



**United States
Department of
Agriculture**

Animal and Plant
Health Inspection
Service

Plant Protection
And Quarantine

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Bilateral Workplan

between

**USDA APHIS
&
Italian Ministry of Agriculture, Food, and Forestry Policies**

for

**Preclearance Operations to Export Apples and Pears
from Italy to the United States**

Version 1.0

Pre-clearance & Offshore Programs

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1. Scope of operations:

The scope of operations for this workplan includes execution, monitoring and oversight of phytosanitary measures in approved production units (APU) and processing facilities (APF); and inspection, certification and clearance in country by USDA inspectors of apples and pears produced in Italy for export to the United States. The phytosanitary requirements specified in this workplan are derived from the United States Code of Federal Regulation 7 CFR 319.56-22. These requirements are obligatory.

Only organizations approved or authorized by the Italian National Plant Protection Organization (NPPO) are eligible to participate in this program. To approve production units and processing facilities, the NPPO must inspect, certify and register production units and packing facilities by examining their physical and operational attributes, verify that the phytosanitary standards and requirements specified in this workplan are met, and prepare an official registry listing the unique identification attributes of the approved organizations. The NPPO may authorize external service providers (ASP) to deliver specific phytosanitary services associated with monitoring and oversight of APUs and APFs. The Italian NPPO is directly responsible for conducting joint preclearance inspections, issuing phytosanitary certificates, and initiating cold treatment.

All costs incurred by USDA pertaining to preclearance program delivery as specified in this workplan will be paid by the Italian NPPO or their recognized industry cooperator. Preclearance program delivery costs may include but are not limited to travel, salary, accommodations, per diem and overhead. Annual budgets will be estimated based on program needs using standard budgeting protocols. Financial transactions will be enabled by a Cooperative Service Agreement activating a USDA trust fund account. Ensuing payment plans will be prepared by USDA and agreed to by participating parties. USDA will prepare monthly statements to inform the NPPO or Cooperator of program financial status.

2. Applicable regulations, authorities and standards:

United States Code of Federal Regulations – 7 CFR 305 (Phytosanitary treatments)

United States Code of Federal Regulations – 7 CFR 319.56-6 (Trust fund agreements)

United States Code of Federal Regulations – 7 CFR 319.56-22 (Apples and pears from certain countries in Europe)

ISPM 5 – Glossary of Phytosanitary Terms

ISPM 12 – Phytosanitary Certificates

ISPM 15 – Regulation of Wood Packaging Material in International Trade

ISPM 31 – Methodologies for Sampling of Consignments

3. Pests of concern:

Pear leaf blister moth, *Leucoptera malifoliella*;

Plum fruit moth, *Grapholita (syn. Cydia) funebrana*;

Summer fruit tortrix moth, *Adoxophyes orana*;

Grape tortrix, *Argyrotaenia ijungiana (syn. A. pulchellana)*,

Pest of quarantine significance to the United States

4. Definitions, abbreviations and acronyms:

AD: Additional Declaration - A statement that is required by an importing country to be entered on a Phytosanitary Certificate and which provides specific additional information pertinent to the phytosanitary condition of a consignment. [FAO, 2002]

APHIS: Animal and Plant Health Inspection Service

APF: Approved Processing Facility - A fruit processing and packing facility approved for participation in the preclearance export program by the Italian National Plant Protection Organization.

APU: Approved Production Unit - The orchard or subunit defined by specific boundaries on a map or aerial photograph and approved by the Italian National Plant Protection Organization for inclusion in this preclearance export program. An APU can consist of any continuous and homogeneous unit planted with apple or pear trees and managed by the same company.

ASP: Authorized Service Provider - The ASP is an external organization authorized by the NPPO to provide specific phytosanitary services. The Italian NPPO may authorize the Provincial Extension Service to function as an ASP. The ASP is not a regulatory body or a certification body. It shall not certify or approve APUs or APFs. It shall not conduct official preclearance inspections, issue phytosanitary certificates or initiate cold treatment. The authorization process and standards are given in **Appendix 4**.

Cooperator: A business entity chosen by the Italian National Plant Protection Organization to be signatory of the Cooperative Service Agreement. The Cooperator also handles financial matters relative to collecting fees from various participants involved in exporting apples and pears under this program and using those funds to pay for the services of APHIS for overseeing and conducting this preclearance program.

CSA: Cooperative Service Agreement - Official Agreement between APHIS and the NPPO or Cooperator, establishing the financial roles and responsibilities of the signatory parties. The signed CSA is used to activate a USDA trust fund account.

CSOSC: The Centro Servizi Ortofrutticoli Societa Cooperativa (Industry cooperator in Italy)

Grower lot: Fruit from a single APU packed at one time at an APF and presented for pre-inspection and Preclearance Inspection as a single unit.

Inspection unit: The aggregate of grower lots combined together and presented for preclearance inspection as a single unit. The minimum allowable inspection unit size is 1000 cartons. Interception of a single living quarantine pest in any part of the Inspection Unit results in action on the entire inspection unit.

IU: Inspection unit

MiPAAF: Ministero delle politiche agricole alimentary e forestali (the Italian NPPO)

NPPO: National Plant Protection Organization

PC: Phytosanitary Certificate - Certificate patterned after the model certificates of the IPPC. [FAO, 2002]

Phytosanitary measure: Any legislation, regulation or official procedure having the purpose to prevent the introduction and/or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests. [FAO, 2002]

Preclearance: Phytosanitary certification and/or clearance in the country of origin, performed by or under the regular supervision of the National Plant Protection Organization of the country of destination. [FAO, 2002]

PIU: Preclearance inspection unit

Quarantine pest: A pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled. [FAO, 2002]

Treatment: Officially authorized procedure for the killing or removal of pests or rendering pests infertile. [FAO, 2002]

Workplan: An official document specifying the phytosanitary measures agreed to by the National Plant Protection Organizations of both importing and exporting countries, intended to prevent the movement of regulated pests while facilitating trade of plants and plants products.

PPQ: Plant Protection and Quarantine

Traceability: As required by 7CFR 319-22(c)(2), a system must be in place in this export program that ensures that the Approved Production Unit of any apple and pear moved under this program can be identified from the time the fruit leaves the APU until it arrives in the United States.

