



USDA APHIS PPQ: Environmental Compliance for New Biological Control Agents: Historical Perspectives and Current Status

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Environmental Compliance Process

- Overview of the process to evaluate “TAG Petitions” and then permit proposed first time environmental release of Weed Biocontrol Agents Under APHIS PPQ Permit
- Flowchart of individual steps
- Detail for critical steps where breakdowns/policy changes occurred
- Status of current petitions in the regulatory process



Permits for first time environmental release of biological control organism new to North America

Prior to the introduction of an organism new to the environment of the United States or territories, environmental risk analyses are required before APHIS issues permits for environmental release. Environmental compliance procedures must be followed.

These procedures are guided by the requirements of the Endangered Species Act (ESA) and the National Environmental Compliance Act (NEPA). Specifically for NEPA, the APHIS NEPA Implementing Procedure regulations apply (7 CFR Part 372).

APHIS Environmental Compliance Process



The Environmental Compliance process is rooted in the writing of the APHIS permit.

This is the “federal action” which triggers the compliance with two Acts:

- The Endangered Species Act (ESA)
(specifically “Section 7” Interagency Cooperation)
- National Environmental Policy Act (NEPA)



Overview of the Process (Flowchart) to Evaluate Proposed Release of Weed Biocontrol Agents Under APHIS Permit

Petitioner biocontrol agent evaluation and selection process: 3 to 7 years

1. OBTAIN THE AGENT

2. SCREENING

3. HOST SPECIFICITY TESTING PART 1

4. HOST SPECIFICITY TESTING PART 2

5. PREPARE PETITION

2 to 4 years

6. PETITION TO TAG

7. TAG REVIEW AND RECOMMENDATION

8. PERMITTING DECISION

9. ENDANGERED SPECIES ACT REVIEW

10. NATL. ENV. POLICY ACT / TRIBAL CONSULTATION

11. PUBLIC COMMENT

12. ENV. FINDING

13. PERMIT COMPLETION

Permits for first time environmental release of biological control organism new to North America

- STEPS in the “Environmental Compliance Process” for Organisms New to the United States and territories:
 1. Researcher submits petition to release new organism and it goes to TAG (Technical Advisory Group) for review
 2. APHIS PPQ PPBP receives a recommendation and comments from TAG and makes permitting decision to move forward or not
 3. If “recommended for release” APHIS contacts petitioner re information needed for next steps (4 & 6)*:
 4. Preparation for ESA Section 7 Consultation with Fish and Wildlife Services (typically includes a Biological Assessment)
 5. FWS either concurs with our decision that release of the BC agent will not adverse effect on T & E species or does not concur.

Permits for first time environmental release of biological control organism new to North America

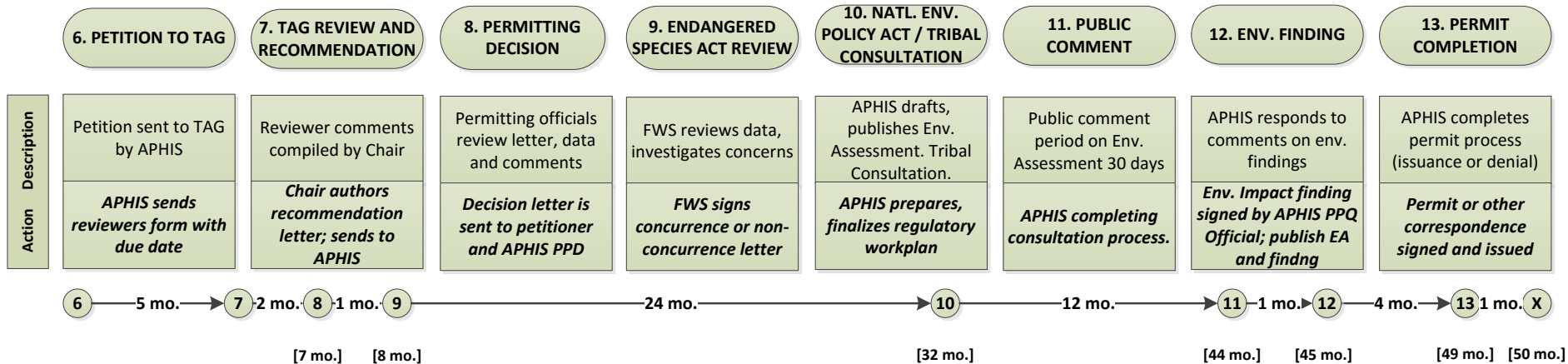
- STEPS in the “Environmental Compliance Process” for Organisms New to the United States and territories, continued:
 6. Preparation of Environmental Assessment (EA) by APHIS
 7. Tribal Review of the Draft EA
 8. Publication of EA in the Federal Register and announce open period for public comment
 9. Evaluate and respond to public comments
 10. Reach a Finding of No Significant Impact?
 11. Preparation of Final EA & signed FONSI, announced in Federal Register and posting EA and FONSI on APHIS web page
 12. Permit organism for release

