



**United States
Department of
Agriculture**

Animal and Plant
Health Inspection
Service

Plant Protection
And Quarantine

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White Paper

Section 10201(d)(1) of the Farm Bill pertaining to Audit-based Certification

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Quarantine Policy Analysis & Support



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Executive Summary

APHIS is collaborating with State regulatory partners, industry stakeholders, research institutions and non-governmental organizations to develop and implement audit-based certification systems in the following ways:

- **Program Development** >>> Collaborate with State regulatory partners, industry stakeholders and non-governmental organizations to formulate policy and procedures, establish infrastructure, and fund audit-based certification programs and pilots
- **Regulatory and Standards Harmonization** >>> Harmonize existing State certification standards and regulations in a manner that supports interstate and foreign trade
- **Audit Training** >>> Develop, test, and deliver audit training to State regulatory partners and industry stakeholders
- **Outreach and Education** >>> Educate cooperators in the value of audit-based certification programs and develop and provide technical materials to aid growers who participate in audit-based certification programs

BACKGROUND

Audit-based certification is a quality management process used to verify that phytosanitary measures meet established standards. Congress recognized the value of audit-based certification systems as indicated by their conference committee notes during reconciliation of the Food, Conservation, and Energy Act of 2008, incorporated herein by reference as the Farm Bill. The conference committee notes make specific mention of creating an audit-based certification approach to protect against the spread of plant pests. They reference RSPM 24, the North American Plant Protection Organization (NAPPO) standard for integrated pest risk management measures for the importation of plants for planting into NAPPO member countries. Congress recognized the U.S. Nursery Certification Program, an audit-based certification pilot for exporting certain nursery stock to Canada. Congress recognized the systems approach and the need for collaboration between key federal and State agencies, industry organizations, and research institutions to improve programs of inspection, certification, and regulations using such systems. Section 10201(d)(1) of the Farm Bill directs the Secretary of Agriculture to use Farm Bill funds to support audit-based certification systems for specialty crops. It states:

“(d) SPECIALTY CROP CERTIFICATION AND RISK MANAGEMENT

SYSTEMS.—The Secretary shall provide funds and technical assistance to specialty crop growers, organizations representing specialty crop growers, and State and local agencies working with specialty crop growers and organizations for the development and implementation of—

“(1) audit-based certification systems, such as best management practices—

“(A) to address plant pests; and

“(B) to mitigate the risk of plant pests in the movement of plants and plant products;

The United States Department of Agriculture Animal and Plant Health Inspection Service (APHIS) is responsible for implementing sections 10201 and 10202 of the Farm Bill and all parts therein. Section 10201 pertains to plant pest and disease management and disaster prevention while 10202 pertains to the National Clean Plant Network (NCPN). Section 10202 directs the Secretary Agriculture to support programs that make clean plant material available to State certification programs. Thus, sections 10201(d)(1), pertaining to audit-based certification, and 10202 are connected. To support sections 10201 and 10202, Congress committed to provide

\$207 million in annual funds over five years for section 10201 (\$12M-FY09, \$45M-FY-10 and \$50M-FY11-FY13); and \$20 million in no-year funds over four years for section 10202.

To secure Farm Bill funding, APHIS was required to craft implementation plans for each section. The implementation plan for section 10201 was organized into six key areas:

1. Enhance analysis and survey
2. Target domestic inspection activities
3. Enhance pest identification and technology
4. Safeguard nursery production
5. Conduct education and outreach
6. Enhance mitigation efforts

Safeguard nursery production consists of two primary goals:

1. Develop science-based best management practices and risk mitigation practices to exclude, contain, and control regulated pests from the nursery production chain, and
2. Develop and harmonize audit-based Nursery Certification Programs

Goal two is aligned with section 10201(d)(1) of the Farm Bill. The implementation plan identified three strategies to achieve Goal two.

1. Develop a harmonized and integrated nursery certification program to facilitate exports and the domestic movement of nursery stock in partnership with State regulatory officials and industry stakeholders.
2. Develop and deliver the training to the cooperators, providing material and technical assistance in developing the quality operational manual for small-scale nurseries.
3. Work with all stakeholders and cooperators to launch and support the pilot programs for the nursery industry.

Guided by the implementation plan, in FY09 we used Farm Bill funds to support four projects: 1) develop harmonized certification standards for fruit trees; 2) pilot harmonized certification standards for fruit trees in three States >>> OR, WA, and PA; 3) train PPQ officers in auditing technique; and 4) education and outreach to State and industry stakeholders on audit-based certification systems. A summary of these projects and their alignment to the implementation plan is given in **Table 1**.

