Example Phytophthora ramorum Compliance Agreement

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control numbers for this information collection are 0579-0054, 0088, 0129, 0198, 0257, 0310, 0317, 0322, 0337, 0346, 0363, and 0369. The time required to complete this information collection is estimated to average 1.25 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED 0579-0054/0088/0129/ 0198/0257/0310/0317/ 0322/0337/0346/0363/

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE PLANT PROTECTION AND QUARANTINE	COMPLIANCE AGREEMENT
1. NAME AND MAILING ADDRESS OF PERSON OR FIRM	2. LOCATION
Name	
Business Name	Full Address
Full Address	
Phone#	[or enter "Same" if mailing address is the same]
Fax#	
e-mail	

3. REGULATED ARTICLE(S)

Hosts and Associated Hosts of *Phytophthora ramorum* and other articles.

4. APPLICABLE FEDERAL OUARANTINE(S) OR REGULATIONS

7 CFR 301.92, and, Section 414 of the Plant Protection Act, 7 USC 7714., 114 STAT. 445, PUBLIC LAW 106–224—JUNE 20, 2000, SEC. 414. (a) and (b).

5. I/WE AGREE TO THE FOLLOWING:

USDA, APHIS, PPQ, will permit your establishment to execute the regulatory requirements outlined in the 7 Code of Federal Regulations (CFR) 301.92. Procedures, protocols and limitations are outlined and attached as exhibits, inclusive and incorporated into this agreement by reference as if fully set out. The exhibits (attached) are binding: Exhibit A - Compliance Terms, Conditions, and Procedures. Exhibit B - Authorization for Certification. Exhibit C - *Phytophthora ramorum* host and associated host plants. Exhibit D – CCP Assessment Findings, Requirement, Remediation, Mitigation Measure, and/or Business or Cultural Practice Records Table, Compliance Table, and Correction Action Log.

The Establishment assumes liability, if any, arising from the manner in which Establishment sells, handles or distributes any regulated host material. NOTICE: Any signatory or employee of any signatory who violates the terms of this compliance agreement may be subject to Civil Penalties pursuant to 7 CFR 301.92, and the Plant Protection Act of 2000. Specifically, any person who knowingly violates the Plant Protection Act (PPA) (7 U.S.C. 7701 et seq.) and/or the Animal Health Protection Act (AHPA) (7 U.S.C. 8301 et. seq.) may be criminally prosecuted and found guilty of a misdemeanor which can result in penalties, a one-year prison term or both. Additionally, any person violating the PPA and/or the AHPA may be assessed civil penalties of up to \$250,000 per violation or twice the gross gain or gross loss for any violation that results in the person deriving pecuniary gain or causing pecuniary loss to another, whichever is greater. "Establishment" here forward is referred to as "nursery" as defined in 7 CFR 301.92-1.

6. SIGNATURE 7. TITLE		8. DATE SIGNED	
The affixing of the signatures below will validate this agreement which shall remain cancelled but may be revised as necessary or revoked for noncompliance. This complisis non-transferable.		9. AGREEMENT NO. 10. DATE OF AGREEMENT	
11. PPQ OFFICIAL (NAME AND TITLE)	12. ADDRESS		
PPQO- (SPHD or designee)	SPHD office address		
13. SIGNATURE			
PPQO- (SPHD or designee)			
14. STATE AGENCY OFFICIAL (NAME AND TITLE)	15. ADDRESS		
SPRO (or designee) - SPRO	SPRO office address		
16. SIGNATURE			
SPRO (or designee) – SPRO			
PPO FORM 519			

SEP 2012

Previous editions before 2010 are obsolete.

SEP 2012

Previous editions before 2010 are obsolete.

PLANT PROTECTION AND QUARANTINE PROGRAMS COMPLIANCE AGREEMENT TERMS, CONDITIONS AND PROCEDURES FOR REGULATED NURSERIES

EXHIBIT A

7 CFR 301.92-1 Definitions: Nursery. Any location where nursery stock is grown, propagated, stored, or sold, or any location from which nursery stock is distributed. Locations that grow trees for sale without roots (e.g., as Christmas trees) are considered to be nurseries for the purposes of this subpart.

