2006 Q37 Summit

Informational Report

Executive Summary

United States Department of Agriculture
Animal and Plant Health Inspection Service
Plant Protection and Quarantine
Plant Health Programs and
Commodity Imports Analysis and Operations

The United States Department of Agriculture (USDA), Animal Plant Health Inspection Service (APHIS), Commodity Imports Analysis and Operations (CIAO) Branch, Plant Health Programs is in the process of revising the regulations that govern the importation of plants for planting, also known as 7 CFR 319.37 or Q-37. Each year, CIAO brings together Plant Protection and Quarantine (PPQ) staffs, selected because of their areas of expertise and experience, to discuss critical issues related to importation of plants for planting and to establish annual priorities for the revision of Q-37. The November 2006 Summit participants focused on seven issues: clarifying size/age limitations, streamlining the pest risk assessment requirements for plants in growing media, categorizing imported plants according to risk, establishing regulatory systems approach protocols, revising the post entry quarantine requirements, improving import data quality, and revising the definition, scope and process for departmental permits. This report presents background information about each topic, summarizes the Summit discussions, and outlines 2007 objectives.

Subject*: Size/Age Prohibitions and Plants in Growing Media*

Background:

The purpose of this session was to discuss issues related to 7 CFR 319.37 (b) and (e). Section 319.37-2(b), prohibits articles from being imported into the United States due to excess size or age (commonly referred to as Size/Age Prohibitions); and 319.37-8(e), imposes additional restrictions on the importation of certain plants established in growing media (commonly referred to as Plants in Growing Media Restrictions).

Currently, there are seven different size/age prohibitions with apparent inconsistencies.

Size/Age Prohibitions:

The size/age prohibitions have been added to the Plants for Planting Regulations (Q37) in response to specific requests over many decades. As a result, some restrictions lack cohesiveness and clarity. In addition, several plant groups are exempt from, these prohibitions: notably artificially dwarfed plants; epiphytes, including orchids, that are not cuttings; and herbaceous perennials not imported as crowns or clumps.

Currently, only eight genera are approved for import in growing media worldwide; in addition, two genera and five species are approved from specific countries.

Plants in Growing Media Restrictions:

Q-37 requires that any plant imported into the USA shall be free of sand, soil, earth, and other growing media. However, plants in growing media restrictions were implemented to allow the importation of specific plant taxa that meet the conditions specified in 319.37-8(e). Exporting countries are required to have an approved program that meets these requirements. New plant taxa are added to the program only after the completion of a pest risk analysis (PRA). There are concerns about delays in the implementation of new programs, lack of resources for oversight, and under-utilization of existing programs.

Summary of Discussion:

Size/Age Prohibitions:

Pest risk related to size/age may differ between taxa. Some may have greater tendency to "collect" pests as they grow older while the opposite may hold for others. Older and larger plants are more difficult to inspect, and the likelihood of not detecting quarantine pests is increased. Other considerations in establishing size/age restrictions include the weight, plant type, plant part, amount and kind of foliage, whether or not plants are flowering or in fruit.

Amendments to the size/age prohibitions should be science-based and operationally feasible.

The PPQ working group concluded that size/age prohibitions are generally justified because of scientific, operational and technical considerations and should not be eliminated. APHIS will review the size/age prohibitions to clarify the requirements, and make amendments to the regulations where justified. For example, similar plant types could be clumped together based on risk. The regulations should more clearly define the different types of dwarfed plants, e.g. artificially dwarfed vs. naturally dwarfed, "starter plants" vs. true bonsai, etc. Production practices influence pest risk and should be considered. Size and weight prohibitions should be established for artificially dwarfed plants.

PPQ will establish and implement a framework that provides criteria for the use in establishing size/age regulatory policy in the revised Q37.

Plants in Growing Media:

The plants in growing media requirements were established to mitigate the risk associated with the importation of plants that are currently admissible as bare rooted plants but are proposed to be imported in growing media. The import requirements for these commodities as bare rooted are less stringent than when they are imported in growing media. PPQ's Center for Plant Health Science and Technology evaluates the risk associated with plants in growing media to ensure that the appropriate level of phytosanitary security can be maintained. The Agency is currently considering developing a pest risk analysis process that

will more efficiently evaluate the added pest risk associated with plants in growing media compared to their importation as bare root products. In addition, standardized risk management and oversight procedures will be developed. PPQ recognizes that more resources will be required to provide oversight, monitoring and auditing.

Next Steps:

Size/Age Prohibitions:

Review current regulations to identify definitions and terms requiring review and clarification.

Define different types of dwarfed plants and establish appropriate size/age requirements, consult with the National Arboretum, the Bonsai Society, and others.

In conjunction with USDA plant inspection stations, identify specific inspectional and operational problems associated with size/age and develop potential solutions.

Plants in Growing Media:

Develop a pest risk analysis process that will more efficiently evaluate the added pest risk associated with plants in growing media.

Develop a standardized risk management and oversight procedures.

Subject: *High Risk/Low Risk Commodities*

Background:

The Plants for Planting Review Group is establishing a process to characterize the risk of plants now being imported.

Plants for Planting are inspected at PPQ's plant inspection stations, and if quarantine significant pests are detected, the commodities are subject to treatment, reconditioning, destruction, or re-export. Frequently, no further action is taken to ensure that the exporting country mitigate the pest risk associated with future shipments of these commodities.