USDA: United States Department of Agriculture

5. Participating organizations:

- 5.1. The Italian Ministry of Agriculture, Food and Forestry Policies - MiPAAF (hereafter referred to as Italian NPPO)
- 5.2. The United States Department of Agriculture Animal and Plant Health Inspection Service (hereafter referred to as APHIS)
- 5.3. The Centro Servizi Ortofrutticoli Societa Cooperativa (hereafter referred to as CSOSC)
- 5.4. Approved Production Units (hereafter referred to as APU)
- 5.5. Approved Processing Facilities (hereafter referred to as APF)
- 5.6. Authorized Service Providers (hereafter referred to as ASP)

6. Participant roles and responsibilities:

6.1. Italian NPPO:

- 6.1.1. Operational workplan: Work cooperatively with USDA, APHIS, PPQ, Preclearance Staff to develop an operational workplan detailing the necessary administrative and phytosanitary measures, procedures, and tasks needed to operate this export program. This includes Appendices which explain survey, sampling, and inspection regimes required by USDA; and the requirements, roles, and responsibilities of all participants.
- 6.1.2. Cooperative service agreement trust fund account: Apples and pears may be imported under a preclearance program only if the NPPO or industry cooperator enters into a Cooperative Service Agreement (CSA) with APHIS establishing a Trust Fund account in accordance with 7 CFR §319.56–6 for the payment of services provided by APHIS in the Preclearance program. The organizational signatory to the Cooperative Service Agreement shall heretofore be known as the Cooperator. It is the responsibility of the Italian NPPO to choose the Cooperator and inform APHIS of their choice.
- 6.1.3. Certify and approve production units: Only apples and pears from approved production units (APUs) may be exported to the United States. Only the Italian

NPPO can certify and approve a production unit. The Italian NPPO will devise a checklist to certify that each APU meets the workplan requirements for this preclearance export program. The Italian NPPO or their ASP shall visit all prospective APUs prior to approval to examine treatment records and control practices to determine that quarantine pests, including *Leucoptera malifoliella* can be kept to non-detectable levels. Each production unit submitted for approval and for participation in the program will be identified by a unique identification number and its geographic boundaries will be delineated for the purposes of identification and traceability. Delineation of boundaries can be achieved through a written description and/or with electronic aerial photographs, such as Google Earth. APUs shall designate an APU contact person who is responsible for demonstrating to the NPPO that pest suppression guidelines have been followed. Because of the intensive inspection requirements of this program, the Italian NPPO must set up internal guidelines, **Appendix 4**, for participating APUs to follow to ensure that the pest *Leucoptera malifoliella* is kept at non-detectable levels in the APUs and on the fruit.

- 6.1.4. Maintain and submit registry of APUs to APHIS: The Italian NPPO will keep a Registry of APUs, their identification numbers, their designated APU contact, and their geographic boundaries. The Italian NPPO will make this list available to APHIS by May 15 of each season and will keep it up-to-date throughout the growing and shipping season.
- 6.1.5. Oversee surveys of APUs: In accordance with 7 CFR 319.56-22(c)(1) the Italian NPPO or their ASP, shall survey, inspect and monitor each APU at least twice between spring blossoming and harvest. A schedule for such surveys will be maintained by the Italian NPPO and updated with the progress of the surveys and results made available to APHIS. See **Appendix 1** for an outline of survey procedures.
- 6.1.6. Certify and approve the processing facilities: Apples and pears for the preclearance export program must be processed, stored and inspected in an approved processing facility (APFs). Only the Italian NPPO can certify and approve a processing facility. The Italian NPPO will devise a checklist of physical facility features and standard operating procedures to certify that each APF meets the workplan requirements for this preclearance export program. The Italian NPPO or their ASP shall visit all prospective APUs prior to approval to examine treatment records and control practices to determine that the standards are met. See **Appendix 4** for standard operating procedures for APFs. Each APF will designate a contact person who is responsible for demonstrating to the NPPO that all aspects of the standard operating procedures have been correctly followed.
- 6.1.7. Maintain and submit registry of APFs to APHIS: The Italian NPPO will keep a registry of APFs, their identification numbers, their designated APF contact, and their physical location. The NPPO will make this list available to APHIS by August 1 of each season.

- 6.1.8. Monitor packing house operations for compliance with program requirements: The Italian NPPO or their ASP will monitor packinghouse operations to ensure that the following activities are carried out adequately: verifying that only fruit from APUs are packed for the preclearance program; ensuring that the APF is complying with the provisions of its standard operating procedures; carrying out or monitoring the required phytosanitary inspections prior to packing and during packing with trained technicians; maintaining a system of APU and APF traceability, safeguarding program fruit to prevent pest infestation or comingling with non-program fruit.
- 6.1.9. Since the Italian NPPO or their ASP must be present to conduct the final pre-inspection, they can monitor the pre-inspections carried out by the APF technicians. The Italian NPPO can also monitor the selection of the preclearance sample, if that procedure is done at the APF.
- 6.1.10. The Italian NPPO or their ASP will monitor all program activities in the APF on a random and unannounced basis. Non-compliance with the provisions of this workplan or the standard operating procedures of the APF will be reported to APHIS and to the APF designated contact.
- 6.1.11. Conduct final pre-inspection prior to the official preclearance inspection: As required by 7 CFR 319.56-22(c)(1)(iii), the Italian NPPO or their ASP must conduct an inspection of every fruit in one carton from each pallet of each grower lot, prior to the official preclearance inspection. To facilitate this inspection and avoid breaking down pallets, a sequential numbering system can be used to randomly identify a carton from each pallet so that it may be removed for inspection before palletizing. This inspection can be conducted in the APF at the time of packing.
- 6.1.12. Conduct official preclearance inspection: As required by CFR 319.56-22(d), the Italian NPPO shall participate side by side with APHIS in the official preclearance inspection. The number of APHIS inspectors required will be decided by APHIS in collaboration with the NPPO and industry cooperator. See **Appendix 2** for procedures for sampling and inspection.
- 6.1.13. Maintain records and notify APFs of pest interceptions: Because there is a penalty system imposed on APUs and APFs based on quarantine pest interceptions, the Italian NPPO must keep accurate records of which pests were intercepted, the APU that produced the infested fruit, and the APF which received the infested fruit. The NPPO will inform APFs immediately when *Leucoptera malifoliella* or other quarantine pests are intercepted. Upon the third detection of *Leucoptera malifoliella*, from a single APU in a given shipping season, approval of that APU will be cancelled by the NPPO for the remainder of the shipping season.
- 6.1.14. Phytosanitary certification: The Italian NPPO will issue an official Phytosanitary Certificate for each shipment that passes all inspections and is cleared for shipment

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under the preclearance program to the United States. The Phytosanitary Certificate will include the number of the APF, and of the APU, and be completed in accordance with International Standard for Phytosanitary Measures, ISPM 12.