In order to prevent the dissemination of *Phytophthora ramorum*, the Administrator of Animal and Plant Health Inspection Service (APHIS) considers it necessary to establish restrictions on the interstate movement of nursery stock from nurseries described in 7 CFR 301.92 and the APHIS *Phytophthora ramorum* Program Manual. The goal of this regulation is to effectively remove *P. ramorum* from nursery cultural and conveyance systems, which authorizes the Secretary of Agriculture to prohibit or restrict the movement in interstate commerce of any plant, plant part, or article, or means of conveyance, if the Secretary determines the prohibition or restriction is necessary to prevent the dissemination of a plant pest within the United States, and is likewise issued pursuant to the regulations, promulgated under the Plant Protection Act, and found at 7 CFR 301.92 *et. seq.* For nurseries (positive March 31st, 2011 or there after) that wish to ship or distribute nursery stock listed in Exhibit C of this document interstate must be inspected, sampled and tested, certified and enter into this compliance agreement. Shipments must be accompanied by a certificate issued under this compliance agreement.

The nursery agrees to the following:

- 1. Inspection, Sampling, and Testing of Regulated Articles which includes but is not limited to nursery stock, soil, container mix, cull piles, pots, water, and other associated articles that the inspector determines may pose a risk of spreading *P. ramorum*:
 - a. The nursery shall allow inspection and sampling of nursery stock and other regulated articles as defined in 7 CFR 301.92 and in the APHIS *P. ramorum* Program manual.
 - b. In order to remain under compliance, the nursery must undergo a minimum of two inspections per year and be tested for *P. ramorum* following procedures as authorized by 7 CFR 301.92. As specified in 7 CFR 301.92 11 (c) (3): If annual certification expires prior to re-inspection, all plants in the nursery are prohibited interstate movement until the nursery is inspected, tested and re-certified in accordance with this section and CFR 301.92-12 unless authorized by a regulatory official.
 - c. The State Department of Agriculture shall use sampling procedures that meet USDA standards for nurseries as detailed in protocols pursuant 7 CFR 301.92. The department or other USDA approved laboratory, using federally approved laboratory protocols, will test the samples.

Nursery	Owner Initial/Date	}

Attachment to PPQ

- d. After initial detection, if *P. ramorum* is not detected during any sampling of articles for three years under this compliance agreement, the nursery is no longer required to be under a compliance agreement and may ship without certification and a federal shield.
- 2. Detections of *P. ramorum* in the nursery:
 - a. In the event *P. ramorum* is detected in the nursery, all nursery stock is on hold until an inspector conducts the delimiting survey. While on hold plants may not be moved or maintained without prior approval. The nursery has 5 business days to provide trace forward information on the varieties confirmed positive in the nursery and of *Camellia* spp., *Kalmia* spp., *Pieris* spp., *Rhododendron* spp. (including azalea), and *Viburnum* spp. nursery stock. The USDA/State Department of Agriculture will delimit and mitigate the presence of the pathogen using the *P. ramorum* manual. To remain under compliance, the nursery must allow the implementation of a follow up Critical Control Point (CCP) assessment.
 - b. Based on the CCP assessment, Appendix D will contain the findings of the CCP assessment detailing the affected areas and will describe the **required** (Table 1) and **strongly recommended** (Table 2) remediations, mitigations, and/or Best Management Practices discussed with the nursery and chosen by the regulatory official as efficacious.
 - c. Appendix D will contain implementation timelines for the mandatory mitigation measures. The nursery will report and correct any deviations from the chosen mitigation and/or specific business/cultural practices. If the nursery is found to be non-compliant with a specific measure within the specified time period, a written Correction Action Request (CAR) will be issued. The written letter will include the corrective action(s) that detail the needed recourse for the non-conformity. The written notice will provide the expected timeline. The protocol for conforming to compliance agreement requirements will be discussed with and provided to the nursery.
 - d. If *P. ramorum* is continuously found in the nursery additional mitigations will be required to ensure the pathogen is not spread during shipping, as described in the APHIS *P. ramorum* program manual. Mitigations that were identified as strongly recommended will become required. These mitigations will be updated in Appendix D and will be required to continue shipping plants interstate.
- 3. The nursery is required to notify receiving state regulatory officials of host plants shipped to shipping states and the origin state at the time of shipment. The notification time period begins upon detection of *P. ramorum* in the nursery and remain until the nursery is no longer under compliance. The USDA and state department of agriculture will provide the information and requirements about the Notify system and its use.
- 4. Listed plants (Exhibit C) may be moved interstate from the date the inspection(s) is/are completed, which includes negative laboratory analysis results of tested articles, or directed

ruisery Owner initial/Date	FORM 519 (Sept 2012)	Nursery Owner Initial/Date
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otherwise by an authorized Regulatory Official.