APHIS Permit assessment and decision process including Environmental Compliance

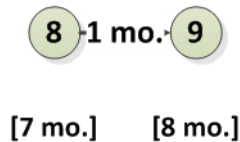
Permitting Decision (APHIS)



2 to 4 years



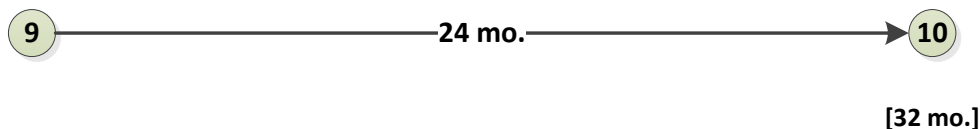
APHIS Environmental Compliance Process



APHIS Permitting Decision

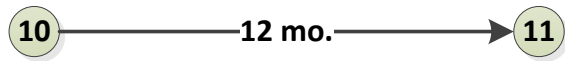
- APHIS Permitting group reviews documents focusing on information/ comments relevant to the **Environmental Compliance Process**, agricultural practices, other economic plants.
- APHIS Permitting writes **Decision Letter** which confirms the decision to proceed with the Environmental Compliance process needed to write a permit to release. The letter outlines the steps in the process and probable time lines.

Endangered Species Act Review



- APHIS PPD Environmental and Risk Analysis Services (ERAS) prepares a Biological Assessment (BA) using information in the Petition
 - Initiates informal “Section 7” consultation with the U.S. Fish and Wildlife Service: this seeks a **concurrence** that the release of the new biological control agent will not “adversely affect” any threatened or endangered species or designated critical habitat.
- BA typically does not restrict release or movement of the biological control agent within the continental United States.
- **The informal consultation has no specific time frame, and may involve review by any of the local field offices of the US F&WS.**
- **If a concurrence from the USFWS is received – APHIS moves ahead with the next step of environmental compliance and triggers the writing of an Environmental Assessment.**

National Environmental Policy Act and Tribal Consultation



[32 mo.]

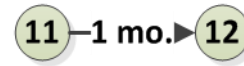
[44 mo.]

- Environmental and Risk Analysis Services (ERAS) prepares Draft Environmental Assessment.
- APHIS Permitting (PPBP) prepares a Regulatory Workplan and submits to Regulatory Coordination and Compliance (PHP, IRM) with the Draft Environmental Assessment.
- PPBP coordinates Tribal contact (usually 45 days) with Field Operations in areas infested by target weed.
- PPQ PHP Regulatory Coordination and Compliance (RCC) approves and prepares necessary documents and submits to Regulatory Analysis and Development (PPD, RAD) for further processing and approvals.



Environmental Compliance Process

Public Comment



[44 mo.]

[45 mo.]

- Notice of Availability of the environmental Assessment is published in the Federal Register giving a 30 day period for public comment.

APHIS Environmental Compliance Process



Environmental Finding

- All public comments reviewed and answered as needed by ERAS (in consultation with PPBP and petitioner).
- APHIS (PHP, PPD) reviews and considers all comments and input from Fish and Wildlife Service, Tribes, and the public to arrive at the Environmental Finding.
- As appropriate, ERAS prepares a document outlining APHIS' "finding of no significant impact" (FONSI) for signature by a PPQ Plant Health Protection official.

Permit Completion !

13 1 mo. X

[49 mo.] [50 mo.]

- Once FONSI is signed, PPQ finalizes the Environmental Assessment incorporating comments and necessary adjustments if needed.
- PPD RAD publishes Notice of Availability of the Final Environmental Assessment and FONSI in the Federal Register.
- Upon this finding, PPBP completes the permitting process and **issues a permit** 😊 allowing the removal of the biocontrol agent from containment facilities for release into the environment.
- PPBP issues additional permits as needed and approved for movement and release in individual states infested by the weed.

