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

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)

Levels of publication
• Advanced Notice of Proposed Rulemaking (ANPR)
• Proposed Rule
• Interim Rule
• Final Rule

Need Identified
Risk analysis prepared if necessary

Work plan prepared, reviewed, and designated “not significant,” “significant,” or “economically significant” by the Office of Management and Budget (OMB)

Proposed rule reviewed by USDA attorneys and policy officials, plus OMB if “significant” or “economically significant”

If an interim rule, effective prior to start of comment period
Comments arrive; Public hearings may be held

Proposed rule published in the Federal Register with 30-day comment period

Issues raised by commenters are considered; decisions made about how to proceed

New work plan for final rule prepared, reviewed, and designated

Final rule reviewed by USDA attorneys and policy officials, plus OMB if “significant” or “economically significant”

Final rule published in the Federal Register

Final rule effective, usually 30 days after publication
**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.

**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.
- Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

**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.

**Typical Time Required for Rulemaking**
<table>
<thead>
<tr>
<th>Work Plan</th>
<th>Proposal</th>
<th>Comment Period</th>
<th>Final Rule</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Not significant” rule: 1 year</td>
<td>“Significant” or “economically significant” rule: 2-3 years</td>
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</tbody>
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**Other Acts & Reviews**
- 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 World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures

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

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

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

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
Evolution of Q-37: Original Intent vs Current Practice

<table>
<thead>
<tr>
<th>Early Years</th>
<th>Now</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trading Partners</td>
<td>Europe (quarantine only)</td>
</tr>
<tr>
<td># of Items Allowed Import</td>
<td>Limited (&lt;100 items) germplasm of clonal material only</td>
</tr>
<tr>
<td>Fumigation</td>
<td>Mandatory on all imported stock</td>
</tr>
<tr>
<td>Likely Purpose of Importation</td>
<td>Nursery propagation program “starter” material</td>
</tr>
<tr>
<td></td>
<td>Slow distribution</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Q-56</th>
<th>Q-37</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enterability</td>
<td>Only specific taxa/country combinations, published</td>
</tr>
<tr>
<td>Risk assessment &amp; mitigation</td>
<td>Required before each importation</td>
</tr>
<tr>
<td>Pre-export mitigations</td>
<td>Systems approaches, fumigations</td>
</tr>
<tr>
<td>Monitoring and audit of pre-export mitigations</td>
<td>Usual</td>
</tr>
<tr>
<td>Port of Entry Inspection</td>
<td>CBP</td>
</tr>
</tbody>
</table>

Comparison of Import Requirements:

Q-56 (consumption items) vs Q-37

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

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

Advance Notice of Proposed Rulemaking (ANPR)

- Published Dec 10, 2004
- “Nursery Stock Regulations”, Docket No. 03-069-1
- Comment Period Open Until March 30, 2005 (extended until April)

Revising Q-37: Highlights of the 2004 ANPR

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

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

3. Improve data collection to determine taxa imported, origin, and volume
- No one source for data
- Ongoing analysis
- Support regulation change, grandfathering taxa

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

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)

“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
**Time Frames**

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
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<tbody>
<tr>
<td>Comment Period Closes, ANPR</td>
<td>March 10, 2005 (extended to April)</td>
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<tr>
<td>Analyze ANPR Comments</td>
<td>Begin March, 2005</td>
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<tr>
<td>Proposed Rule, Departmental (Research) Permit</td>
<td>2005</td>
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<tr>
<td>Import of Christmas and Easter Cactus IGM from the Netherlands and Denmark (Proposed Rule)</td>
<td>2005</td>
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<tr>
<td>Proposed Rule, Standards for Including Species on “Exclude Pending PRA List”</td>
<td>Early 2006</td>
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<tr>
<td>Continuing work with NAPPO and globally on development of standards for clean stock programs</td>
<td>2005</td>
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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.

**Implementation**

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

- 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
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

Permits, Registrations & Imports (PRI) Structure

- Permit Services
  - Issues all types of PPQ permits
  - Administrative functions for permits and select agent registration

- Pest Permit Evaluation
  - Scientific review, risk analysis, issuance of pest permits
  - Select Agent registration
  - Scientific support

- Commodity Import Analysis and Operations
  - Import Policy
  - Q-37 Revision and Policy
  - Risk Management