After the first Q37 Summit Meeting in October, 2005, Plant Health Programs formed the Plants for Planting Review Group (PPRG) to characterize the risk of plants for planting imports. The PPRG has been tasked with identifying:

1. Plants for planting currently being imported that have a record of numerous pests detected by PPQ officers at plant inspection stations indicating that they present a significant risk. It is APHIS goal to require additional safeguarding activities in order to mitigate the pest risk in the country of origin prior to exportation of these commodities. APHIS will work with the exporting countries to decrease the pest risk associated with the importation of these plants for planting.
2. Plants for planting currently being imported that have an import history indicating that they do not present a significant pest risk will be candidate genus-country pairs for the AEPI (Assessed and Enterable with Phytosanitary certificate. Low risk imports will be subject to port of entry Inspection) category.

The risk ranking process will allow PPQ to dedicate more resources to mitigating the risks associated with plants for planting imports with higher risk rankings.

To these ends, the PPRG group is establishing a two-part process. The first part of the process is to devise an algorithm (a finite set of well defined instructions) for ranking all current imports according to risk. This algorithm will make use of the information collected at the plant inspection stations and recorded in the PPQ 280 and Pest ID databases. The algorithm will be sensitive enough to give an accurate representation of risk but simple enough to be carried out with some frequency. The second part of the process is to identify the risk management

options that will mitigate the pest risks associated with plants for planting with a high risk pest detection score determined by application of the algorithm, or add low ranking imports with low pest detection score to the AEPI list.

Three years of data would be a minimum to support an Agency decision to categorize a host genus as high or low risk.

The following factors were reviewed to determine how they would be integrated into the initial risk ranking process for all propagative plant imports:

- Frequency of interceptions.
- Size of inspected shipments yielding interceptions.
- Risk of specific pests detected (including level of taxonomic identification).
- Variety of pests detected.

Summary of Discussion:

It was generally agreed that the process developed by the PPRG to categorize imports according to risk will be an effective tool to focus the Agency's resources on mitigating the pest risk associated with imported plants for planting that have an unacceptably high number of pest detections.

Additional data would be helpful, but expanding data collection requires extensive changes to current practices. Specifically, the part of the plant imported, and host plant species would help to identify high and low risk commodities. The group discussed the benefits of collecting grower information; however, the cumbersome task of collecting grower information may not be feasible.

Two years ago, data collection at the plant inspection for imported host plants expanded from categories of plants (such as tropical foliage plants) to include genus level identification. Three years of data might be a minimum necessary to support an Agency decision to categorize a host genus as high or low risk. Quality control of the data is critically important, and needs improvement.

High risk commodities:

A new inspection protocol could be adopted for low risk imports, to allow plant inspection personnel to focus more time on inspecting high risk imports

Currently, foreign growers have little incentive to mitigate pest risks before shipping commodities to the United States. If port of entry inspectors find actionable pests, PPQ fumigates, or applies other approved treatments to the commodities with little cost to the importer or exporter. For the shipper, treatment at the port of entry usually costs less than initiating risk mitigation practices at the growing site. USDA is considering the establishment of user fees for port of entry treatments, which will alleviate this situation.

When the PPRG identifies a commodity as high risk, PPQ's first step should be to notify the National Plant Protection Organization (NPPO) of the exporting country. A regulatory systems approach protocol (RSAP) could be developed to mitigate the pest risk. If the exporting country is unwilling or unable to resolve the pest issues, APHIS could implement mandatory phytosanitary measures.

The new inspection protocol would be monitored through the use of random blitz inspections.

The PPRG suggests that hitchhiking pests should be treated differently from host specific pests. However, detecting non-quarantine hitchhikers could trigger dialog with the NPPO of the exporting country about the general effectiveness of their programs to exclude pests, these detections alone would not necessarily be used to classify an import as high risk.

Low risk commodities (AEPI list):

Adding plants to the AEPI list could be as simple as identifying commodities with 3 or more years of import history with no quarantine pest interceptions. We would cross check the host status of the commodity using pest databases such as the Global Pest & Disease Database and the Virus Identification Data Exchange (VIDE) database. Candidates for AEPI that pass these screens would be referred to the PPRG, which may enlist additional expert opinion to verify candidates for AEPI. Ideally, the AEPI list would include plant genus/ origin/ plant part combinations, since all parts of the host may not be pathways for the pest(s).

An interception rate of 1% might be allowable for AEPI

candidates if pests associated with the commodity have been identified only to a high taxonomic level, such as family or order. As molecular tools for pest identification are developed, immature pests associated with these AEPI candidates could be reared to rule out actionable quarantine pests. Exporting country NPPOs could conduct pest surveys in the growing areas to determine the absence or presence of quarantine pests.

Red flags would trigger re-evaluation.

A new inspection protocol for imports on the AEPI list could prove to be beneficial because a less rigorous inspection protocol would save plant inspection station personnel time, allowing inspectors to focus their efforts on high risk commodities. A new inspection protocol for AEPI commodities could be 50% of the normal inspection rate, which varies according to the size of the shipment, but usually is in the range of 2% to 10%, has been suggested for consideration.

To monitor AEPI commodities, PPQ could use random intensive inspections (blitzes), taking seasonality into account to target periods when interceptions would be most likely**.** These intense random inspections might result in the detection of pests that have never been found.

Certain "red flags" indicators could trigger a re-evaluation of AEPI commodities, such as interceptions of new pests, an increase in the number of interceptions, a pest alert from the exporting country, or signs of substandard shipping practices, such as dirty containers.