5. Restriction on Sources of Regulated Articles:

The nursery may receive plants from sources within the quarantine areas or from regulated establishment only under the following conditions:

If Plants listed in Exhibit C originate from nurseries located in the **quarantine** areas, those nurseries must have a PPQ approved compliance agreement for *P. ramorum* and are accompanied by an appropriate certificate.*

• Interstate movement of plants listed in Exhibit C from a nursery located in the quarantine area without a compliance agreement is a violation of 7 CFR 301.92.

If Plants listed in Exhibit C originate from *P. ramorum* regulated establishments, those nurseries must have a PPQ approved compliance agreement for *P. ramorum* and are accompanied by an appropriate certificate.*

• Interstate movement of plants listed in Exhibit C from a regulated establishment without a compliance agreement is a violation of 7 CFR 301.92.

6. Maintain Identity

The nursery shall maintain the identity of all listed plants in Exhibit C. The nursery shall maintain the identity of all listed plants that originated from other sources.

7. Requirements for Interstate Movement

The nursery shall ensure that a USDA certificate or stamp (Exhibit B) stating compliance with 7 CFR 301.92, accompany each shipment of plants listed in Exhibit C that is moved interstate. The USDA certificate or stamp (PPQ form 570, Exhibit B) may also be used to indicate nursery compliance with 7 CFR 301.92 for the movement of listed (Exhibit C) nursery stock intrastate.

The nursery agrees to comply with all other applicable federal and state regulations related to the importation or distribution of plant material.

8. Records

The nursery shall maintain records of all incoming and outgoing shipments of host and associated plants. This information is to be used to track and record shipments and for the development of any Trace Forward or Trace Back Shipments. The following data must be maintained: Plants shipped or received (Genus, species, variety if known); Origin of plants; Receiver name; Street address, City, State, and Zip code; Contact Phone Number; Date of Shipment; Invoice Number; Number of Plants Shipped; and if applicable Store Number. The nursery shall also maintain records of fungicide applications. All records are to be kept for as long as the nursery is under in this compliance agreement. These records shall be made available

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for periodic inspection by an approved Regulatory Official upon request to verify compliance with this provision.

If *P. ramorum* is detected in the nursery, the nursery agrees to keep records for auditing purposes, as appropriate, that involve a given remediation, mitigations, and/or specific business or cultural practices listed in Appendix D. These records will be kept for as long as the nursery is under this compliance agreement.

In addition, records must be available as required by other Federal or state authorities.

9. Monitoring

Federal or State Regulatory Officials shall be granted access to the nursery during normal business hours to evaluate whether the nursery and its operations are in compliance with the applicable provisions of this agreement. Violation of any of these compliance agreement provisions may be cause for termination of the agreement.

10. Notice

The nursery shall provide advance notice to the State Department of Agriculture Regulatory Official when requesting an inspection.

11. *A USDA form 527, or 540 (certificate or stamp) is an appropriate certificate.

In the case of a nursery that is located on leased land then nursery has the responsibility to inform the landowner of the *P. ramorum* positive plants and any work that may need to be completed on the property to accommodate required or recommended mitigations listed in Exhibit D. If the nursery moves from the leased land, they are responsible for mitigating *P. ramorum* on the land so *P. ramorum* is not spread into the natural environment.

This agreement may be immediately canceled or revoked for noncompliance. Violation of these Federal regulations can result in a criminal penalty of up to a \$5,000 fine, one year in jail, or both, or a civil penalty of up to \$1,000 per violation.