6.1.15. Pest identification: Technicians doing field surveys and program inspections will direct suspected program pests to the Italian NPPO or their ASP. This ASP specialist shall be recognized by the NPPO as having the expertise and authority to officially identify program pests. Records will be kept of all program-related pest identifications and specimens retained until the end of the export season.

6.1.16. Authorize phytosanitary service providers (ASP): ASP's are external organizations authorized by the Italian NPPO to perform specific phytosanitary services pursuant to this workplan, contingent on their expertise, experience, and training, **Appendix 4**. The responsibilities of the ASP may include oversight of APU pest surveys, sampling and inspection of the fruit in the final pre-inspection required by the regulation, and sampling of fruit for the official preclearance inspection. Duties can also include monitoring of activities in the APU and APF that would otherwise be done by the Italian NPPO. The ASP shall not function as a regulatory or certification body. It shall not certify and/or approve APUs and/or APFs. The ASP shall not conduct official preclearance inspections, issue phytosanitary certificates or initiate cold treatment.

6.1.17. Initiate cold treatment: The Italian NPPO will initiate cold treatment, schedule T107-a, in the maritime containers certified by USDA for this treatment.

6.1.18. Safeguard Maritime Container with APHIS Seal: Following initiation of the cold treatment the Italian NPPO will seal each maritime container with a strap seal provided by APHIS. The number of the strap seal associated with each container will be communicated to the APHIS inspector for inclusion in the PPQ Form 203.

6.2. APHIS:

6.2.1. Signatory of operational workplan and cooperative service agreement: The APHIS, Plant Protection and Quarantine (PPQ), Preclearance Staff will work cooperatively with the Italian NPPO to develop an operational workplan detailing necessary administrative, and phytosanitary measures, procedures, and tasks needed to operate this preclearance export program. APHIS will also sign the Cooperative Service Agreement with the industry cooperator recognized by the Italian NPPO.

6.2.2. Conduct preclearance inspections: As required by CFR 319.56-22(d), the APHIS preclearance inspectors shall participate side by side with the Italian NPPO inspectors in the official preclearance inspection. If an inspection unit is rejected because pests are intercepted in the preclearance inspection, no subparts of the inspection unit are eligible for re-inspection.

- 6.2.3. Monitor technical aspects of operational workplan: APHIS preclearance officers are responsible for execution of this workplan. As time permits, they should monitor all aspects of the program, including compliance by APUs and APFs. Monitoring activities may include reviewing treatment records of APUs; oversight of pre-inspections by APFs and Italian NPPO; monitoring activities of Italian NPPO employees; safeguarding and record keeping activities in the APFs, reviewing the integrity of the traceability system and if logistically possible, monitoring initiation of the cold treatment by the Italian NPPO.
- 6.2.4. Issue of preclearance inspection certificate: The APHIS preclearance inspector will complete and sign the preclearance inspection certificate, PPQ Form 203, upon verification phytosanitary requirements are met.
- 6.2.5. Providing APHIS Seals: APHIS will provide to the Italian NPPO a sufficient number of strap seals to be used to safeguard the maritime containers.

6.3. Industry cooperator:

- 6.3.1. Sign cooperative service agreement: The cooperator is a private organization recognized by the Italian NPPO. The Italian NPPO and APHIS recognize The Centro Servizi Ortofrutticoli Societa Cooperativa (CSOSC) as the industry cooperator. CSOSC is the signatory of the cooperative service agreement with USDA, and oversees certain business issues for their industry in this preclearance export program.
- 6.3.2. Fees to Italian industry: CSOSC will charge program costs to participating Italian industry organizations in an equitable, non-discriminatory and transparent manner.
- 6.3.3. Establish trust fund account: CSOSC will work with APHIS to establish a trust fund account for depositing funds from which APHIS may draw to pay for services rendered by APHIS or its representatives, including site visits of program operations and preclearance oversight activities including inspection. Site visits may be required by APHIS to initiate the preclearance program or to resolve program problems. Adequate funds must be deposited in the trust fund account in advance of services rendered by APHIS or its representatives.
- 6.3.4. Advise APHIS of resource needs: CSOSC will provide at least 30 days' notice to APHIS about the need for preclearance officers, changes in needs, or termination of shipping. In addition CSOSC will provide estimates in advance of the program about expected volumes of export, and timetables.
- 6.3.5. Provide inspection facility acceptable to the Italian NPPO and APHIS: The preclearance inspection site could be a centralized location where inspection units can be inspected and cleared. CSOSC must ensure these facilities have adequate light, inspection tables, space, communication (including telecommunication), and sanitary facilities.

- 6.3.6. Provide logistical support for preclearance officer: Provide local logistical support for preclearance officer including finding suitable lodging, providing a means of transportation and other basic needs necessary for living and working in the work area.

6.4. Approved production units (APUs):

- 6.4.1. File application with Italian NPPO requesting approval: Prospective APUs or their associated Cooperatives, shall apply directly to the Italian NPPO for approval as an APU proper for the preclearance export program. All necessary business information requested by the Italian NPPO will be included on the application. The APU must designate a point of contact responsible for demonstrating compliance with program requirements.
- 6.4.2. Demonstrate compliance with program requirements: Follow guidelines set by the Italian NPPO to ensure that the pest *Leucoptera malifoliella* is kept at non-detectable levels in the APUs and on the fruit. Maintain records of treatment schedules and pest surveys. Monitor the APU for *Leucoptera malifoliella*. Cooperate fully with Italian NPPO in performing their two required surveys of each APU for *Leucoptera malifoliella* and other quarantine pests.
- 6.4.3. Maintain system of marking for traceability and record keeping: Comply with program requirements for marking or labeling bins or boxes to indicate the APU from which the fruit was harvested. This marking system will be included in guidelines set by the Italian NPPO. Ensure that all fruit labeled as originating from an APU was actually harvested from that APU.