Next Steps:

Publish the final rule for the 4th periodic amendments, which include a requirement for genus level identification on the phytosanitary certificate, and species level identification when the regulations place restrictions on individual species within the genus. The regulations will state that identification of the species is strongly preferred

Consult with the PPQ database managers and Plant Inspection Station personnel about adding species level identification of host plants whenever possible to the import data fields.

Through the PPRG, identify several high risk commodities now being imported and initiate a cooperative effort with the exporting country to mitigate the risk.

Through the PPRG, finalize the criteria for adding low risk commodities to the AEPI list. Evaluate the effectiveness of a revised inspection protocol for these commodities.

The risk associated with plants for planting has increased significantly since 7 CFR 319.37 was promulgated because of increases in the volume and diversity of imported plants and the diversity of exporting countries.

Evaluate the feasibility of implementing user fees for commodity treatments of plants for planting at the port of entry.

Establish linkages between the PPRG and others who are working on similar issues, such as the Plant Inspection Station Working Group, which deals with PIS issues of national significance, the Agriculture Quarantine Inspection Monitoring (AQIM) group, and International Services.

Explore the use of the AQIM database to validate inspection data and to collect data on blitzes to monitor the AEPI commodities

The implementation of Regulatory Systems Approach Protocols (RSAPs) will mitigate the pest risk associated with the importation of plants for planting. The goal is to ensure that the importation of these plants meets the acceptable level of phytosanitary security of the United States

Subject: *Regulatory System Approach Protocols (RSAPs)*

Background:

Off-shore risk management measures for propagative commodities, other than specific seed treatments, are currently contained in the Code of Federal Regulations (CFR), 7 CFR 319.37-5 (Special foreign inspection and certification requirements), and 319.37-8 (Growing Media). The risk associated with plants for planting has increased significantly since these parts were promulgated before recent increases in the volume and diversity of imported plants and the diversity of exporting countries. The 1999 National Plant Board review and the report *Safeguarding American Plant Resources* recommended that APHIS reduces reliance on port of entry inspection as primary risk mitigation measure. APHIS should increasingly move pest risk management off-shore, and hold the

exporting countries more responsible for risk mitigation programs.

The Agency is proposing to add a section to 7 CFR 319.37 to establish Regulatory System Approach Protocols (RSAPs). This section will describe the minimum standards that all plants for planting requiring RSAPs will have to comply with before importation into the United States. In addition to these minimum standards, RSAP requirements specific to individual programs will be addressed in individual work plans and bi-lateral agreements.

APHIS will be requiring RSAPs in the future for the importation of all types of plants for planting that require systems approaches to mitigate pest risk.

The proposal will also transfer into this section several existing programs currently listed in 7 CFR 319.37-5 which meet the requirements of an RSAP. APHIS will continue to modify and adapt remaining programs listed in 7 CFR 319.37-5 and 319-37.8 to meet the new RSAP standards and migrate these programs into this section through notice and comment rule making. These proposed changes will be designed to promote transparency and clarity within existing regulations.

A systems approach implies that more than one phytosanitary measure is needed for the mitigation of pest risk. APHIS will be requiring RSAPs in the future for the importation of all types of plants for planting that require systems approaches to mitigate pest risk.

Summary of Discussion:

The discussion of the establishment and implementation of RSAPs was organized around the following questions:

Are there key elements that should be added to the proposed RSAP performance standards?

The group discussed potential issues that could be added to the performance standards outlined in RSPM no. 24 and the document entitled *Basics of a Proposed Regulatory Systems Approach Protocol – Plants for Planting*, available at http://www.aphis.usda.gov/ppq/Q37/revision.html. These documents indicate the minimum standards that will pertain to all proposed RSAPs. RSAP requirements that are specific to country-commodity-pest complexes will be outlined in individual work plans and bi-lateral agreements.

Should the following programs be included in the proposed subpart?

The initial performance standard for RSAPs will describe the minimum standards for all plants for planting requiring RSAPs will have to comply with before importation into the USA.

a. Pelargonium/Ralstonia Import Certification.
b. High risk genera identified through the Plants for Planting Review Group.
c. Fruit trees from five European Union countries: United Kingdom, The Nederlands, Belgium, Germany, and France.
d. Plants in growing media.
e. All genera listed in 7 CFR 319.37-5.
f. Other categories or genera.

This re-organization may render the regulations more user-friendly. Furthermore, some current protocols address various pests in addition to the quarantine pest that they target. For example, the Ralstonia/Pelargonium protocol also mitigates other organisms, such as various waterborne bacteria and fungi. Some of these programs may provide examples of RSAPs.

Requirements specific to individual programs will be addressed in individual work plans and bi-lateral agreements.

How should RSAPs be initially implemented?

The initial performance standard will provide the broader framework and general principles to guide specific programs. Responsibilities and resource allocation should be established. Coordination of responsibilities includes those of the facility and the exporting National Plant Protection Organization (NPPO). Commitment from the NPPO is essential. Import requirements that mitigate the risk associated with specific quarantine pests are addressed in each work plan and/or bi-lateral agreement for individual programs. The critical control elements will be identified, minimum criteria to evaluate the program will be established, and monitoring and auditing procedures will be determined. The key elements of an RSAP include:

- General principles based on regional and international performance standards;
- Requirements specific to targeted quarantine pests, as established in bi-lateral work plans;
- Development and review of program manuals, and
- Development of a monitoring and compliance component.