Table 1: FY 2009 Projects

Title	Cooperator(s)	Strategy linkage	Funding
Development of a harmonized certification standard for fruit trees and pilot demonstration	PA Dept. of Ag., OR Dept. of Ag., MI Dept. of Ag.	Regulatory and standards harmonization	\$ 159,694
Development of outreach and education materials for audit-based certification	University of MD	Outreach and education	\$ 66,000
Audit training pilot for PPQ field officers	N/A	Audit training	\$ 24,323
Total			\$ 250,017

Since crafting the implementation plan in the spring of 2009 and funding the FY09 projects, APHIS has held numerous stakeholder meetings, teleconferences, and webinars to obtain feedback. The most significant meetings impacting section 10201(d)(1) were held in June, September and December, 2009. Stakeholder feedback from these meetings is summarized in **Appendices 1-3**. On the basis of stakeholder feedback, the strategic approach was refined. The strategies listed below represent the current approach and are suggested as a revision to the plan. A timeline for executing the strategies is given in **Table 2**.

1. Program Development – Collaborate with State regulatory partners, industry stakeholders and non-governmental organizations to formulate policy and procedures, establish infrastructure, and fund audit-based certification programs and pilots
2. Regulatory and Standards Harmonization - Harmonize existing State certification standards and regulations in a manner that supports interstate and foreign trade
3. Audit Training – Develop, test, and deliver audit training to State regulatory partners and industry stakeholders
4. Outreach and Education – Educate cooperators in the value of audit-based certification programs and develop and provide technical materials to aid growers who participate in audit-based certification programs

Table 2: Timeline for executing strategies

Strategy	Target
Program development	FY10-13
Regulatory and standards harmonization	FY09-12
Audit training	FY09-12
Outreach and education	FY09-13

In FY10 we expanded the regulatory and standards harmonization strategy to strawberries, raspberries, and blue berries; expanded the audit training strategy to State inspectors and industry stakeholders; expanded the education and outreach strategy to include development of technical materials targeted at industry stakeholders; established work group to assess the needs for a unified audit-based certification framework; and funded feasibility, economic and efficacy studies comparing audit-based certification systems to conventional certification systems. These efforts will pave the way toward a unified audit-based certification framework for use in State nursery certification programs aimed at interstate movement and exports of greenhouse and nursery stock. A summary of these projects and their alignment to the implementation plan is given in **Table 3**. Preliminary results from the feasibility study as determined by a group of traditional and non-traditional stakeholders who met in August, 2010, is provided in **Appendix 4**.

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Table 3: FY 2010 Projects

Title	Cooperator(s)	Strategy linkage	Funding
Development of a harmonized certification standard for fruit trees and pilot demonstration	PA Dept. of Ag., OR Dept. of Ag., MI Dept. of Ag.	Regulatory and standards harmonization	\$ 138,983
Development of outreach and education materials for audit-based certification	University of MD	Outreach and education	\$ 48,840
Audit training for PPQ and State regulatory officers		Audit training	\$ 38,550
Development of harmonized standards for blueberry certification	University of AR	Regulatory and standards harmonization	\$ 31,600
Development of harmonized standards for strawberry certification	OR Dept. of Ag.	Regulatory and standards harmonization	\$ 67,526
Development of harmonized standards for raspberry certification	University of AR	Regulatory and standards harmonization	\$ 30,000
Comparison of the efficacy of three certification schemes to mitigate the risk of spreading plant pests through trade in nursery stock	OR Dept. of Ag.	Program development	\$ 135,382
Efficacy assessment of the US Greenhouse Certification program	University of FL	Program development	\$ 177,576
NPB assessment of audit-based certification in domestic commerce of nursery stock	NPB	Program development	\$ 100,000
Evaluation of the US Nursery Certification program	Horticulture Research Institute and George Washington University	Program development	\$ 100,000
Feasibility of audit-based certification for the US nursery and greenhouse industry	Northeast/Midwest Institute	Program development	\$ 50,000
Movement of plant pests on certified nursery stock in domestic trade	University of MD	Program development	\$ 122,475
Development of a generic certification manual and training program	OR Assoc. of Nurseries	Outreach and education	\$ 65,000
Development of audit-based certification for high risk conifer nurseries	MI Dept. of Ag.	Program development	\$ 50,000
Total			\$1,155,932

