Potentially Actionable Suspect Sample (PASS) <u>Federal Confirmation in PPO</u> <u>General Policy</u>

A Potentially Actionable Suspect Sample (PASS), in its simplest form, is a sample of a plant pest or pathogen of regulatory concern (including bacteria, viruses, nematodes, weeds, insects, mites, mollusks, etc.) that has been presumptively identified by a laboratory without federal confirmatory authority. Under these circumstances, confirmatory testing by a federally authorized laboratory would be required. These plant pests are defined by the Plant Protection Act (2000) as "new to or not widely distributed" and are regulated by the Animal and Plant Health Inspection Service (APHIS) in order to protect U.S. agriculture and natural resources. Confirmation by a federally authorized laboratory would mean that Federal regulatory action would result from the confirmation, and/or Federal funds would be utilized in response to the confirmation of the pest or pathogen.

The presumptive identification of a PASS by an unauthorized laboratory would result in the sample(s)/specimen(s) or its biological extracts (DNA, RNA, and/or proteins) being forwarded to a Federally authorized laboratory for confirmatory testing with the appropriate validated diagnostic test(s). Subsequent 'suspect' positive samples from within an APHIS-defined quarantined and/or regulated area related to the specific PASS would not require Federal confirmatory testing unless it represented a new host(s) or in other unusual circumstances. New finds outside of the APHIS-defined quarantined and/or regulated area are considered a new PASS. Typically, a sample considered a PASS would also encompass any sample, within or outside of a quarantined and/or an APHIS-defined regulated area, which could involve unusual or unexpected circumstances, an atypical biology of the pest or pathogen, or a potential bio-terrorism act.

The PASS policy for a specific pest or pathogen is based on what is known on the biology of the organism and epidemiology of the disease.

Potentially Actionable Suspect Sample (<u>PASS) Policy for</u> <u>Elsinoë australis</u>, Sweet Orange Scab (SOS) Revised 4 February, 2011

Complete, definitive identification of the fungus *Elsinoë australis* (and other *Elsinoë* species) is accomplished through analysis of DNA extracts from plant or fruit tissue suspected of containing the fungus.

<u>'Suspect' samples from outside a state, county/parish or other quarantined or</u> <u>regulated area with a confirmed positive.</u> A 'suspect' *E. australis*-positive sample from any citrus plant or fruit(s) from <u>outside</u> a state or county/parish or other quarantined or regulated area with a confirmed positive, is categorized as a PASS. Any sample determined to be a PASS must be forwarded to the USDA Plant Protection and Quarantine (PPQ) designated laboratory. The Molecular Diagnostic Laboratory (MDL) in Beltsville, MD will complete federal confirmatory testing. MDL is the APHIS PPQ National Identification Services recognized taxonomic authority for this pathogen.

<u>'Suspect' samples from within a state, county/parish or other quarantined or</u>

<u>regulated area with a confirmed positive.</u> A 'suspect' *E. australis*-positive sample from <u>within</u> a state, county/parish or other quarantined or regulated area with a confirmed positive is not considered a PASS. If such a sample <u>represents a new host, an unusual</u> <u>circumstance or a yet unconfirmed *Elsinoë* species</u>, it is categorized as a PASS and must be forwarded to the USDA PPQ designated laboratory. The MDL in Beltsville, MD will complete federal confirmatory testing. *E. australis* identification from 'suspect' positive samples that are not categorized as PASS may be completed in an accredited¹ state or regional laboratory under the National Plant Pathogen Laboratory Accreditation Program using Work Instructions (including primers) that have been validated for program use by USDA PPQ National Plant Germplasm & Biotechnology Laboratory.

¹ Diagnosticians within an accredited laboratory must be certified to perform the E. australis diagnostic by successfully completing the SOS proficiency test (PT) panel when it becomes available.