The review and monitoring of RSAPs will require a dedicated staff.

The United States Nursery Certification Program (USNCP) provides valuable examples, and APHIS could adapt domestic experience to the development of processes for the review and approval of RSAPs for foreign facilities. With the exception of Canada, such programs do not currently exist for foreign nurseries. Therefore, standards will need to be developed for international programs.

How should monitoring be implemented?

Monitoring activities will be developed based on the level of risk involved and the level of certification required.

Audit checklists will be used to facilitate monitoring, which will comprise a component of all RSAPs. Monitoring activities will be developed based on the level of risk involved and the level of certification required. Establishment of an audit team is being considered with an audit manager and a dedicated staff to coordinate monitoring and review of manuals. Through the USNCP, PPQ has already begun the process of establishing an auditing program for exportation of nursery stock. This could provide a model for an import monitoring and auditing program.

USNCP conducts a "systems audit" once the manual for a facility is complete. A small team of auditors reviews every aspect covered in the manual, including records, and each member of the team performs specific tasks. When the facility successfully passes the systems audit, it is admitted to the certification program. This "systems audit" is similar to the "surveillance audit" described in the RSPM no. 24.

The intensity and frequency of monitoring and auditing are influenced by several considerations, e.g.:

- More frequent and specialized audits are required for new, unique programs, or when there are compliance issues, a high turnover of people, or systems are modified.
- Initial inspections are more time intensive.
- Less frequent and less specialized monitoring is required for routine programs.
- Monitoring is often reduced over time based on conformance records, but may increase again if non-compliance is an issue.

The magnitude of non-compliance could be determined by a critical effect system. There are generally three levels of non-compliance – minor, major, and critical. These are based on the critical elements specific to each system and the pests involved. This system will determine the resulting penalties and standards for reinstatement of the facility.

How should manual development and review be implemented?

The review and monitoring of manuals will require a dedicated staff. It is advisable to form a committee, with a lead person to facilitate manual review teams. Once a manual is reviewed and approved, a systems audit will be conducted. If the facility passes, it will be allowed in the program. Subsequently, regular surveillance audits will have to be conducted to ensure that the facilities continue to comply with the standards that have been established. Performance standards will be published in the CFR to outline the critical control elements and guide the development of manuals. The exporting entities cooperating with the NPPO of their country will provide the specific details in the manual that meet the established criteria.

Next steps:

Amend 7 CFR 319.37 to establish a subpart for RSAPs and implement RSPM no. 24.

Establish an RSAP working group to accomplish the following tasks:

- Identify and evaluate critical control elements for risk management.

- Define the minimum performance standards to be used to evaluate and monitor RSAPs.

- Review existing protocols and programs, both domestically and internationally, to identify risk management strategies for inclusion in RSAPs.

- Develop templates for manuals, standard operating

procedures, and monitoring and auditing procedures.

- Define non-compliance criteria and associated penalties.

Establish audit teams responsible for manual review, auditing, and monitoring.

The post-entry quarantine program is currently set up as a "safety net" for imports of large amounts of plant material considered medium or low risk.

Subject: *Post-entry Quarantine*

Background:

Section 319.37-2 of the regulations prohibits certain plant genera from designated countries and localities from being imported or offered for entry into the United States, mostly for concerns with disease causing organisms.

Section 319.37-7 lists restricted articles from foreign countries or localities that are authorized to undergo postentry quarantine (PEQ) in a State that has previously entered into a written agreement with APHIS. The postentry quarantine conditions allow PPQ, via the States, to screen imported plants from the non-prohibited countries.

319.37-7 (a) provides a list of plant material that is associated with quarantine pathogens. However, 319.37-7 (b) provides a list that is not associated with specific organisms of concern. The rationale for the postentry safety net is that APHIS doesn't know how the listed genera are traded internationally or if the country of export has any quarantine restrictions (like those listed in 319.37-2) that would protect the country from quarantine pests. APHIS is aware of only three other countries: Croatia, Slovenia and the Philippines with PEQ programs similar to PPQ's. These postentry quarantine regulations allow foreign countries to export commodities without a pest risk assessment being completed first.

Should the agency determine that the pest risk associated with some of the postentry plant material can be mitigated in the country of origin, this may lead to disruption of current

procurement practices. USA importers of postentry plant material generally buy smaller and less expensive plants that reach saleable size during the quarantine period. If some or all of the genera are removed from the PEQ restrictions, Industry may wish to import larger plants which might not be consistent with the current size/age requirements. APHIS should review the impact that changing PEQ requirements may have on trade of these commodities.

Pest risk assessments are required to determine the appropriate level of risk management.

Summary of Discussion:

Should changes be made to remove some genera regulated under 319.37-7?

PPQ should develop criteria for placing a plant genus on the list of PEQ plants and for removing a genus from the PEQ list. APHIS will evaluate if a plant genus on the (a) list and with no interceptions of the disease of concern from a specific country should continue to have PEQ restrictions from that origin. For example, a review of the PEQ history and pest risk associated with importation of *Prunus, Pyrus* and *Malus* from five European Union countries listed in 319.37-7(a) will determine if the requirement for PEQ can be removed allowing the plants to enter the USA as unrestricted after Plant Inspection Station processing. Although PEQ may no longer be required, samples from shipments would continue to be sent to Beltsville National Plant Germplasm Quarantine Center for indexing, testing and monitoring.

