



United States Department of Agriculture

## **USDA APHIS PPQ Plant Health Protection Pest Permitting Branch**

# **Regulatory Requirements in the United States**

### **For Release of Non-indigenous Entomophagous Biological Control Agents**

**NAPPO Workshop : Preparation of Petitions for First Release of  
Non-indigenous Entomophagous Biological Control**

**Ottawa, Ontario, Canada**

**7-8 July 2015**

**Bob Tichenor,  
Sr. Entomologist  
Biological Control**



# Topics

Review APHIS Authority

Relationship between Permitting and Review  
Committee recommendation

Environmental Compliance Processes for First  
Time Environmental Release of Entomophagous  
Biological Control Organisms New to North  
America (or U.S.), including:

- Recommendation on Petition;
- Endangered Species Act, and;
- National Environmental Policy Act procedures)



# APHIS PPQ Regulatory Authority - Biocontrol

APHIS regulation of biological control organisms is based on Plant Protection Act of 2000 (7 U.S.C. 7701 et seq.) APHIS has broad authority to regulate plant pests, including “indirect plant pests”.

Biocontrol organism = Any enemy, antagonist, or competitor used to control a plant pest or noxious weed.

# 7 CFR 330.200: Scope and General Restrictions

- ▶ Plant pests, biological control organisms, and associated articles require a permit to be:
  - ❑ Imported into US and Territories
  - ❑ Moved interstate (including territories)
  - ❑ Possessed (continued curation) after end of permit (certain species)
  - ❑ Moved out of a containment facility (non-established species typically require confinement within a containment facility)

# PPQ 526 Permits are required from APHIS for any of the following

1. **Importation** of live Biological control organisms into the United States and its Territories (Importation Permits)
2. **Interstate movement** of live Biological control organisms (By policy Commercial biological control organisms are not required to obtain these permits)
3. **Retaining** live biological control organisms in containment facilities after expiration of a permit (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.**

# First time environmental release: Permitting Requirements, Process/Steps

- The Petition (NAPPO RSPM 12)
- Review of the Petition by Canadian Biological Control Review Committee
- Recommendation from Committee to APHIS
- APHIS evaluation of recommendation and other information
- Process for the Endangered Species Act (ESA) with F&WS concurrence, as needed
- Tribal contact (consultation?)
- The NEPA process
- FONSI and release permit

# Documents Required by APHIS for First Time Environmental Release of Biocontrol Organisms

1. **Petition** (RSPM 12) to the Canadian Biological Control Review Committee to release a biological control agent (\*provided by the applicant/researcher)
2. Recommendation from the BC Review Committee to release a biological control agent
3. Environmental Assessment (EA)
4. Endangered Species Act Section 7 effects determination (from US F&WS) **when needed**
5. Finding of No Significant Impact (**FONSI**)



# Initial Environmental Release Processes

The Canadian Biological Control Review Committee solicits input from “outside groups of experts” with whom APHIS may consult regarding help determine the “danger of plant pest dissemination into the United States” (7 CFR 330.202)

Recommendations from Canadian Biological Control Review Committee are thus advisory to APHIS



## **STEPS** in the **“Initial Environmental Release Process”**

If APHIS decides to go forward with “recommended for release”  
APHIS contacts petitioner re information needed for next steps

1. Preparation for Section 7 Consultation with Fish and Wildlife Services (not usually needed for entomophagous biocontrol)
2. Preparation of Environmental Assessment EA by APHIS for NEPA requirements, and Publication of EA in the Federal Register
3. Tribal Review (usu. concurrent with internal USDA review of EA)
4. Evaluate and respond to public comments: Reach a Finding of No Significant Impact?
5. Preparation of Final EA & signed FONSI and posting EA and FONSI on APHIS web page
6. **Continue processing of Permit**



# Initial Environmental Release Processes

NEPA Implementing Procedures in 7CFR part 372 to “assur[e] early and adequate consideration of environmental factors in APHIS planning and decision-making ... and promot[e] the effective efficient integration of all relevant environmental requirements under the National Environmental Policy Act.”

