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# Basics of a Proposed Regulatory Systems Approach Protocol – Plants for Planting

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## Introduction

The goal of a regulatory systems approach protocol (RSAP) is to ensure that the importation of plants for planting meets the acceptable level of phytosanitary security of the United States. The goal of an industry clean stock program is to produce planting material free of certain pests/pathogens; or if pests/pathogens are present, then below levels that will have a significant effect on the main production crop. APHIS is proposing implementation of regulatory systems approach protocols to mitigate the pest risk associated with the importation of plants for planting. RSAPs will incorporate management practices from existing industry clean stock programs or industry best management practices to the greatest extent possible. In order for the Agency to revise Q-37 and implement RSAPs as conditions of entry of certain classes of plants for planting, the effectiveness of the measures must be evaluated.

Most industry clean stock programs address the basic elements as presented in this paper. While no two programs are identical, they are all designed to manage either general or specific pest risks by reducing those risks to a level acceptable to both the program manager and the user of the material produced by the program.

Industry clean stock programs are generally implemented for pests and pathogens that cause serious effects on the production, yield, and quality of the final product; in other words, to produce a high quality product that is free of harmful pests. The most frequent use of industry clean stock programs is for the elimination or reduction of harmful plant pathogens in vegetative planting material used for the production of the main crop. Industry clean stock programs frequently include quality and purity requirements in their

standards and they are available in many different forms, for a number of different crops, both vegetatively and seed propagated.

Elements from industry clean stock programs have also been used to manage quarantine pests. The risk management measures for quarantine pests can be as simple as improving existing measures, but may require new measures that can be incorporated into the existing industry clean stock program. The *Pelargonium/Ralstonia* quarantine program (7CFR 319.37-5(r)) is an example where both existing measures were improved and new measures instituted to provide a RSAP to manage the risk associated with a pest of quarantine concern for the United States within places of production.

The basic elements described here address the common steps that have an impact on minimizing the risks of movement of pathogens and pests.

## Definitions

Area - An officially defined country, part of a country or all or parts of several countries based on the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures [FAO]

Commodity - A type of plant, plant product, or other article being moved for trade or other purpose [FAO]

Control point - A step in a system where specific procedures can be applied to achieve a defined effect and can be measured, monitored, controlled and corrected [FAO]

ELISA (enzyme linked immunosorbent assay) – A serological test in which one antibody carries with it an enzyme that releases a colored compound [Agrios, 97]. Used to detect and identify plant pathogens

Establishment – Perpetuation, for the foreseeable future, of a pest within an area after entry [FAO]

Field - A plot of land with defined boundaries within a place of production on which a commodity is grown [FAO]

Free from – Of a consignment, field or place of production, without pests (or a specific pest) in numbers or quantities that can be detected by the application of phytosanitary procedures [FAO]

Germplasm - Plants intended for use in breeding or conservation programs [FAO]

Growing Medium - Any material in which plant roots are growing or intended for that purpose [FAO]

Index – Tests using biological, immunological and/or molecular methods to determine the presence of pathogens in plants

Industry Clean Stock Program – The integration of pest management measures to ensure that the product meets a standard for low or no pest presence and dissemination

Introduction - The entry of a pest resulting in its establishment [FAO]

Nuclear stock – A plant or plants which were originally tested and found free of pests and pathogens (or free from specific pests and pathogens) and maintained in such a way as to retain their pest free status

National Plant Protection Organization – Official service established by a government to discharge the functions specified by the IPPC [FAO]

NPPO – National Plant Protection Organization [FAO, ICPM]

Official – Established, authorized or performed by a national plant protection organization [FAO]

PCR (polymerase chain reaction) – A technique that allows an almost infinite amplification (multiplication) of a segment of DNA for which a primer (a short piece of that DNA) is available [Agrios, 97] Used to detect and identify plant pathogens

Pest - Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products [FAO]

Pest Risk Management (for quarantine pests) - Evaluation and selection of options to reduce the risk of introduction and spread of a pest [FAO]

Place of Production - Any premises or collection of fields operated as a single production or farming unit. This may include production sites which are separately managed for phytosanitary purposes [FAO]

Plant Products - Unmanufactured material of plant origin (including grain) and those manufactured products that, by their nature or that of their processing, may create a risk for the introduction and spread of pests [FAO]