Rosa is the PEQ genus with the most frequent shipments and the largest number of plants. Rosa spp. are restricted commodities, and can only enter the U.S. subject to PEQ because of the risk associated with rose wilt. A Pest Risk Assessment (PRA) has been requested to determine if rose wilt should be deregulated. The PRA will evaluate other pests associated with *Rosa* which may remain on the PEQ program if it is found to be associated with quarantine pests that are not readily detectable by routine inspections.

Genera listed in 319.37-7(b) should be evaluated to determine if some of the genera should be removed. Currently, there are no PRAs that support PEQ requirements for the genera listed on

319.37-7 (b) and a PRA will identify quarantine significant pests associated with these genera and enable the agency to determine the appropriate level of risk mitigation for the pests associated with these plants for planting.

The PEQ database indicates five commodities that are high volume imports and that appear to have low pest risk based on their PEQ history. The PEQ database entries showed that *Juglans, Litchi, Olea, Psidium* and *Vaccinium* constituted the largest number of importations, both in number of shipments and number of plants.

APHIS wants to evaluate more effective methods to enforce the permit conditions that set the limits on the volume of plants that enter the USA in a way that don't overwhelm the services of State personnel conducting inspections.

Should changes be made to add genera to the PEQ list?

The number of plants recognized as *P. ramorum* hosts continues to grow, and it may no longer be operationally feasible to inspect all host genera that would require PEQ as a condition of entry. Additional stress will be placed on State Departments of Agriculture.if the number of P. ramorum hosts placed on the PEQ list is further increased.

Should/can the size of the shipments of PEQ genera be limited?

Currently, many nurseries have exceeded the number of trees on PEQ than were approved by their permit. There isn't a system in place to monitor and enforce the volumes approved on the import permit. As a consequence, many shipments on PEQ sites may be too large for the State personnel resources to perform appropriate inspections. In some cases even 1% of inspection of large shipments is very labor intensive.

The implementation of the next phase of APHIS e-permit system will enable the USDA State Plant Health Director (SPHD), the State Plant Regulatory Official (SPRO), and Plant Inspection Station personnel to track when the importer is exceeding the volume authorized by the State when the permit application was approved. When this change in the e-permits occurs, PPQ personnel can inform the State when the allowance is exceeded, and they can decide if the shipment will be permitted to enter PEQ. This would enable the State officials to determine the number of plants for which they have adequate resources to conduct the inspections. Any increase in plant number would

have to be authorized by the State before the inspection station personnel releases a shipment over the originally authorized number. Industry may be concerned about a proposal to decrease in numbers and/or size of shipments.

Another option to alleviate the State's PEQ inspection workload was considered. PPQ could require an Additional Declaration (AD) on the Phytosanitary Certificate, certifying that the disease(s) of concern for the PEQ genus is not in the country of origin. The National Plant Protection organization would need to provide evidence to support our recognition of pest free areas. Commodities originating from pest free areas would exempt that shipment from PEQ.

Should the name "Postentry Quarantine" be changed?

Most foreign countries use the postentry term for restricted plants grown in containment facilities. These programs are similar to those that are currently used in the USA for commodities imported under USDA Departmental permits. The USA uses the term PEQ for both containment programs and for less restrictive programs including some that include field grown plants. Terms and definitions should be standardized and aligned with those used by the international community, and term PEQ may be reserved for activities such us plant material indexing tests conducted at government approved facilities.

Is the length of the quarantine period, too long, too short, or just right?

Currently, not all inspections are done at the appropriate time to observe the symptoms. For example, inspectors should look for virus symptoms when they are most evident, after the leaves are fully expanded, and while the temperatures are cool enough for the expression of symptoms. Lots of plants would not be released until the next growing season if the inspection can not be done at the proper time of the year.

The APHIS new e-permit system should include reminders about proper times for inspections. These could be put on the permit as directives for the State inspector. A specific inspection schedule (window) should be indicated in either the permit conditions or a compliance agreement. Instead of years, the inspections and

length of PEQ could be based on growing seasons that differ based on climate and genera.

Should hosts listed as PEQ because of rusts diseases be confined in an APHIS approved facility rather than field grown?

There is a high risk of dispersal and establishment of air-borne pathogens and APHIS should consider requiring that PEQ for host plants should be limited to APHIS approved enclosure.

Next Steps:

Perform PRA for genera and countries that have been identified as possible candidates to be removed from PEQ including *Juglans, Litchi, Olea, Psidium and Vaccinium*.

Discuss candidate commodities with the SPROs and experts in potentially impacted States to determine the potential impacts of removing the genera from the list in 7(a) to 7(b), or removing the PEQ requirement.

Evaluate the results of the indexing tests conducted on the monitoring samples of *Pyrus, Malus and Prunus* obtained from The National Plant Germplasm Quarantine Center to determine if PEQ can be removed.

Complete the development of the PRA for *Rosa*, and establish regulatory policy regarding rose wilt and other quarantine pests that are associated with the importation of *Rosa*.

Review and work with the States to determine if a statistically valid inspection can be performed based on the size of shipments.

As part of the Q37 revision, rename PEQ to reflect high risk importations, and find a new name for low and medium risk importations, currently called PEQ.

PPQ will evaluate a policy pertaining to the timing of growing season inspections.

Current and future uses of

the various USDA databases should be reviewed to determine whether the data collected is sufficient to Q37 revisions.