# Information for the NAPPO Petitions

## “APHIS Highlights”

- 1. Taxonomic certainty and integrity of source colony;**
- 2. Expected Geographic and ecosystem ranges**
- 3. Target Pest Impacts**
- 4. Non-Target Impacts, especially T & E species, Pollinators, other Biocontrol organisms**
- 5. Interactions with other agents (+ & -) = “indirect” impacts**
- 6. Post Release Monitoring**

# Questions?



**As time allows – or for reference**

# Information for the NAPPPO Petition (RSPM No. 12)

- 
1. Proposed Action (Purpose, need, methods, etc)
  2. Target Pest Information
  3. Biological Control Agent Information
  4. Environmental & Economic Impacts of Proposed Releases
  5. Post Release Monitoring



# Information for the TAG and NAPPO Petitions “APHIS Highlights”

1. Taxonomic certainty and integrity of source colony
2. Expected Geographic and ecosystem ranges
3. Target Pest Impacts
4. Non-Target Impacts, especially T & E and Beneficials
5. Interactions with other agents (+ & -) = “indirect” impacts
6. Post Release Monitoring

# Information for the NAPPO Petition (RSPM No. 12): “Highlights”

## (3) Biological Control Agent Information

3.1 & 3.2 **Taxonomy** [APHIS “Highlights -1]

3.4 Natural and Expected (US) **Geographic Range** [2]

3.5 **Source** (including where originally collected) [1]

3.6 & 3.7 Biology and life history information

3.8 **Known host range** from literature, records, etc. [3, 4]



# Information for the NAPPO Petition (RSPM No. 12): “Highlights”

## (4) Environmental and Economic Impacts of the Proposed Release

- 4.1 Known impact on vertebrates including humans.
- 4.2 Implications of not releasing this biological control agent (e.g., pesticide use, physical controls).
- 4.3 **Direct impact of the biological control agent on target pest and non-target species. [3, 4]**

# Information for the NAPPO Petition (RSPM No. 12): “Highlights”

- (4) Environmental and Economic Impacts of the Proposed Release
- 4.4 Effects on physical environment (e.g., water, soil and air resources).
  - 4.5 **Indirect effects** (e.g., potential impacts on organisms that depend on the target pest and non-target species, **including potential competition** with resident biological control agents). **[5]**
  - 4.6 **Possible direct, or indirect effects on threatened and endangered species** in North America **[4, 5]**

# Information for the NAPPO Petition (RSPM No. 12): “Highlights”

## (5) Post-Release Monitoring [6]

5.1 Establishment and spread

5.2 Changes in density of Biocontrol Organism and pest

5.3 Host specificity/attack rates on the target pest and selected **non-target species for which potential impacts are identified** ...

5.4 Changes in the target pest and in the growth, survival, and reproduction of selected non-target species.

5.5 Changes in species diversity and community structure.

# Information for the TAG and NAPPO Petitions “APHIS Highlights”

## 4. Non-Target Impacts: Questions

(a) Host specificity (general)

(b) Host range includes T&E species or relatives?

(c) Host range includes “beneficials”

(entomophagous), or crops (weed biocontrol)?

# Information for the TAG and NAPPO Petitions “APHIS Highlights”

## 4. Non-Target Impacts: Issues

- (a) Host specificity – **What is host specific enough?**
- (b) Host range includes T&E species or “beneficials” or crops: **What is meant by “host range”? What about data that shows non-target acceptance – will this always “doom” the candidate? (Is there still a way through to a FONSI?)**



# Proposed Plant Pest Regulatory Policy Amendments –Related to Biological Control

**Exemption of certain organisms from permit requirements for movement and release**

**Petition process for being included on “exempt list”**

**Biocontainment facilities: application, inspection, approval and maintenance processes**