Planting (including replanting) - Any operation for the placing of plants in a growing medium, or by grafting or similar operations, to ensure their subsequent growth, reproduction or propagation [FAO]

Plants - Living plants and parts thereof, including seeds and germplasm [FAO]

Plants for Planting - Plants intended to remain planted, to be planted or replanted [FAO]

Regulatory Systems Approach Protocol – The integration of phytosanitary measures with best pest management practices to mitigate the risk associated with regulated pests

## General

Industry clean stock programs have two principal components; a production practices component and a quality control component. The production practices component starts with material that is free of pests of concern to the program (usually economically important and/or quarantine pests). This nuclear stock is then increased through one or more cycles (generations) until sufficient material is available for production of the main crop. Each generation has it own standards for "cleanliness". The place of production is responsible for ensuring that the plant material meets their own, and/or an agreed upon (usually with a regulatory agency), standard of "cleanliness". There are a multitude of procedures to determine pest freedom, including bio-indicators, culturing, serology (ELISA), molecular (various types of PCR) and visual inspection. There are also a number of terms to describe these initial pest-free plants (nuclear, foundation, basic, mother, elite stock/block, etc. or a combination of terms). Likewise, there are a multitude of terms to describe the increase generations (elite, foundation, G1-Gx, basic, certified). In this paper we use the term nuclear stock to indicate the highest level of pest freedom.

In many of these programs subsequent generations of increase are held to decreasing rigorous standards. However, for certain endemic pests (e.g. certified potatoes – ring rot disease) and for quarantine pests the standard is freedom from the pest in all generations.

The quality control component ensures that the plant material produced in each generation of the industry clean stock program meets the rigorous standards for that generation. Many seed and plant propagation companies use a clean stock program to produce high quality seed and propagative material with good germinability and vigor and "freedom" from pests/pathogens that will affect the production crop.

In RSAPs, a government agency or its official designee provides oversight of all generations to ensure that the exported plant material is free of quarantine pests and may have responsibility for the first generation (highest level of pest freedom) of plant material.

There are a number of examples of industry clean stock programs for specific crops with some of the programs regulated by various levels of government. The U.S. Nursery Certification Program is another example of an industry clean stock program that is regulated by State governments. These programs also meet the "cleanliness" standards of the Federal Seed Act.

State regulated certification programs in the United States include potato; strawberry; grapevine; stone, pome and citrus fruit trees; nut trees; and some seed crops, e.g. lettuce. Currently, the United States is in the process of harmonizing many of these export

programs with Federally-regulated Canadian programs. The newly adopted RSPM no. 24 will promote this harmonization effort.

Examples of current APHIS regulatory programs for plants for include: *Pelargonium/Ralstonia*, plants in growing media, pome and stone fruit trees from the five European countries (although these programs do not yet contain all of the elements discussed in this paper). Industry clean stock programs are usually implemented through a combination of regulatory (or company policy/directives) and more specific operational workplans (or company standard operating procedures (SOPs).

The industry driven requirements of the geranium (*Pelargonium*) clean stock programs have been in existence for about 40 years and are used to produce planting material that is free or substantially free of pests that affect the production of the crop. Until recently, the geranium clean stock program was the sole responsibility of a particular company. The identification of geranium as a host of the quarantine pest *Ralstonia solanacearum* race 3 biovar 2 caused a reevaluation of the import program and the implementation of a regulatory program which required an increase in the efficacy of existing measures, the implementation of additional measures for the elimination of this bacterial pathogen, and official oversight of the *Ralstonia* part of the pest management plan. RSAPs will include to the greatest extent possible the existing pest management practices of the regulated entity; however, *Pelargonium* production companies will continue to maintain their own clean stock program to control pests other than *Ralstonia*.

## Production Practices

Production practices for industry clean stock can be divided into a number of different categories:

- pest management practices, including pesticides, isolation, sanitation, and other measures to avoid, exclude or eliminate pests;
- good agronomic practices to produce healthy plants;
- administrative practices, including SOPs to documentation of practices, and status and location of plant material in program;
- training of personnel at place of production, for audits; etc.

The production practices can also be categorized according to the generation of increase of the propagation increase, for example nuclear, foundation, registered, certified or Generation 0 through Generation (x). The terms nuclear and generation 0 are frequently used for the mother stock that has the highest level of pest freedom. Candidate plant material is tested and/or inspected, found free of pest, or pests of concern, before being entered as nuclear stock, Multiple tests can be used including bio-indicators, culturing, ELISA, PCR. As necessary these plants could be maintained under a high level of protection to prevent re-infestation, for example tissue culture, clean room, screened enclosure, isolation, and frequent pest control.