Subject: *Imports Data Collection and Analysis*

Background:

Issues related to the current and future uses of the various USDA databases for the revision of Q37 are being considered. The following three areas are critical to use in supporting import regulatory policy.

Risk Assessment:

There is currently no efficient, universal way of tracking the number of plants entering the country under a particular permit. Abuse of permit conditions may lead to increase pest risk.

Progress with the Q37 revisions is contingent on the agency's ability to harmonize the phytosanitary standards for current imports and future, potential imports. Implicit in these revisions is the need to evaluate the risk of current imports, and whether the information currently available at the national level is sufficient for these purposes.

Off-shore Risk Mitigation:

Implicit in much of the proposed revisions to Q37 is the understanding that APHIS's current regulations place much of the burden of safeguarding at our points of entry (inspection and fumigation). Many of the proposed changes would move some of that safeguarding burden off-shore. The discussion analyzed requirements to carry out these tasks and the flow of information within the agency and to exporting countries.

Regulatory Strategy:

Q37 revisions include proposals to develop a more efficient PRA process. The agency proposes to group PRAs under broad categories (e.g. fruit trees/ grape vines; bulbs and plant parts, herbaceous tropical/ temperate plants). General requirements for each category would be established in the Regulatory Systems Approach Protocol (RSAP), and published in the CFR. Specific details of the regulations for a particular country/ genus / type of import would be handled within a bilateral work plan. There is a need to analyze how information requirements for PRAs change under the proposed strategy.

Summary of Discussion:

Providing timely feedback to exporting countries about pest interceptions at the USA ports of entry can be extremely useful in devising and maintaining off-shore pest mitigation strategies.

The following two topics were discussed: The data requirements for Post-entry quarantine tracking, and Off-shore mitigation.

Post-Entry Quarantine Tracking:

The group noted that there is currently no efficient, universal way of tracking the number of plants entering the country under a particular permit. The result is that the quota for the number of plants allowed under a particular permit is often exceeded. This is an abuse of the permit contract which may lead to an increase risk of pest introduction from these imports.

Preventing such infringements of the permit regulations requires a nation-wide tracking of the number of plants entering the country under each permit. The tracking information must be available to inspectors at the Plant Inspection Stations (PIS) in time for them to deny entry to material for which the permit quota had been exceeded. State Plant Health Directors and other regional officials should have access to this information as should the permit staff at headquarters. The possibility of linking the proposed database with information about pest interceptions made on permit material was discussed. Running queries on this joint database of permit imports could help to hold importers accountable to the obligations of the permit.

Off-Shore Mitigation:

The Q37 revisions provide a mechanism for the Agency to include off-shore programs as a means to safeguarding against pests which may follow the pathway of plants for planting imports. The proposed RSAP would provide growers with a plan for pest monitoring, detection and mitigation agreed at the NPPO level. Providing timely feedback to exporting countries about pest interceptions at the USA ports of entry can be useful in devising and maintaining pest mitigation strategies such as RSAPs in these countries.

Capturing the grower information for each shipment was seen as key to this feedback and the pros and cons of capturing this

information were discussed at length. Grower information is often available for shipments but currently it is not comprehensively captured in any of the electronic USDA databases.

Difficulties with capturing grower information include the intermittent availability of this information and the technical difficulties associated with including this information in one of the existing USDA databases. This task would be easier if grower information was only captured for shipments with intercepted pests. Collection of grower information would place an extra burden of data entry that this would place on port and plant inspection station officers. However, if the overall result of providing feedback with grower information to exporting countries reduces the number of fumigations, then the net effect would be a reduction in the plant inspection station workloads.

The benefits of capturing grower information are not limited to the service that this would provide to off-shore RSAP programs. The group agreed that the likelihood of making a pest interception on a shipment correlated best with grower level information for that shipment (more than, for example, importer level information or even more detailed field information). Capturing grower information in a national database could facilitate the sharing of relevant risk information among the PISs as well as formalize some of the empirically noted risk for various commodities.

Next Steps:

Post-Entry Quarantine Tracking:

It was suggested that permit requirements as well as real-time tracking of the number of plants that have already entered the USA under the permit should be linked, by an automatic pop-up advisory, to one of the currently used national databases. This function should be made available at all plant inspection stations so that the terms of the permit contract are used to control the entry of permit material. This suggestion will be voiced to the Permit Services Staff for their consideration.

In the last quarter of the 20th century, plant research and private industry interests have dramatically increased the volume of foreign origin prohibited plant material into the USA focusing upon the promotion of agricultural business.

Off-Shore Mitigation:

Although there was broad consensus among the group for the usefulness of collecting grower information on incoming shipments, there was no agreement that the value of this information outweighed the costs of implementation. In order to properly balance the costs and benefits, more detail is needed about how the collection of grower information would be implemented, which staffs would be affected, the frequency with which the reports could be written and how the information would be used.

Subject: *Departmental Permits Conditions*

Background:

USDA issues Departmental Permits to establish conditions under which prohibited propagative plant material, plant products and other prohibited class of plant articles can be imported into the United States for limited scientific, analytical or experimental purposes. Traditionally and historically documented in the CFR, these permits have been reserved for use by USDA agencies and related programs; however, in recent years their use has expanded to other entities. PPQ Commodity Imports Analysis and Operations (CIAO) is currently reviewing the USDA's Departmental Permit Policy in order to potentially revise its scope.