6.5. Approved processing facilities (APFs):

- 6.5.1. File application with Italian NPPO requesting approval: Prospective APFs will apply to the Italian NPPO, acting on behalf of the cooperator, for approval as an APF proper for the preclearance export program. All necessary business information requested by the Italian NPPO will be included on the application. The APF must designate a point of contact responsible for demonstrating compliance with program requirements. The APF must provide a list of the APUs that will supply the fruit that will be packed for the preclearance program.
- 6.5.2. Payment of program fees: A registration fee agreed to by the Italian NPPO and CSOSC will be charged to each APF requesting participation in the program. CSOSC will be responsible for collecting fees from participating APFs for services provided by APHIS.
- 6.5.3. Standard operating procedures: The APF will comply with the checklist of guidelines or standard operating procedures provided by the Italian NPPO, for packing fruit for this preclearance export program. It will include the following:

training requirements for APF technicians performing phytosanitary inspections of the apples and pears for the program; inspection guidelines for conducting the entry point inspection and the grading/packing line inspection; box marking and paperwork needed to ensure traceability of boxes to the APU of origin and the APF; safeguarding procedures for fruit to prevent co-mingling with non-program fruit; and other requirements of 7CFR 319-22. See **Appendix 4** for standard operating procedures for APF.

- 6.5.4. Accepting fruit only from APUs: The APF will only accept apples and pears from APUs that they previously listed in their application to the Italian NPPO. The APF shall corroborate the origin of fruit arriving for packing through marks and paper work and document the origin of the fruit in the APF's records.
- 6.5.5. Dedicated or disinfection packing lines: As required by 7 CFR 319.56-22(c)(3)(ii), packing lines used to sort, grade, and pack preclearance program fruit must be either dedicated to program fruit, or be washed with water or receive an equivalent treatment prior to packing of program fruit, **Appendix 4**.
- 6.5.6. Conduct initial pre-inspections prior to official preclearance inspection:
 - 6.5.6.1. First pre-inspection (entry point inspection): Prior to apples and pears entering the grading/packing line of at the APF, trained, designated technicians of the APF will inspect all fruit from one carton on every third pallet, or 80 fruit from every third field bin. All pest interceptions will immediately be reported to the Italian NPPO. Suspect pest specimens will be retained in a location and manner designated by the Italian NPPO.
 - 6.5.6.2. Second pre-inspection (grading/packing line inspection) - The APF will establish two points (inspection stations) along the packing line. All suspect fruit passing that point will be inspected for pests. Periodically, the technicians will select fruit from the packing line and inspect the calyx and stem ends carefully. All pest interceptions will immediately be reported to the Italian NPPO. Suspect pest specimens will be retained in a location and manner designated by the Italian NPPO.
- 6.5.7. Select fruit for official preclearance inspection: If the official preclearance inspection is conducted offsite from the APF, the technicians of the APF will select the boxes for the official sample, prior to commercial palletization. The interval between boxes selected for sampling will be determined by the Italian NPPO and/or APHIS, prior to the start of sampling, as described in **Appendix 2**. The sampled boxes will be placed on a separate pallet and sent to the remote inspection station.
- 6.5.8. Safeguard program fruit: Fruit from the preclearance export program will probably be stored in cold rooms for a period before packing. During this time the fruit must be placed in a clearly designated space and be safeguarded to prevent

mixing with non-program fruit and be readily identifiable as preclearance program fruit.

6.5.9. Traceability of fruit: Apple or pear boxes presented for preclearance inspection must be marked with an identifiable grower lot identification number, which are traceable to the APU where they were harvested as well as the APF. This identity must be maintained until the fruit arrives in the United States.

6.6. Authorized service providers (ASPs):

6.6.1. Meet the standards and competencies specified by the Italian NPPO in **Appendix 4**.

6.6.2. Enter into agreement with the NPPO to deliver specific phytosanitary services according to standards in **Appendix 4**:

6.6.3. Survey APU's according to standards in this workplan and Appendix 2: Document and report field observations according to standard protocols.

6.6.4. Conduct preliminary inspections of apples and pears at APFs according to standards in this workplan: Document and reports inspection results according to standard protocols.

6.6.5. Monitor compliance with phytosanitary procedures as specified in the workplan according to standards in **Appendix 4**: Document and report non-compliances in a timely manner to Italian NPPO and APHIS for taking appropriate actions.

7. Phytosanitary measures, procedures, and inspection procedures:

For many of the activities and responsibilities described in the previous sections, the participants have leeway in mutually deciding how they will be carried out. Following are specific instructions or descriptions of the operational procedures and protocols required by APHIS for the preclearance export program for apples and pears from Italy.

7.1. **APU Surveys:** Two surveys are required in each APU between blossom and harvest. The first survey is to be carried out after the flowering and the second survey two to three weeks before to harvest. The Italian NPPO or their ASP has responsibility for conducting these surveys and collecting samples according to the protocol described in **Appendix 1**. Since the primary pest, *Leucoptera malifoliella* is best detected in the larval or pupal stage, the survey procedures will rely on leaf and fruit inspection. Procedures for taking samples are in **Appendix 1**. If *Leucoptera malifoliella* is detected in an APU, that APU cannot export fruit to the United States for the remainder of that growing season. If the Italian NPPO or their APS finds *Grapholita (syn. Cydia) funebrana*, *Adoxophyes orana*; or *Argyrotaenia ijungiana* (syn. *A. pulchellana*) in an APU registered in this program, that APU and apple and pears in commercial APUs within 1

kilometer will be treated by a pesticide approved by APHIS or the infested APU cannot export its fruit to the United States for the remainder of that growing season.