The nuclear stock is used to initiate first of one to several generations to increase the amount of propagative material sufficiently to use as planting stock for the main production crop. In fruit trees, propagative material (first generation) from the nuclear stock is used to establish mother blocks at the nursery. Propagation material (budwood) from the nursery mother blocks are then used as scions for the production of trees for sale and planting in an orchard. In potatoes, there are several generations of increase before the plant material is used to produce certified seed which is used to plant the main crop. Because of increasing size of each subsequent generation and/or distance in time from the nuclear stock, the tolerance for pest presence usually increases. However, for quarantine pests and for certain endemic pests, pest freedom must be maintained throughout all increase generations.

Examples of some pest mitigation measures industry clean stock programs that could be components in a RSAP:

**Fungi:**

- tissue culture, for long term maintenance and propagation
- indexing or testing, broad spectrum or specific, 100% for nuclear stock, random sampling for later generations
- water management, clean water, humidity, free moisture
- agronomic management, maintain vigor
- prevent movement of water between plants, back-flow prevention
- pesticides, preventative and curative
- pest survey
- roguing
- controlled access
- sanitation, facility, workers, and material entering facility
- isolation, area or season
- exclusion, protected area, foot bath, wash stations

**Bacteria:**

- tissue culture, for long term culture and propagation
- indexing or testing, broad spectrum or specific, 100% (nuclear) or sample
- water management, clean water, humidity, free moisture
- agronomic management, maintain vigor
- prevent movement of water between plants, back-flow prevention
- pest survey
- roguing
- controlled access
- sanitation, facility, workers, and material entering facility
- clean growing medium, fumigation, pasteurization
- isolation, area or season
- exclusion, protected area, foot bath, wash station

**Virus-like organisms:**

- vector control within facility and surroundings, insects, nematodes, human
- tissue culture, for long term culture and propagation
- indexing or testing, broad spectrum or specific, 100% (nuclear) or sample
- pest survey
- roguing
- isolation, area or season
- exclusion, protected area

**Arthropods:**

- tissue culture
- screened or enclosed facilities
- pesticides
- pest survey
- isolation, area or season
- exclusion, protected area, double doors
- traps, attractants

# Performance Standards for a Regulatory Systems Approach Protocol (RSAP) – Plants for Planting

**Production Practices**

Nuclear stock is pest free.

All other increase generations are free of quarantine pests and below tolerance levels for other pests. The exporting country NPPO must ensure that the plant material in each generation of the RSAP program meets the rigorous standards for each generation.

Pest management practices, including pesticides, sanitation, and measures to avoid, exclude or eliminate pests, prevent quarantine pests from being introduced into the growing system. Non-quarantine pests are at or below agreed upon tolerance levels.

Procedures are in place to determine pest freedom, including bio-indicators, culturing, serology (ELISA), molecular (various types of PCR), visual inspection.

Agronomic practices are in place to produce healthy plants.

Pest mitigation measures address all categories of pests; fungi, bacteria, virus-like organisms, arthropods and weeds.

Administrative practices, including SOPs, document the facility practices, and the status and location of plant material.

## Quality Control

**Responsibilities**: The place of production is ultimately responsible for the development, implementation, operation and biosecurity of the clean stock program. Both NPPOs provide approval and oversight to ensure that the program meets the established standards, especially with respect to notification of deficiencies and corrective action, and new pest presence.

**Documentation:** required by this standard is maintained by the exporting place of production and made available to official representatives of the exporting and importing country NPPOs upon request.

**Oversight**: The place of production must be open to necessary and reasonable audit, monitoring and evaluation of compliance by exporting country NPPO and APHIS. The management of the place of production must be fully accountable to both NPPOs to ensure compliance with the system. Management must specify the roles and responsibilities of its personnel to perform program activities. The place of production must notify the exporting country NPPO of deficiencies detected during internal audits.

### Training

A training program for employees/workers must be established, documented and regularly conducted at the place of production. The training program must ensure that all those involved in the export program possess the specific knowledge related to the relevant components of the program and a general understanding of the requirements.