The following CFRs list Departmental Permit authorization for imports into the USA: 319.8–20 Subpart Foreign Cotton and Covers, 319.24 Subpart—Corn Diseases, 319.37 Subpart —Nursery Stock, 319.40 Subpart—Logs, Lumber, and Other Unmanufactured Wood Articles, 319.59 Subpart—Wheat Diseases, 319.75 Subpart —Khapra Beetle Restrictions on importation of restricted articles

The following CFRs list Departmental permits within Domestic Regulations: 301.38-1—Black Stem Rust, 301.64-1—Mexican

Fruit Fly Quarantine, 301.74-1— Plum Pox, 301.75-1 —Citrus Canker, 301.92-1—*Phytophthora ramorum*, 301.97-1 —Melon Fruit Fly.

In accordance with the CFR, the permittee must apply to the Secretary of Agriculture (who has delegated the responsibility to PPQ) for permission to import plant material which has an otherwise prohibited entry status. If the applicant can demonstrate that the perceived pest risk is mitigated sufficiently to satisfy the CFR requirements, PPQ may issue a Departmental Permit. A copy of the permit is forwarded for review and concurrence to the Department of Agriculture in the State where the research will be conducted. The State may share inspection, validation and monitoring responsibilities with the PPQ State Plant Health Director's (SPHD) Office.

*Three options were presented for revision of the USDA Departmental Permit Process, and several questions were discussed regarding the reorganization of Departmental Permits, and the impact to Plants for Planting regulation*s

Summary of Discussion:

The group identified several options:

Option 1. Modify the existing regulations, maintain the same system.

Expand the existing regulations to recognize entities "other than USDA" as importers of prohibited plant material. This option would broaden the scope of the current regulations to provide additional entities such as universities and private industry with opportunities to import prohibited plant material for scientific research similar to those that are currently available to USDA researches.

The intended use aspect of Departmental Permits would be modified to include those organizations that have a valid need for prohibited plant material for scientific research. The proposal will include private industry that seeks to import prohibited plant material for purposes of market/ business product development or horticultural and ecological compatibility evaluations. However, in some cases this research and development may not be viewed as equal to scientific evaluation, and would not be eligible.

Option 2. Modify the existing regulations and expand the system.

Prohibited plant material imports have traditionally been issued on a case by case basis. A policy can establish a process that will clarify how the Agency will consider requests of Agri-business and the scientific interests of the research community based on need and intended use pathways. Only an authorized importer of prohibited plant material may import into the USA as prescribed by the language of the permit.

The regulations could be modified based upon the requirements of existing departmental plant material that has been historically authorized into the USA under prescribed safeguards. Additionally, the CFRs would require the implementation of a systems approach based on the pest risk and environmental precautions. Monitoring and compliance components will be included in the systems approach.

This option allows USDA to realign stakeholders seeking to import prohibited plant material with a regulatory change that focuses upon mitigating pest risk as a condition of entry. It can remove the limits of USDA as the importer of record and allows USDA to establish who may be qualified as an "Authorized Importer" status.

All references to Departmental Permits in 7 CFR 319 need to be reviewed, evaluated and modified. This may be an exhaustive process as the current language to Departmental Permits is often loosely defined and allows broad interpretation of the CFRs when issuing the permit. Option # 2 will require an "over-haul" of the current permit process and may cause delays with issuing the new permit classes until the new system is incorporated into the permitting process.

Option 3. Maintain the existing process and policy.

Maintaining the current process will have less impact to the work load of PPQ staff. Permits can be issued and may have a faster turnaround time than would be necessary for processing permit applications in proposed options 1 or 2.

However, the current use of Departmental Permits to resolve unconventional importation applications may continue to be perceived as unacceptable by State Department of Agriculture

and APHIS staff due to inconsistencies in the system. In addition, the current policy may not in the long run, provide adequate federal oversight for importation of prohibited plant material.

Can a permit system be developed which allows prohibited plant material to enter the USA for research and developmental purposes for either Government or Private use?

The group generally agreed that the permits could be divided into two categories based on their intended use:

1. Material destined for destruction, and
2. Material not destined for destruction.

Additional classifications from these two categories could be added to provide specific requirements for the different levels of pest risk. The following permit categories were proposed:

1. Restricted plant material for research.

- Admissible with post entry quarantine.
- The permit allows the importation and the final conclusion of the permit shall be the destruction of all foreign imported plant material.

2. Prohibited plant material- not intended for propagation.

- No additional propagation of the imported material is allowed.
- Final conclusion of the permit shall be the destruction of all nuclear foreign imported plant material.

3. Prohibited plant material for growing and eventually destroyed.

- Allowed to mature, or is maintained within controlled horticultural and environment restrictions for a specific amount of time.
- No division or sexual propagation of the imported nuclear material is allowed.
- All material is eventually destroyed.

4. Prohibited plant material- intended for division or sexual propagation, nuclear material eventually destroyed.

- Prohibited foreign origin nuclear plant stock is imported and allowed to mature or is maintained within controlled

horticultural and environment restrictions for specific amount of time with the intent to propagate either sexually or asexually.

- The propagules/divisions from the nuclear stock are collected for intended release of regulatory control. Nuclear material is eventually destroyed.

5. Prohibited plant material for growing and nuclear material eventually released.

- Prohibited foreign nuclear plant stock is maintained under controlled environmental conditions to verify freedom from disease and pest presence, nuclear stock is eventually released from APHIS regulatory control.