Appendix 1. Stakeholder concerns and APHIS responses at June, 2009 meeting

Category	Response
Scope	Stakeholders questioned the geographic scope of the Nursery Safeguarding Initiative. We explained that our initial focus is on domestic interstate movement but our goal is to establish common national standards to enable interstate movement and export. Stakeholders questioned Federal and State regulatory authorities and certification requirements in terms of being voluntary or mandatory. Many States have mandatory certification requirements codified in their regulations. Federal requirements under a national standard are intended to be voluntary but not replace existing State programs. Stakeholders questioned the scope of pests and commodities under a national certification program. We explained that our approach is holistic with the intention of covering the broadest possible spectrum of pests and commodities. We conveyed that our pest priorities are quarantine and non-quarantine regulated pests while acknowledging other significant economic pests.
Communication	Stakeholders placed strong emphasis on communication, transparency, and clarity of information. They expressed confusion over various certification programs. They repeatedly sought definition of terms. They recommended scoping sessions, more meetings, and outreach and extension.
Harmonization	Stakeholders recognized the importance of harmonization but acknowledge the difficulty of achieving a national standard. We explained that harmonization is stakeholder driven.
Incentive	Stakeholders emphasized the importance of incentives to obtain industry participation. They recommended several options including reduced insurance premiums, brand recognition, and improved market access.
Complexity	Stakeholders emphasized the complexity of the nursery industry in terms of economies of scale. They expressed concern about technology transfer pertaining to operational changes needed to engage in complex certification programs.
Economics	Stakeholders emphasized the need for an economic analysis of nursery certification programs to demonstrate the economic benefits to the industry.
US Nursery Certification Program	Stakeholders expressed interest and support for the U.S. Nursery Certification Program. They also recommended an independent economic analysis and quantitative assessment of the pest management effectiveness and to determine the benefits and liabilities of the program.
National Ornamentals Research Center	Stakeholders expressed mixed messages about NORS-DUC. Those in favor of the program argued that information generated by the research would be valuable to the industry. Those critical of the program argued that the scope is too limited and that it should be industry funded.
National Clean Plant Network	Stakeholders expressed support of NCPN but suggested clean plant programs should be industry funded. They acknowledged a need to integrate clean plant programs with nursery certification systems.

Appendix 2. Summary of stakeholder feedback from spending plan meeting, September, 2009

Concept	Feedback
National Audit-based Certification Program	<ul style="list-style-type: none"> • This audit-based program needs a lot more discussion and understanding to proceed further. The existing programs are not fully implemented enough to determine their success. • Must include current State certification systems. But States must have minimum requirements in the State laws. The NPB has a model law that should be a guide. But States must be accredited inspection and certification requirements???? • Inappropriate for team lead to be major requestor • Need personnel to implement inspection and improve overall capacity. • National program/State balance to \$\$??? • Audit-base proposal @ USDA level seems appropriate. • What problem is this solving? Harmonizing State regs. for domestic trade? • Must be based on industry practices (consistent with), e.g. need stronger national stakeholder involvement in program design – not just states (This is major!!)
Document and Validate Nursery Certification Program	<ul style="list-style-type: none"> • Good focus on verification of certification program. Verification is important. Is it doing what it is supposed to do? Probably need more focus on this. • Must be based on industry practices (consistent with), e.g. need stronger national stakeholder involvement in program design – not just states (This is major!!)
Efficacy Study of Audit-based Certification Programs	<ul style="list-style-type: none"> • Best to determine first if audit-based certification programs are needed and worth the investment, therefore an efficacy study should be a first priority. • Audit-based certification programs should be reviewed first before tying up large amounts of funding for development and implementation. • Local level analysis for audit-based programs should be incorporated into USDA proposals. • This is foundational work, other proposals are similar. APHIS should work with stakeholders to identify goals. ANLA would like to participate in this effort.

Appendix 3. Summary of stakeholder feedback from section 10201(d) business meeting, December, 2009

