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Plant Protection and Quarantine  
SE-EPPC 5-3-05

## Federal Noxious Weed Regulation & Proposed Revision of Quarantine 37: Reducing the Pest Risk Associated With the Importation of Plants for Planting

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## What is a rule and when must APHIS conduct rulemaking?

- Under U.S. law, a rule is any requirement of general applicability and future effect
- An agency may issue rules only within the scope of its authorizing legislation
- APHIS must conduct rulemaking whenever it wishes to enforce a rule

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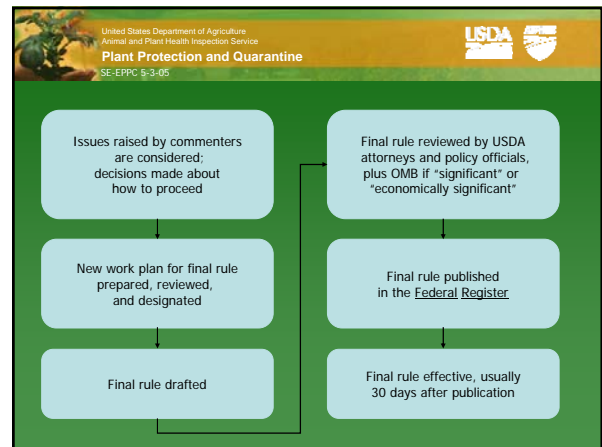
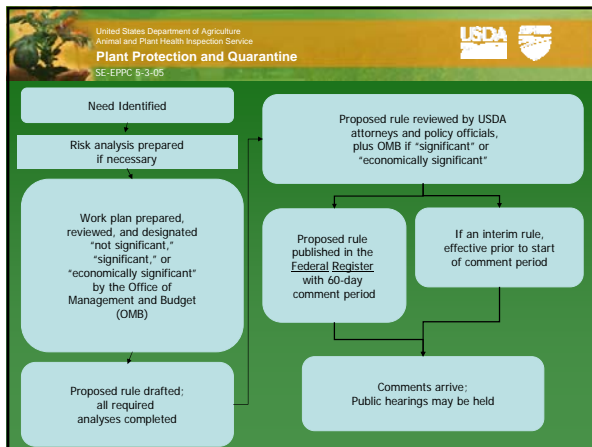
## What is the rulemaking process?

- The principal requirements for rulemaking are set by the Administrative Procedure Act (APA) (5 U.S.C. 551 et seq.)
- Agencies can enforce rules that are properly issued. Rules that are not properly issued may be successfully challenged in court (arbitrary and capricious)

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## Levels of publication

- Advanced Notice of Proposed Rulemaking (ANPR)
- Proposed Rule
- Interim Rule
- Final Rule



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**Not significant:**

- This term has nothing to do with an action's importance or priority; it simply means that OMB has decided not to review the docket.

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**Significant: An action that is likely to:**

- Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a section of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
- Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
- Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

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**Economically significant:**

- An action likely to result in the effects listed in (1) on previous slide:
  - Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a section of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

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<p><b>"Not significant" rules:</b></p> <p><u>USDA Clearances:</u></p> <ol style="list-style-type: none"> <li>1. Office of General Counsel</li> <li>2. Deputy Administrator</li> <li>3. Administrator</li> <li>4. Office of Budget and Program Analysis</li> <li>5. Under Secretary, Marketing and Regulatory Programs</li> </ol>	<p><b>"Significant" or "economically significant" rules:</b></p> <p><u>USDA Clearances:</u></p> <ol style="list-style-type: none"> <li>1. Office of General Counsel</li> <li>2. Deputy Administrator</li> <li>3. Administrator</li> <li>4. The General Counsel for USDA</li> <li>5. Office of Budget and Program Analysis</li> <li>6. Office of the Chief Economist</li> <li>7. *Office of Risk Assessment and Cost-Benefit Analysis</li> <li>8. Assistant Secretary for Administration</li> <li>9. Office of the Chief of Information</li> <li>10. Under Secretary, Marketing and Regulatory Programs</li> <li>11. Secretary</li> <li>12. Office of Management &amp; Budget</li> </ol> <p><small>* For economically significant rules only</small></p>
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**Typical Time Required for Rulemaking**

Work Plan - Proposal - Comment Period - Final Rule - Effective Date

"Not significant" rule: 1 year	"Significant" or "economically significant" rule: 2-3 years
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Some take a little less time; some take longer.