### Pest Management Program

The place of production must develop and implement an approved pest management program that contains ongoing surveillance, and procedures for the containment and control of pests to prevent introduction and spread. The place of production must obtain material used to produce plants for planting from sources approved by the NPPO. All pest management activities must be well documented. All sources of plants for planting and the phytosanitary status of those plants must be well-documented and the program for producing plants for planting for export to the USA carefully monitored.

### Internal Audits

The place of production must perform, or designate parties to perform internal audits that ensure that the exporting country NPPO approved and documented plan is being followed and is achieving the appropriate level of pest management.

### Traceability

The place of production must implement a procedure approved by the NPPO or its designee that documents and identifies plants from propagation through harvest and sale

to ensure that plants can be traced forward and back. The system must at least account for:

- the origin of mother stock;
- the year of propagation;
- the place of production;
- geographic location of the field of production;
- location of plants for planting within the place of production;
- the genus; species; variety; hybrid, origin, and
- the purchaser's identity

**Documentation of Program Procedures**

A place of production must develop a manual that guides its operation and which includes the following components:

- administrative procedures (including roles and responsibilities, training procedures);
- pest management plan;
- place of production internal audit procedures;
- management of non-compliant product or procedures;
- traceability procedures;
- record-keeping systems.

**Records**

A place of production must maintain records on its premises as specified by the exporting country NPPO and APHIS. These records must be made available to auditors for either NPPO upon request. These documents include all the elements described herein and copies of all external audit documents/reports.

**Responsibilities of the NPPOs**

Both APHIS and the exporting NPPO are responsible for collaborating to establish program requirements, including regulations, workplans and compliance agreements as necessary for recognizing and implementing a particular import program. Technically justified modifications to the program may be negotiated.

The administration of program requirements should include such elements as clarification of terminology, testing and re-testing requirements, eligibility, the nomenclature of certification levels, horticultural management, isolation and sanitation requirements, inspection, documentation, identification and labeling, quality assurance, non-compliance and remedial measures, and criteria for post-entry quarantine. Both APHIS and the exporting NPPO should jointly develop and agree upon criteria for approval, suspension, removal, and reinstatement of a place of production in the program. The exporting country NPPO and APHIS will exchange information through officially designated contact points in each country.

**Auditing** – (Requirements for auditing should be agreed to bilaterally)

The APHIS should evaluate the proposed RSAP before acceptance. This could consist of documentation review, site visits, and inspection and testing of plants produced under the system. Ideally, the proposed RSAP is already functioning as part of industry clean stock programs in the exporting country. The review and evaluation of a new program should be more intense and include additional testing of the exported product from each place of production.

Following approval, the APHIS or its designee should monitor and periodically audit the system to ensure that it continues to meet the stated objectives. Audits should include inspection of imported plants for planting, site visits and review of the integrated pest management measures of the exporting NPPO and internal audit processes of the exporting NPPO and the place of production.

The exporting NPPO must audit the RSAP on a regular basis. Audits should verify that program participants are complying with the specified standards and that the integrated pest management measures continue to meet the requirements of APHIS and the bilateral arrangements.

Audits must be conducted by the place of production (quality control) and both NPPOs or designees and will consist of inspection or testing of plants for planting and the documentation and management practices as they relate to the program.

**Non-compliance and Remedial Measures**

APHIS and the exporting country NPPO should agree bilaterally on what instances of non-compliance are considered significant (ISPM No 13). Both major and minor infractions should be well defined. Examples of major infractions that indicate that the integrity of the system is compromised are; the detection of regulated pests, deficiencies in documentation, failures to maintain traceability of plants. Minor infractions, such as detection of common pests above established thresholds, should be indicators of potential program failure. Infractions not reported by the place of production should be considered more serious than those reported. Instances of non-compliance could be identified by audits by either NPPO, by port of entry inspection, etc.

The APHIS should specify the consequences of non-compliance to the exporting NPPO. The exporting NPPO should specify the consequences of non-compliance to the participants in the program. These may vary depending on the nature and severity of the infraction. In addition, remedial measures should be specified to enable a suspended or de-certified place of production to become eligible for reinstatement or re-certification. Timely remedial action must be taken by the place of production in order to remain in the program.

Places of production that do not meet the conditions of the program must be suspended or removed from the program. Plants for planting must not be exported from a place of

production that has failed to meet the program requirements.

The effectiveness of remedial measures taken must be verified before reinstatement to the program by the exporting NPPO, and where appropriate, by APHIS.

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