The revision would include additional conditions that would maintain a high level of pest risk control over the plant material with a specific amount of valid time or use for the permit

6. Prohibited plant material imported with conditions and nuclear material eventually released.

- Nuclear foreign origin prohibited plant material imported for a specific reason and appropriate mitigation measures are maintained.
- The plant material is eventually destroyed or released from APHIS regulatory control.

Special Class of Departmental Permits:

A permit option for "extra-ordinary circumstances" or for a political purpose is a small but important category of permits. There is a valid need to allow access into the USA under "extra-ordinary circumstances" and a restricted use permit could be expanded to Classification # 6 where prohibited plant material is imported under controlled conditions and eventually subject to USDA-APHIS release restrictions. This class of permit may require or have specific criteria placed upon the import to ensure that the material is properly safeguarded against the introduction of quarantine pests and this should be published in the CFR to allow for transparency for importers and regulatory officials working at the field level.

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There were several suggestions for the name of this permit class where the intended use is to meet a political or administrative need, but was not in consensus to the best name option. Consideration was given to the interpretation of the following

names: Special Use Permit, Administrators Permit, Diplomatic Permit, Extraordinary Circumstance Permit, Restricted Use Permit and Emergency Use Permit. Prohibited plant material that would be imported under this provision is often associated with unique requirements and conditions of permit would be resolved on a case by case basis.

Compliance Review:

There was discussion of instituting a permit evaluation process which would provide a level of review and accountability beyond the decision making by a single individual. Such processes as a review panel or utilizing collaborative efforts of the Pest Risk Specialists under the responsibilities of the SPHD could be involved to monitor and validate the permit process. The greatest concern focused on situations such as when the importer fails to meet the permit restrictions or violates the terms of the compliance agreement. The Agency should maintain oversight and appropriate accountability should be placed with the responsible party.

Next Steps:

Reorganize the Departmental Permit process to create a system that addresses pest risk and movement of prohibited plant material into the USA when destined for a specific production/handling process that mitigates the plant pest appropriately.

Propose changes to the CFR to establish a permit process that address prohibited/ restricted plant material for research and for business development.

Incorporate the resources of the State Plant Health Director into the Departmental Permit notification process.

Utilize the communication structure from Headquarters to Regional Offices to State Plant Health Directors (SPHD) to State Plant Regulator Officials (SPRO) to provide notification of Departmental Permits and improve accountability. This will require commitment and support from the PPQ Region and

SPHD to provide communication to applicants and feedback to Headquarters pertaining to problems or recommendations to revoke permits pending site inspections.

APPENDIX

Following the input and recommendations from the 2006 Q-37 Summit, PPQ staff continued with the revision process for USDA Departmental Permits. Of the six categories previously identified for material imported under a Departmental Permit, two were very similar in scope and intended use and were merged into one single class. Additionally PPQ staff determined that the plant material under Post Entry Program (7 CFR 319.37-7*)* were sufficiently similar to requirements within the new permit class to facilitate combining regulated prohibited and restricted plant material for entry into the USA. The result, five broad categories within a single permit system; addressing intended use and perceived level of plant health risk.

PPQ proposes to revise the USDA Department Permit process into a permit that will take into consideration the potential for dissemination of plant pests and counter balance to the intended utilization of the plant material. Under specific controlled entry import processes, plant material which is restricted (7 CFR 319.37-7) or prohibited within 7 CFR 319 would be allowed entry into the USA only through restrictive conditions and specific safeguarding requirements that address plant health risk. The new permit has been identified as the **Controlled Import Permit** (CIP). The proposal has 5 classes of CIPs, each based upon intended use and perceived plant health risk.

CIP- 1. "Analytical Research" Plant Material – not intended for propagation with eventual destruction.
Plant material with either enterable restriction status for propagation purposes (Post Entry Quarantine –PEQ 7 CFR 319.37-7) but the importer's requirement do not include propagation elements and also prohibited plant material which is not intended for propagation. The final conclusion of the permit shall be the destruction of all imported plant material.

CIP- 2. Regulated plant material with limited propagation and eventual destruction.
Restricted or prohibited foreign origin nuclear plant stock which is allowed to mature or it is maintained within controlled horticultural environmental containment or with restrictions applied to limit growth for a specific amount of time. No divisions or sexual propagation of the imported nuclear material is allowed. The final conclusion of the permit shall be the destruction of all foreign imported plant material.

CIP- 3. Regulated plant material- intended for division or sexual propagation; imported nuclear material eventually destroyed.
Foreign origin nuclear plant stock maintained within controlled horticultural – environment containment or with restrictions that limit growth within a specific period of time. Propagation occurs either sexually or asexually from the nuclear imported material. The propagules/divisions from the nuclear stock are validated as plant pest free followed by release of regulatory control. Nuclear imported material is eventually destroyed.

CIP- 4. Regulated plant material verified foreign plant pest free and eventually released.
Restricted or prohibited foreign nuclear plant material maintained under controlled environmental or logistical requirements for a specific amount of time. The safeguarding process includes testing and control measures that verify freedom from quarantine disease and pest presence that are not observable at the time of importation. Upon meeting all safeguarding requirements and when the plant material is certified as foreign plant pest free, the imported material is released from APHIS regulatory control.

CIP-5. Prohibited plant material imported with limiting conditions and nuclear material eventually released.
Any prohibited plant material imported for an identified situation or under strict monitoring requirements. Appropriate mitigation measures are established, maintained and enforced. Safeguarded by specific conditions and limitations the plant material is eventually released from APHIS regulatory control.

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