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**Other Acts & Reviews**

- Executive Order 12866 of Sept. 30, 1993, "Regulatory Planning and Review"
- The Regulatory Flexibility Act (5 U.S.C. 601 et seq.)
- The National Environmental Policy Act (42 U.S.C. 4321 et seq.)
- Section 7 of the Endangered Species Act (16 U.S.C. 1536)
- The Congressional Review Act of 1996 (5 U.S.C. 801 et seq.)
- The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)


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## The World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures


- Principles of:
  - Transparency
  - Harmonization
  - Equivalence
  - Risk assessment
  - Regionalization

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## Q-37 Revision


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## Plants for Planting (Q-37)

- Code of Federal Regulations (CFR), 7 CFR Part 319.37 (Q-37)
  - The principal regulation governing the import of plants for planting
- Other related regulations also covered in the revision (all 7 CFR)
  - 319.15 Sugarcane
  - 319.19 Citrus & related genera
  - 319.24 & .41 Corn & related genera
  - 319.55 Rice
  - 319.59 Wheat
  - 319.8 Cotton

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## Why Does Importation of Plants for Planting Present Significant Risks

- Difficult to determine origin
- Difficult to inspect at ports of entry
- Many pests borne internally (e.g., diseases, small invertebrates)
- Introduced pests relatively likely to become established
- Production facilities moving off shore to remain competitive
  - examples: geranium, tropical foliage, poinsettia
- Inadequate information on pests that may have quarantine significance


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## Pests That Have Entered, (or May Have Entered) With Plants for Planting

<ul style="list-style-type: none"> <li>Citrus Canker</li> <li>Day lily rust</li> <li>Dogwood anthracnose</li> <li>Eucalyptus pitch canker</li> <li><i>Phytophthora ramorum</i> (Sudden oak death)</li> <li>Plum pox potyvirus</li> <li>Ralstonia solanacearum race 3, biovar 2</li> <li>Corn cyst nematode</li> </ul>	<ul style="list-style-type: none"> <li>Emerald ash borer</li> <li>Hemlock woolly adelgid</li> <li>Karnal bunt</li> <li>Longhorn beetles, cedar, citrus, Asian</li> <li>Pink hibiscus mealybug</li> <li>Red gum lerp psyllid</li> <li>Devil's tearthumb</li> <li>Japanese knotweed</li> <li>Tropical Soda apple</li> </ul>
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## Basic Premise of Current Q-37

- Majority of plant taxa are enterable with only a port of entry inspection
- Some plants for planting are further restricted by additional requirements
- Pest risk analysis required only for certain types of importations

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## Evolution of Q-37: Original Intent vs Current Practice

	Early Years	Now
Trading Partners	Europe	Worldwide
# of Items Allowed Import	Limited (< 100 items) germplasm of clonal material only	Unlimited
Fumigation	Mandatory on all Imported Stock	Only When Quarantine Pest Found
Likely Purpose of Importation	Nursery propagation program "starter" material <b>Slow distribution</b>	Direct field/homeowner planting <b>Immediate distribution</b>

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## Comparison of Import Requirements Q-56 (consumption items) & Q-37

	Q-56	Q-37
Enterability	Only specific taxa/country combinations, published	All taxa except specifically prohibited
Risk assessment & mitigation	Required before each new importation	Only for Plants In Growing Media (PIGM)
Pre-export mitigations	Systems approaches, fumigations	Only for PIGM and fruit trees from 5 countries
Monitoring and audit of pre-export mitigations	Usual	Seldom
Port of Entry Inspection	CBP	PPQ

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## Comparison of Import Requirements Q-56 (consumption items) & Q-37

	Q-56	Q-37
Genera imported	@200	Several thousand
Origin of import	Part of PRA and Regulated	Difficult to determine source, lineage
How long does risk last ?	Days to weeks	Months to years
Risk Reduction	Risk assessment, pre-export mitigation, auditing, visual inspection	Visual inspection at port
Suitable host/environment for establishment	Less likely	More Likely

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## Revision of Q-37 Involves Multiple Phases / Activities / Challenges

- Operational:
  - Will affect mostly PPQ, but also DHS-CBP
- Regulatory:
  - Multiple regulatory changes will be needed
  - Goal... minimize impact on trade while maximizing reduction in pest risk
- Stakeholder:
  - Some new requirements
  - Greater protection of assets

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## Advance Notice of Proposed Rulemaking (ANPR)

- Published Dec 10, 2004
  - "Nursery Stock Regulations", Docket No. 03-069-1
- Comment Period Open Until March 10, 2005 (extended until April)
- View ANPR and comments at: <http://www.regis.usda.gov/regprd/nursery/>

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## Revising Q-37: Highlights of the 2004 ANPR

- Programs to reduce risk of entry and establishment of plant pests
- Establish a new import entry category
- Improve data collection to determine taxa imported, origin, and volume
- Reevaluate taxa currently prohibited
- Incorporate all plants for planting into one regulation

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## 1. Programs to reduce risk of entry and establishment: Clean Stock Program

Elements of an Accredited/Certified Clean Stock Program:

- Clean stock produced by foreign exporters
- Best practices for importers
- Incentive for grower participation
- NAPPO set standard, provide review, approval and oversight
- Accredited grower pest management program (e.g., best practices, ISO)
  - including pest free propagation material
- US review and approval
- NAPPO and US monitor and audit production and shipments
- Penalties and remedial action for non-compliance

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## 2. Establish a new import entry category

Plant taxa would be “Excluded pending risk evaluation and approval” (Q-56 model)

- Two approaches possible
  - All taxa that have not already entered the US
  - Only for taxa where reasonable indication of pathway for invasive pest or is invasive pest
- Criteria science-based but less stringent than PRA


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## 3. Improve data collection to determine taxa imported, origin, and volume

- No one source for data
- Ongoing analysis
- Support regulation change, grandfathering taxa


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## 4. Reevaluate taxa currently prohibited

- Not just Q-37, also Q-19, 41, 55, etc.
- Consider pests associated with plant taxon
- Need PRA to determine all pests of concern

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## 5. Incorporate All Plants for Planting Into One Regulation

- Promote clarity, consistency, and transparency
- Possibly include Noxious weeds and other regulated taxa (e.g., CITES)


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## “Departmental” Permits

- For prohibited articles
- Original intention... research, by USDA
- Current usage... various, insufficient oversight
- Strategy for improvement:
  - Phase 1 (now): More appropriate conditions, and more involvement of State Officials
  - Phase 2: Modify name to “Research”, expand beyond USDA
    - Proposed Rule (draft) to modify existing regulations
  - Phase 3: Create new classes of permits (intended use)
    - Example, commercial development


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## Time Frames

Comment Period Closes, ANPR:	March 10, 2005 (extended to April)
Analyze ANPR Comments	Begin March, 2005
Proposed Rule, Departmental (Research) Permit	2005
Import of Christmas and Easter Cactus IGM from the Netherlands and Denmark (Proposed Rule)	2005
Proposed Rule, Standards for Including Species on "Exclude Pending PRA List"	Early 2006
Continuing work with NAPPO and globally on development of standards for clean stock programs	2005


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## ANPR

- APHIS is currently in the process of summarizing and evaluating the comments received.
- Public comments range
  - from opposition to regulatory changes because of possible impacts on gardening and small businesses (such as nurseries) to
  - unequivocal support for more stringent regulations.
- A public hearing will be held in Riverdale, MD May 25, 2005 to discuss the proposed new exclusion category, and criteria for including and removing taxa from the category.

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## APHIS Noxious Weed Program Manager



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## Noxious Weed Control and Eradication Act of 2004 (WCEA) (S144/H.R.119) adopted as P.L. 108-412 10/10/2004 (7 USC 7781-86)

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Pest Detection & Management Programs


Biological Control Technical Advisory Group Meeting April 2005

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- Plant Protection Act (7 U.S.C. 7701 et seq.) is amended
- Under authority of Secretary of Agriculture

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## Implementation

- Delegation details are in progress 4-7-05 submitted to Office of General Council)
- Interim planning for implementation is in progress in case funding becomes available before full plan is finished
- Request for Proposals (RFP) is in draft
- Planning is beginning for:
  - Staffing
  - Operations including grant application process
  - Grant/Agreement Management
  - Target setting


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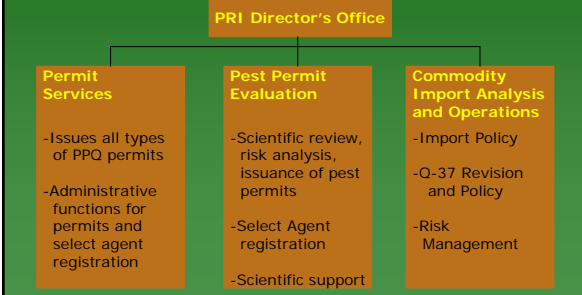
## Summary

- Implementation details under development
- Total in bill authorized per year as \$7.5 million for matching grants, \$7.5 million for agreements
- Authorized for years 2005 to 2009
- Under authority of Secretary of Agriculture (PPA activities are delegated to APHIS)
- While authorized for years 2005 to 2009, no appropriated funds are currently available

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## Permits, Registrations & Imports (PRI) Structure



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graph TD
    PDOP[PRI Director's Office] --> PS[Permit Services]
    PDOP --> PPE[Pest Permit Evaluation]
    PDOP --> CIAO[Commodity Import Analysis and Operations]
  
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Permit Services	Pest Permit Evaluation	Commodity Import Analysis and Operations
-Issues all types of PPQ permits	-Scientific review, risk analysis, issuance of pest permits	-Import Policy
-Administrative functions for permits and select agent registration	-Select Agent registration	-Q-37 Revision and Policy
	-Scientific support	-Risk Management