Action Item	Description
Program Plan	<p>Develop a comprehensive Accreditation/Certification Program Plan that considers matters such as definitions, relevant issues, and program components.</p> <ul style="list-style-type: none"> • Seek ‘baseline’ data; determine what a ‘baseline’ program might look like • Provide information on what an expanded/continued effort might look like for existing programs • Provide added resources to bottom-up approach regarding new/individual crops (e.g. fruit trees, berries, grapes) being provided via NCPN program
Supporting State Programs	Ascertain how it is that we do or might support State Certification programs
Evaluate Program Efficacy	<p>Evaluate the efficacy of accreditation/certification programs, including items such as the efficacy of pest reduction and cost/benefit analyses. Programs might include:</p> <ul style="list-style-type: none"> • Oregon – Efficacy Studies • NPB/HRI – 3rd Party Validation Studies • Other Studies also encouraged
Validate USNCP Efficacy	<p>This program has an established track record. Evaluate aspects of this program as a learning experience</p> <ul style="list-style-type: none"> • Validate the performance and efficacy of programs shipping material to Canada. • Ascertain program needs, including documentation issues • Compare cost/benefit to program efficacy <ul style="list-style-type: none"> ○ Cost/Benefit analyses should be done by an ‘outside/independent’ entity; e.g. PPD or even contracting this out ○ Do a business process review – qualitative vs. quantitative ○ Look also into what Canada has done
Education/Outreach	<p>Launch into an education/outreach program; consider bringing together some ‘partners’ in outreach to help determine how all the pieces might fit together. This program might also be used to help establish necessary baseline data.</p> <ul style="list-style-type: none"> • The question of ‘Definitions’ might be handled here
Pilot Programs	Consider piloting State administered NCP’s. Do this as an expansion of the USNCP
Streamlined Manual	<p>Determine what a ‘lite’ version of the manual might be. Incorporate this matter as part of the education/outreach question.</p> <ul style="list-style-type: none"> • Also develop training in manual development and use.
Audit Training	<p>Conduct audit-based training of various persons including Federal, State, and others (e.g. associations).</p> <ul style="list-style-type: none"> • Develop and expand training to others such as hort. Inspection societies
Conference Workshops	<p>Some eastern and western States already talking re issues such as State Import requirements (e.g. Chili Peppers). Develop a Conference/Workshop on the question of Interstate Movement. Participants would include PPQ ER/WR, the Plant Board, etc. This question is linked to NPB Strategic Planning</p>
Economies of Size	Launch a pilot program looking at the impact of accreditation/certification programs on nurseries of various sizes
Best Management Practices	Review and facilitate implementation of BMP’s put together by industry. Have the BMP’s been evaluated? Do they work?

Appendix 4. Feasibility of audit-based certification, August 2010

The desirable components of an audit –based certification system supported by all horticulture stakeholders are:

1. Structure: The desired structure of a harmonized audit-based certification system is that it be:
 - a. Science-based (guidelines)
 - b. Audit-based
 - c. Adaptive
 - d. A tiered system
 - e. Flexible to accommodate different pests and new methods as they arise
 - f. Apply a systems approach with critical control points and a menu of options including best management practices and “other” approaches as they come available.
2. Incentives: Offers Incentives for participating and sanctions, when appropriate.
3. Standards: Is based on standards reflecting a minimum acceptance level addressing ecological parameters and evolving conditions.
4. Sustainable: Is sustainable and feasible because it is practical, enforceable, and meets user needs; economical; web-based and user friendly.
5. Science-based: Has a scientific and results- based design which allows for method variability; is verifiable and funded to quickly address new or emerging problems.
6. Education/Outreach: Includes user education and outreach.
7. User Support: Offers readily accessible and user friendly technical support to users, as needed.
8. Results: Demonstrates effective “on the ground” impacts relative to mitigating or eliminating invasives.

The common measures of success which emerged across all four stakeholder groups were:

1. Reduction in pests and invasives: Ultimately, the most significant measure of success is the desired reduction, elimination and control in detection and outbreaks of pests and invasives as well as reductions in interceptions and rejections of shipments due to pests of concern.
2. Participation levels and demonstrated buy-in from stakeholders: The percentage of industry, federal and state and international regulators and trading partners accepting, participating and supporting the system. Also the level of consumer recognition and demand for certified products would be a key measure.
3. Net economies and benefits to society and nurseries: Cost avoidance relative to impacts of invasives as well as increase in industry profitability would be key indicators.
4. Cost efficient and practical: The extent to which the system is funded, financially feasible, flexible, cost and time savings for shippers and regulators, revenue generated by prevention and treatment, etc.

5. Level of participation or rate of application of program components such as number of state and federal regulators trained and stakeholder use of protocols would be clear indicators.

Recommendations of next steps consisted of actions about structure, leadership, baseline assessment and communications, and outreach. The proposed short and long-term next steps are as follows:

Short –Term (over the next 12-24 months)

Establish a formalized structure, organization and dedicated resources for the continued development effort. Establish clear program active leadership and a cross-stakeholder advisory or steering body to make recommendations to APHIS on all follow- work.

1. Engage the Plant Board.
2. Identify barriers to industry participation and buy-in to a certification program.
3. Begin to establish a baseline all data and information on pest presence.
4. Promote piloting Best Management Practices by industry leaders.
5. Begin evaluating existing programs.
6. Survey industry for critical control points and future mitigation strategies.

Long-Term (Beyond 24 months)

Conduct outreach, marketing and program branding to seek greater awareness and participation.

1. Devise customer buy-in strategies.
2. Implement a pilot program based on current program evaluations.
3. Continue base lining activities.
4. Continue current program evaluations.

Discussions clearly identified the need to establish structure and dedicate support to this effort as the first critical next step. Additionally, while identified as needing resources, assessing the effectiveness of current programs and moving toward implementing a pilot program were deemed to be important next steps.