- 7.2. **APF entry point inspection:** There will be three pre-inspections required in the APF prior to the official preclearance inspection. The first pre-inspection is done prior to entering the grading/packing line. If the fruit is arriving from the field for direct packing, then this inspection is done at the point when the fruit enters the APF. If the fruit is coming from cold storage, then this inspection is done prior to entering the packing line. Fruit may be kept in cold storage at a facility other than the APF prior to arrival at the APF for processing and packing.
 - 7.2.1. The two purposes for entry point inspection are to find quarantine pests and to verify that the fruit originated from an APU. This inspection is performed by APF technicians trained in both tasks, and identified in the standard operating procedures agreed upon with the Italian NPPO. APF entry point inspection will be monitored by the Italian NPPO or their ASP on a random and unannounced basis. The Italian NPPO will also be responsible for checking that the technicians were adequately trained and their inspections were well performed.
 - 7.2.2. The technicians will inspect all fruit in one carton on every third pallet, or at least 80 fruit in every third field bin (if the fruit is not in cartons), for each grower lot (all fruit delivered for processing from a single APU at a given time). Each grower lot will be designated as “accepted” or “rejected” and the basis for any rejections recorded. Complete records on all grower lots presented will be reported to the Italian NPPO, which will maintain and compile these records.
- 7.3. **Safeguarding fruit in storage prior to processing and packing:** Preclearance program fruit placed in cold storage prior to processing and packaging must be located in clearly designated areas to prevent mixing with non-program fruit. The Italian NPPO or their ASP will monitor preclearance program fruit in cold storage and ensure safeguarding requirements are met.
- 7.4. **APF grading/packing line inspection:** The second pre-inspection takes place while the fruit is in line to be graded and packed. The APF must establish two inspection stations along the grading/packing line. Trained APF technicians will periodically pull passing fruit off the line and inspect it for quarantine pests. In particular the technicians will look for *Leucoptera malifoliella* in the calyx and stem ends of the fruit. Pest interceptions will be reported immediately to the Italian NPPO. Suspect pest specimens will be retained in a location and manner designated by the Italian NPPO.
- 7.5. **Dedicated or cleaned grading/packing lines:** The grading/packing line must be dedicated to fruit in the preclearance program, or the line must be washed with water or receive an equivalent treatment prior to grading/packing the preclearance program fruit.
- 7.6. **Third pre-inspection prior to official preclearance inspection:** Prior to the official preclearance inspection, the Italian NPPO or their ASP must conduct an inspection of

every fruit in one carton from each pallet. To facilitate this inspection and avoid breaking down pallets, a sequential numbering system can be used to randomly identify a carton from each pallet so that it may be removed for inspection before palletizing.

- 7.7. **Official preclearance inspection:** Preclearance inspection will be conducted on an inspection unit consisting of a minimum of 1,000 cartons of apples or pears. The cartons examined during any given preclearance inspection will be called an inspection unit. The sample size for the inspection unit will be determined according to the hypergeometric distribution in ISPM 31, Methodologies for Sampling of Consignments, using a two percent level of detection tolerance and 95% confidence level. For example, the sample size for a 1000 carton inspection unit is 138 cartons, **Appendix 2**.

Because the inspection units are so large, they may include multiple grower lots from different APFs that have been aggregated for this preclearance inspection and shipment. For this reason, the site of the Preclearance inspections should be centrally located. APHIS and the Italian NPPO will perform side by side inspection.

Preclearance inspectors will inspect biometrically selected samples using the protocol in **Appendix 2**. The complete inspection unit will be presented for inspection and approval before shipment. Because there is a penalty system imposed on APUs and APFs based on quarantine pest interceptions, the Italian NPPO must keep accurate records of which pests were intercepted, the APU that produced the infested fruit, and the APF which received the infested fruit. The NPPO will inform APFS immediately when *Leucoptera malifoliella* or other quarantine pests are intercepted.

- 7.8. **Pest identification and viability:** Technicians doing field surveys and program inspections will direct suspected program pests to the Italian NPPO or their ASP. This specialist should be recognized by the NPPO as having the expertise and authority to officially identify program pests. Technicians shall have an opportunity to determine the viability of intercepted specimens using criteria in **Appendix 3**. APHIS shall make the final determination of specimen viability. Records will be kept of all program-related pest identifications and specimens retained until the end of the export season.
- 7.9. **Cold treatment:** The Italian NPPO will initiate cold treatment, Schedule T107-a, in maritime containers certified by USDA for this treatment.
- 7.10. **Safeguard maritime container with official APHIS seal:** Following initiation of the cold treatment the Italian NPPO will seal each maritime container with a strap seal provided by APHIS. The number of the strap seal associated with each container will be communicated to the APHIS inspector for inclusion in the PPQ Form 203.

8. Auditing:

- 8.1. **APHIS** will conduct a preliminary site assessment to determine program feasibility and inform the development of this workplan. The frequency of subsequent program assessment and auditing will be determined by phytosanitary performance. All expenses incurred resulting from program and assessment and auditing shall be paid for by the cooperator through the program trust fund account.
- 8.2. **USDA APHIS PPQ and the Department of Homeland Security (DHS)** are responsible for confirming that cold treatment was properly applied by examination of vessel records and verifying cold treatment efficacy by a standard sampling and inspection protocol for each cold treated consignment. Furthermore, DHS reserves the option to inspect any shipment by way random and sometimes targeted inspections upon arrival at the port of entry.

9. Documentation, labeling and marking:

- 9.1. **Traceability of boxes arriving at APFs:** Bins or boxes of apples or pears intended for export to the United States must have marks that identify the APU from which they were harvested.
- 9.2. **Traceability of packed fruit:** Apple or pear boxes presented for preclearance inspection must be marked with an identifiable lot identification number, which will be traceable to the APU where they were harvested as well as the APF. This identity must be maintained until the fruit arrives in the United States.
- 9.3. **Phytosanitary certification:** The Italian NPPO will issue an official Phytosanitary Certificate for each shipment that passes all inspections and is approved for shipment under the preclearance program to the United States. The Phytosanitary Certificate will include the number of the APF and of the APU and be completed in accordance with the International Standard for Phytosanitary Measures #12.
- 9.4. **PPQ form 203:** The APHIS Preclearance inspector will complete and sign the preclearance inspection document, PPQ Form 203.
- 9.5. **Official seal:** APHIS will provide the Italian NPPO with an adequate supply of official APHIS strap seals. The Italian NPPO will apply the strap seal to the container after initiation of cold treatment for export.

