proceed with the Environmental Compliance process described in Step 4 below.

When release of the weed biological control agent is not supported by APHIS (typically when the TAG-BCAW does not recommend release), then APHIS will convey the reasons for not supporting release in the letter to the Petitioner, and may outline steps to take if the Petitioner wishes to improve the petition. At this point, it will be the decision of the Petitioner or other researchers whether to invest additional time and resources to improving the petition and submitting an amended petition to the TAG-BCAW Executive Secretary. The subsequent submission of a new or amended petition may or may not lead to a recommendation for release, or support for release by APHIS. APHIS will deny any application submitted for removal from containment and therefore will not proceed with the Environmental Compliance process described in Step 4 below.

Step 4: Environmental Compliance in Support of Petition for Release

Issuance of permits by APHIS for the environmental release of nonindigenous weed biological control organisms is considered a Federal action and triggers compliance with the Endangered Species Act (ESA) and the National Environmental Policy Act (NEPA). Steps and procedures APHIS follows to comply with

these acts regarding the proposed release of a biological control agent against weeds are described below in steps 3.1 and 3.2 respectively.

The petitioner should apply for a PPQ 526 permit to remove a weed biological control organism from containment (see Step 2.4) after receipt of a letter from APHIS indicating support of the request to release the weed biological control organisms into the environment of the United States. APHIS proceeds with the steps for compliance with these environmental acts in response to receipt of the application for the permit to release (removal from containment).

Step 4.1 Compliance with the Endangered Species Act

According to the ESA, any action that is authorized, funded, or carried out by a Federal agency must comply with the consultation requirements of Section 7 of the ESA. (See Section 7 Consultations on page 6-1-1 ESA; Compliance on page 6-1-1.). Although the researcher should have received input from the USFWS or possibly the National Marine Fisheries Service (referred to collectively as the “Services”) from the beginning, APHIS-PPQ determines if consultation with the Services must be conducted at this point in the process. If the proposed release will have no effect on listed species or designated critical habitat, no consultation with the Services is required.

Informal consultation with the Services occurs when the release of the biological control organism “may affect, but is not likely to adversely affect” listed species or designated critical habitat.

The document required for Section 7 consultation with the Services is a biological assessment. This document is prepared by APHIS and is submitted to the Services. . The BA includes several elements:

1. A description of the action to be considered.
2. A description of the specific area that may be affected by the action.

3. A description of any listed species or critical habitat affected by the action
4. A description of the manner in which the action may affect any listed species or critical habitat and an analysis of any cumulative effects.
5. Relevant reports, including any EA or EIS.
6. Other relevant information on the action, affected listed species, or critical habitat.

The USFWS reviews the BA, and if they concur with the “may affect, not likely to adversely affect” determinations, they will send APHIS a concurrence letter and the consultation process is complete. Once complete, PPQ incorporates the concurrence from USFWS) into the environmental assessment (EA), and makes any final changes necessary.

In very rare cases, APHIS may pursue formal consultation with the USFWS. Formal consultation is required when APHIS determines that the proposed release “may affect and is likely to adversely affect” listed species or designated critical habitat. Typically, APHIS does not proceed with formal consultation except under the unusual circumstances, where the adverse effect may be in doubt, or is likely to be very limited.

Step 4.2 Compliance with the National Environmental Policy Act.

The document required for NEPA compliance is the Environmental Assessment (EA), a concise public document that provides evidence and analysis to determine whether a Finding of No Significant Impact (FONSI) can be reached. The EA is prepared by APHIS staff scientists. The EA provides the public with the potential positive and negative environmental impacts, both direct and indirect, that may occur following release into the environment. Petitioners from other Federal agencies must also consider their own NEPA implementing procedures specific to any proposed actions.

Once the EA has been completed, PPQ publishes a 30-day notice of availability of the EA in the Federal Register to allow public comment on the proposed action. After considering the comments, PPQ does one of the following:

- Reaches a finding of no significant impact (FONSI) and can process a pending permit application for movement out of containment; or
- Is unable to reach a FONSI, and concludes that preparation of an Environmental Impact Statement is required. An EIS is a document prepared in compliance with NEPA when significant impacts are expected from the proposed action, although typically, APHIS does not support the release of a proposed agent if significant impacts are possible and thus, would not prepare an EIS.

If a FONSI has been reached, APHIS will publish the availability of the FONSI in the Federal Register and post the final EA and FONSI on the APHIS website

http://www.aphis.usda.gov/plant_health/ea/index.shtml.

At this point, APHIS will proceed with processing the PPQ Form 526, Application to Move Live Plant Pests or Noxious Weeds so that the weed biological control agent may be moved out of containment facilities and subsequently released into the environment.

Step 5: Compliance with Executive Order 13175

APHIS, like other federal agencies, is bound to comply with various Executive Orders (EO), some of which apply to these proposed actions. EO 13175, “Consultation and Coordination with Indian Tribal Governments”, was issued to ensure that there would be “meaningful consultation and collaboration with tribal officials in the development of Federal policies that have tribal implications.” Therefore, APHIS implements contact and communication with federally recognized Tribal Governments regarding the proposed environmental release of weed biological control organisms. Typically, prior to the publication of the EA in the Federal Register, APHIS staff prepares a letter describing the proposed Federal action and

requests review and input from Native American Tribes in any area likely to be inhabited or affected by the release of the proposed biological control agent against weeds. If the tribal governments request documentation, then the draft EA is sent to them for their review. Any concerns they pose are addressed by APHIS and the petitioner. If a Tribal government requests consultation with APHIS, Environmental Compliance and other actions in preparation of the proposed release are paused until consultation is concluded.