EXHIBIT B

Authorization for Certification

Nursery Name

Nursery agrees to the following:

- 1. Reproduce the Federal certificate following dimensions in example below and using exact language in the example.
- 2. Use Federal certificate to certify interstate shipments of regulated plant material shipped from the nursery named in this compliance agreement.
- 3. Use Federal certificate to certify regulated plant material shipped from the nursery that has been inspected and found free of *Phytophthora ramorum* by agricultural officials during the annual inspection.
- 4. Maintain records of all interstate shipments certified with Federal certificate and make such records available to agricultural officials upon request.
- 5. Delegate to one person only the authority to reproduce Federal certificate and use to certify interstate shipments of regulated articles.



Stamp Description:

Minimum Size: 2"x4" Font: Arial Black Font Size: 11

Nursery or Compliance Agreement Numbering System:

Each state shall use the Nursery number or Compliance Agreement numbering system that is appropriate for their state. If a nursery has multiple growing locations, the state shall ensure that the individual growing locations can be distinguished, one from the other, via a Compliance Agreement numbering system that is appropriate for their state.

Authorization for Certification

By signing below, Nursery agrees to follow all instructions contauthorization for Certification.	tained in Exhibit B,
Printed Name of Nursery Representative	
Signature of Nursery Representative	Date
Printed Name of Federal, State or County Representative	
Signature of Federal, State or County Representative	Date

EXHIBIT C

APHIS List of Regulated Hosts and Plants Associated with Phytophthora ramorum

Please see the most current host list at:

https://www.aphis.usda.gov/sites/default/files/usdaprlist.pdf



Exhibit D

CCP Assessment Findings, Requirements including Remediation, Mitigation Measure, And/or Business or Cultural Practice Records Table

Table 1. Required Actions I. POSITIVE SITE

1. Block 1. Positive site

1. CCP Assess ment Date	2. CCP	3. Positive article	4. Requirement, Remediation, Mitigation, Bus. or Cultural Practice Measure to Address CCP Options	5. Start Date	6. Standard or Performa nce Measure	7. Mitigatio n / Action Chosen by Nursery Owner / approve d by Regulato ry Inspecto	8. Time- frame for Comple tion	9. Measur e ID # for compli ance inspecti on	10. Monito ring action/ date complet ed and observe d
						-			

• The standard or performance measure is what the nursery and the inspector note as successful or requires correction. So it must be as objective, tangible and measurable.

Table 2. Strongly Recommended Practices, if additional positive samples continue to be confirmed these measures will become required.

1. CCP Assessment Date	2. CCP	3. Remediation, Mitigation, Bus. or Cultural Practice Measure to Address CCP Options	Monitoring Action/Date

Compliance Tables

These two tables can be one long table.

Corrective Action Requests

Measure Identification Number	Compliance Incident? (y/n)	Root Cause	*CARS # (1 st or 2 nd ?)	CAR issue date

Detailed Corrective Action Log

Measure Identification #	CARS # (1 st or 2 nd ?)	CAR Issue Date	Letter of Finding or Warning Letter?	Findings of CAR visit with Nursery: Problem/Follow Up Action Description (root cause of failure, corrective action, and new timeframe allotted, and, regulatory action if appropriate)	Problem Rectified Date or Moved to Critical Non- Compliance?
			1		

Agreement to follow results for CCP Assessment

By signing below, Nursery agrees to follow all requirements and a contained in Exhibit D,	agreed upon recommendations
Agreement.	
Printed Name of Nursery Representative	
Signature of Nursery Representative	Date
Printed Name of Federal, State or County Representative	
	Date

Any person who knowingly violates the Plant Protection Act (PPA) (7U.S.C. §§ 7701 et. Seq.) and/or the Animal Health Protection Act (AHPA) (7U.S.C. §§ 8301 et. Seq.) may be criminally prosecuted and found guilty of a misdemeanor which can result in penalties, and one year prison term, or both. Additionally, any person violating the PPA and/or the AHPA may be assessed civil penalties of up to \$250,000 per violation or twice the gross gain or gross loss for any violation that results in the person deriving pecuniary gain or causing pecuniary loss to another, whichever is greater.

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^{*} Corrective Action Requests (CARS) outline: 1) what was required and what the failure was, 2) Root cause (why it happened), 3) specific required mitigation (what is required to correct it), and, 4) the timeframe allotted.