10. Non-compliance and resulting actions:

- 10.1. **Penalties for pests detected in APU surveys:** If *Leucoptera malifoliella* is detected by the Italian NPPO or their ASP in an APU, that APU cannot export fruit to the United States for that growing season. If the NPPO finds *Cydia funebrana*, *Adoxophyes orana*, or *Argyrotaenia pulchellana*, in an APU registered in this program, that APU and apple and pears commercial APUs within 1 kilometer will be treated by a pesticide approved by APHIS or the infested APU cannot send its fruit from that growing season to the United States.

- 10.2. **Penalties for pests intercepted in pre-inspections, prior to the preclearance inspection:** If *Leucoptera malifoliella* is intercepted in any of the three pre-inspections, the grower lot will be rejected and the APU from which the fruit was harvested will be prohibited to ship fruit to the United States for the remainder of the shipping season. Detection of other quarantine pests would require rejection only for that grower lot.
- 10.3. **Penalties for pests intercepted in the official preclearance inspection:** If *Leucoptera malifoliella* is intercepted in the preclearance inspection, the entire inspection unit will be rejected. Only the APU from which the infested fruit was harvested will be prohibited from shipping to the United States for the remainder of the shipping season. Other APUs represented in the rejected Inspection Unit will NOT be affected because of this rejection. If other quarantine pests are intercepted in the Inspection Unit, the entire Inspection Unit will be rejected. There can be no reconditioning of a rejected inspectional unit.
- 10.4. **If three inspection units are rejected from an APU for *Leucoptera malifoliella*** in a shipping season, then that packing house is suspended from packing for this program for the remainder of that shipping season.
- 10.5. **The export program will be terminated** for the remainder of the shipping season if rejection rates for *Leucoptera malifoliella* reach any of the following levels:
- 10.5.1. Five inspection units in sequence among inspection units 1–20, or a total of 8 or more of the inspection units 1–20;
 - 10.5.2. Five inspection units in sequence among inspection units 21–40, or a total of 10 or more of the inspection units 1–40;
 - 10.5.3. Five inspection units in sequence among inspection units 41–60, or a total of 12 or more of the inspection units 1–60;
 - 10.5.4. Five inspection units in sequence among inspection units 61–80, or a total of 14 or more of the inspection units 1–80;
 - 10.5.5. Five inspection units in sequence among inspection units 81–100, or a total of 16 or more of the inspection units 1–100;
 - 10.5.6. Five inspection units in sequence among inspection units 101–120, or a total of 18 or more of the inspection units 1–120.
 - 10.5.7. The sequence above can be continued in increments of 20 inspection units by increasing the number of rejected inspection units by 2.
- 10.6. **Termination because of findings of other plant pests:**

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10.6.1. The preclearance program will be terminated with Italy when, in one shipping season, inspection units are rejected because of other insect pests as follows:

10.6.1.1. Ten or more of the inspection units 1-20;

10.6.1.2. Fifteen or more of the inspection units 1-40;

10.6.1.3. Twenty or more of the inspection units 1-60;

10.6.1.4. Twenty-five or more of the inspection units 1-80;

10.6.1.5. Thirty or more of the inspection units 1-100; or

10.6.1.6. Thirty-five or more of the inspection units 1-120.

10.6.1.7. The sequence above can be continued in increments of 20 inspection units by increasing the number of rejected inspection units by 5.

11. Duration and review:

Procedures herein established are subject to revision as situations warrant; however they will remain in effect until revised by mutual agreement (appendices may be updated each season).

12. Amendment Record:

12.1. **Amendments to this workplan** will be given a consecutive number, dated, and filed with APHIS Headquarters in Riverdale, MD. Amendments will be documented in the workplan by recording updates in the amendment table.

12.2. Amendment table

Version	Amendment Content, Pages, and Sections	Entered by	Date:
1.0	Final, signed by USDA 9/10/13	USDA	09/10/13

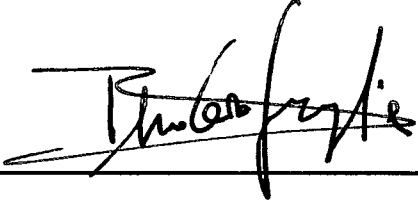
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13. Effective date:

This work plan is effective upon signature by the Italian Ministry of Agriculture, Food, and Forestry Policies and USDA APHIS.

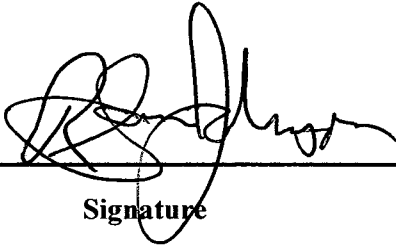
Italian Ministry of Agriculture, Food, and Forestry Policies



Signature

Date

USDA APHIS



Signature

9/10/13

Date

Appendix 1. APU survey protocol:

The National Plant Protection Organization (NPPO) of Italy, or their authorized service provider (ASP), must survey each APU registered in this export program twice between spring blossom and harvest. The second survey will be done two to three weeks prior to harvest. If *Leucoptera malifoliella* is detected in an APU, that APU cannot export fruit to the United States from that year's production. If the NPPO or their approved representative finds *Grapholita (syn. Cydia) funebrana*; summer fruit tortrix moth, *Adoxophyes orana*; or grape tortrix, *Argyrotaenia iungiana (syn. A. pulchellana)* in an APU registered in this program, that APU and commercial apple and pears APUs within 1 kilometer will be treated by a pesticide approved by APHIS or the infested APU cannot send its fruit to the United States.

Since the primary pest, *Leucoptera malifoliella* is best detected in the larval and pupal stages to determine if an APU is infested, the survey procedures will rely on leaf and fruit inspection.

Leucoptera malifoliella has about three generations per growing season and the larva feed on the leaves. The larvae create blister-like mines in the upper layer of the infested leaf. The small pupae are yellow or brown and are found in a white cocoon. The larvae pupate on the leaves (mainly first generation) and later on the bark, plant debris or on the calyx or stem ends of the fruit.