Historical Perspectives and Changes:

1. **2000 – 2009:** Average time for approved petitions from TAG to Permit for release was 13.5 months (range 4 to 26 months)
2. **2010 – 2011:** No petitions were approved through TAG
3. **2012 – Many petitions recommended for release - BUT – Changes at FWS**

John Fay who had handled the ESA process retired and was replaced with someone not comfortable with Biological Control

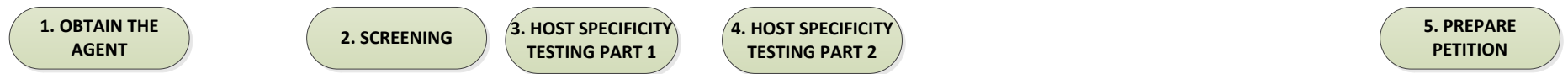
Greater concern with indirect effects as observed with *Diorhabda*

Increased demands on researchers to produce data on potential effects on T&E species even if less closely related

4. **Process ground to apparent halt – No Approvals 2013-2015**

Overview of the Process (Flowchart) to Evaluate Proposed Release of Weed Biocontrol Agents Under APHIS Permit

Petitioner biocontrol agent evaluation and selection process: 3 to 7 years



2 to 4 years



↑
4 years +

Historical Perspectives and Changes:

1. **2015:** FWS came out with formalized guidance for petitions for Biological Control agents vs weeds – has improved the ability of scientists to know where the bar is for approval.
2. **2015-16: APHIS** Began interagency consultation for ways to expedite what had become dysfunctional and unwieldy system. Remove roadblocks in both FWS and APHIS related to signatories that may not have been scientists and were uncomfortable with Biological Control and potential risks for releasing exotic organisms.
3. **2016/17: APHIS funded** Jeff Herod with FWS 75% specifically to shepherd Biological Control petitions through FWS (and work with other specific plant issues).

Historical Perspectives and Changes:

1. **APHIS** – Dealt on a lesser scale with similar issues – Modified NEPA process in 2013-2014 which slowed petitions and had signatories that were unfamiliar or uncomfortable with releasing Biological Control agents of invasive weeds
2. **In House** – **We have improved education** and transfer of information and and continue to streamline the process
3. **These efforts have been fruitful: Currently**, APHIS PPBP and ERAS are working well with FWS.
4. **APHIS and FWS** are working together to move relatively quickly through the backlog and have communicated with researchers to solicit submissions for the coming year.



Agent	Target	TAG	FWS	NEPA (Tribal)	NEPA Fed Reg.	Permit
<i>Parafreutreta regalis</i>	Cape Ivy	X	X	X	X	May 2016
<i>Lasioptera donacis</i>	Giant reed	X	X	X	X	Dec 2016
<i>Hypena opulenta</i>	Swallow-worts	X	X	X	X	Aug 2017
<i>Rhinusa pilosa</i>	Yellow toadflax	X	X	X	X	Jan 2018
<i>Aceria drabae</i>	Hoary cress	X	X	X	X	March 2018



Agent	Target	TAG	FWS	NEPA (Tribal)	NEPA Fed Reg.	Permit
<i>Calophya latiforceps</i>	Brazilian peppertree	X	X	X	In Prog	
<i>Pseudophilothrips ichini</i>	Brazilian peppertree	X	X	X	In Prog	
<i>Aphalara itidori</i>	Japanese Knotweed	X	X	X	In Prog	
<i>Sericothrips staphylinus</i>	Gorse	X	Very Soon			
<i>Cheilosia urbana</i>	hawkweeds	X	X	X	In Prog	



Agent	Target	TAG	FWS	NEPA (Tribal)	NEPA Fed Reg.	Permit
<i>Ramularia crupinae</i>	Common crupina	X	Fall 2018			
<i>Bikasha collaris</i>	Chinese tallow	X	In Prog			
<i>Ceutorhynchus scrobicollis</i>	Garlic mustard	X	In Prog			
<i>Lilioceris egena</i>	Air potato	X	Near Sub			
<i>Ceratapion basicorne</i>	Yellow starthistle	X	X			

APHIS PPQ: BA's, EA's, and FONSI's

Questions ?