Grapholita (syn. Cydia) funebrana attacks the fruit during the growing season causing damage similar to the codling moth. Its normal hosts are plums and other stone fruit and rarely attacks apples or pears.

Adoxophyes orana attacks the flower, leaf and fruit during the growing season. This leaf roller spins webs and is easily found through external inspection.

Argyrotaenia iungiana (syn. pulchellana) attacks the leaf and may also feed on the bud or fruit of its host. This leaf roller both skeletonizes the underside of the leaf and creates folds on the leaf. It is also detected through external inspection.

First Survey - Since the first generation of *Leucoptera malifoliella* larvae and pupae are associated most commonly with the leaves, the first survey is composed of leaf samples. The biometric samples will consist of:

1. Selecting 25 trees from each APU. The first 12 of these trees are from the perimeter of the APU each about equidistant from each other, three trees each from the north, east, south and west sides and these should be from either the 2nd or 3rd row from the outside. The other 13 trees should be selected from a diagonal line through the production APU, also about equidistant apart.
2. From each of the 25 trees blindly (without bias) select 12 leaves, three each from the north, east, south and west sides.

Second Survey - The second survey will consist of:

1. A leaf survey conducted the same as above.
2. From each of the 25 trees select 4 fruits, from each side of the trees.

A hand lens should be used during the surveys. If potential quarantine pests are observed, the infested fruit and leaf samples should be collected. If no pests are detected, the leaves and fruit can remain attached to the tree (not collected). The identification of the pest is the responsibility of the NPPO.

The two leaf surveys each provide about a 95% confidence level of detecting a 1.0% infestation level for leaves for the various pests of concern at that APU. The fruit survey provides about a 95% confidence level of detecting a 3.0% infestation level for fruit for the various pests of concern.

Appendix 2. Protocols for selecting export cartons for inspection:

Third pre-inspection prior to official preclearance inspection: The Italian NPPO or their ASP must conduct an inspection of every fruit from one carton per pallet, prior to the official preclearance inspection. To facilitate this inspection and avoid breaking down pallets, this inspection can take place at the APF at the end of the packing line. At the end of the packing line the APF employee generally pulls the packed cartons off the packing line and places them on a pallet in order to build the palletized units for shipment. During this process the inspector can select one carton from each incomplete pallet and inspect all the fruit from the carton. The APF shall provide an inspection table of adequate size with good lighting in a safe area for this inspection.

Official preclearance inspection: Preclearance inspection will be conducted on an inspection unit consisting of a minimum of 1,000 cartons of apples or pears. The cartons examined during any given preclearance inspection will be called an inspection unit. The sample size for the inspection unit will be determined according to the hypergeometric distribution in ISPM 31, Methodologies for Sampling of Consignments, using a two percent level of detection tolerance and 95% confidence level. For example, the sample size for a 1000 carton inspection unit is 138 cartons. To facilitate this inspection and avoid breaking down pallets, a systematic sampling system can be used to randomly identify the required number of cartons for inspection before palletizing at the APF. Systematic sampling involves drawing samples (carton) from an inspectional unit at fixed, predetermined intervals. However, the first carton selection must be made at random. The procedures are as follows:

1. Selecting the inspection unit sample where all the grower lots are from the same APF:
 - a. The APF establishes the number of cartons in the preclearance inspection unit (PIU), e. g. The APF selects 1008 as the PIU size which is 24 pallets of 42 cartons for this example.
 - b. Using ISPM 31 hypergeometric distribution, Table 1, two percent level of detection tolerance and 95% confidence level, a sample size of 138 cartons is required.
 - c. To determine the inspection interval, divide the PIU by the sample size. The dividend in this case is 7.3 (e. g. $1008/138 = 7.3$). Round to nearest whole number, in this case 7 is the interval for this PIU. In other cases, the nearest whole number may be the next higher one.
 - d. To select the first carton for the sample, randomly select a number between 1 and the interval size (number 7 in the above example). The randomly selected number will be used to select the first carton for the inspectional sample. For example if the random number is 3, the 3rd carton arriving at the end of the packing line would be part of the sample to be inspected. This is the number of the first carton to be selected for inspection. To select the random number you can use a computer program, a web site or random number tables.

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- i. <http://www.random.org/> and <http://www.randomnumbergenerator.com/> are two web sites that will generate random numbers. Set the generator between 1 and your interval number.
- e. To determine the second carton, add the sampling interval (7) to the first carton number (3): $7 + 3 = 10$; thus 10 is then the number of the second carton. To determine the third carton, add the sampling interval (7) to the second carton number (10): $7 + 10 = 17$; thus 17 is the number of the third carton. Continue this process.
- f. In the case of larger inspection unit and consequently larger sample size (see b above) the system will be properly calculated.

The sample cartons should be numbered as each is selected. The number should reflect the sample interval. In the above example the cartons would be numbered 3, 10, 17, etc. There is no additional numbering required for non-sampled cartons from the consignment. The numbered sample cartons should be placed on a separate pallet (each grower lot on a separate pallet), clearly identified as inspectional samples. These cartons should not be opened until the official preclearance inspection. Even if the grower lots are not processed on the packing line one after another (e. g. the third lot is processed two days later) the same random number can be used.

The selection of the cartons to be inspected needs to be supervised by the Italian NPPO or their ASP. The third pre-inspection discussed above can be conducted at the same time as the official sample is taken, thus the Italian NPPO or their ASP can inspect the one carton per pallet and supervise the selection of the official sample. The Italian NPPO or their ASP does not open and/or inspect any of the selected sample cartons for the official preclearance inspection until the entire inspection unit is assembled and presented for inspection. Only the Italian NPPO is authorized to perform the official preclearance inspection alongside the APHIS inspector.

If a grower lot is rejected during the third pre-inspection, a substitute grower lot of the same size needs to be added to the PIU and the sample cartons selected using the same interval.

After the above procedures, the PIU including the inspection samples need to be safeguarded until they are exported. Only the sample needs to be transported to the preclearance inspection site.

2. Selecting the inspection sample for consignments consisting of fruit from two or more APFs:

On condition the PIU is no less than 1000 cartons, industry establishes the number of cartons in the preclearance inspection unit (PIU) and the number of cartons each APF contributes. The sample interval is determined in the same manner as in section 1, by dividing the sample size from the ISPM hypergeometric distribution table into the

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number of cartons in the PIU. Each APF selects the first carton by using a random number as in section 1. The rest of the procedure is the same as above.

3. After sample cartons pass inspection, industry can incorporate back into the PIU, save for a future US export, or not export to the United States.

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Table 1: Table of minimum sample sizes for 95% and 99% confidence levels at varying levels of detection according to lotsize, hypergeometric distribution

Number of units in lot	P = 95%(confidence level)					P = 99%(confidence level)				
	%level of detection × efficacy of detection					%level of detection × efficacy of detection				
	5	2	1	0.5	0.1	5	2	1	0.5	0.1
25	24*	-	-	-	-	25*	-	-	-	-
50	39*	48	-	-	-	45*	50	-	-	-
100	45	78	95	-	-	59	90	99	-	-
200	51	105	155	190	-	73	136	180	198	-
300	54	117	189	285*	-	78	160	235	297*	-
400	55	124	211	311	-	81	174	273	360	-
500	56	129	225	388*	-	83	183	300	450*	-
600	56	132	235	379	-	84	190	321	470	-
700	57	134	243	442*	-	85	195	336	549*	-
800	57	136	249	421	-	85	199	349	546	-
900	57	137	254	474*	-	86	202	359	615*	-
1 000	57	138	258	450	950	86	204	368	601	990
2 000	58	143	277	517	1553	88	216	410	737	1800
3 000	58	145	284	542	1895	89	220	425	792	2353
4 000	58	146	288	558	2108	89	222	433	821	2735
5 000	59	147	290	564	2253	89	223	438	840	3009
6 000	59	147	291	569	2358	90	224	442	852	3214
7 000	59	147	292	573	2437	90	225	444	861	3373
8 000	59	147	293	576	2498	90	225	446	868	3500
9 000	59	148	294	579	2548	90	226	447	874	3604
10 000	59	148	294	581	2588	90	226	448	878	3689
20 000	59	148	296	589	2781	90	227	453	898	4112
30 000	59	148	297	592	2850	90	228	455	905	4268
40 000	59	149	297	594	2885	90	228	456	909	4348
50 000	59	149	298	595	2907	90	228	457	911	4398
60 000	59	149	298	595	2921	90	228	457	912	4431
70 000	59	149	298	596	2932	90	228	457	913	4455
80 000	59	149	298	596	2939	90	228	457	914	4473
90 000	59	149	298	596	2945	90	228	458	915	4488
100 000	59	149	298	596	2950	90	228	458	915	4499
200 000+	59	149	298	597	2972	90	228	458	917	4551

Values in Table 1 marked with an asterisk (*) have been rounded down to a whole number because scenarios resulting in a fraction of a unit being infested (for example, 300 units with 0.5% infestation corresponds to 1.5 infested units in the shipment) are not possible. This means that the sampling intensity increases slightly, and may be greater for a shipment size where the number of infested units is rounded down than for a larger shipment where a larger number of infested units are calculated (for example, compare results for 700 and 800 units in the lot). It also means that a slightly lower proportion of infested units might be detected than the proportion indicated by the table, or that such infestation is more likely to be detected than the confidence level shown.

Values in Table 1 marked with a dash (-) refer to scenarios presented that are not possible (less than one unit infested).

Appendix 3. Criteria to help determine if the intercepted lepidopterous pests are alive or dead:

Using these guidelines, the APHIS inspector will determine if the insect specimen is alive or dead. The decision of the APHIS inspector is final.

The larvae and pupae of *Leucoptera malifoliella* and the other lepidopterous pests of concern arriving directly from the production sites can be parasitized at the 20% level. In addition, pests found on fruit that has been in cold storage for any length of time are subject to mortality. For example, cold storage for 40 days at 0° C is used as a quarantine treatment for oriental fruit moth, *Grapholita molesta* with apples. If these stored fruit are under controlled atmosphere the mortality can be expected to be even higher. For these reasons, it is important to determine if the pest detected in the packing shed inspections or during the preclearance inspection are alive or dead.

1. Quarantine action is unnecessary if the pests detected during these inspections are dead. If the intercepted larvae and pupae come from cold fruit (fruit from cold storage or directly from the farm during cold weather) the pest should be warmed up so you can see the pest move.
2. Place the pest in a clean dry vial and elevate the temperature to approximately 20-25⁰ C;
3. Use a hand lens to observe movement as you gently probe the specimen with an instrument such as an insect pin or toothpick;
4. Gently depress the body of the intercepted specimen to determine if the exoskeleton is hard (brittle) or soft (fleshy). The body walls of live moth larvae are soft and the body walls of pupae are fairly soft. The wall of either should be pliable/flexible if they are alive.

Appendix 4. Operational manual of standard operating procedures (SOPs):

The Operational Manual precisely describes the standard operating procedures (SOPs) for the implementation of various competencies and is divided into the following ten sections:

- I. Procedures to identify and authorize the phytosanitary service provider
- II. Authorized service provider (ASP) competencies
- III. Procedures to certify and approve production units for participation in the preclearance program
- IV. Phytosanitary measures for approved production units (APUs)
- V. Procedures to certify and approve processing/packing facilities for participation in the preclearance program
- VI. Transportation, storage, selection, processing/packaging and phytosanitary measures for approved processing facilities (APFs)
- VII. Inspection and certification of fruit
- VIII. Phytosanitary certificate and other documents
- IX. Non-compliance and corrective actions
- X. Pre-cooling, cold treatment and official seals
- XI. Duration and review

I. Procedures to identify and authorize the phytosanitary service provider:

The National Phytosanitary Service or the Regional Phytosanitary Services shall identify and authorize the phytosanitary service provider through a specific executive decision of the Phytosanitary Service's Supervisor. Once identified, the prospective service provider shall sign an agreement with the Italian NPPO. To remain authorized, authorized service provider (ASP) must comply with the requirements of the Regional Phytosanitary Service while carrying out all phytosanitary services.

To become authorized, the prospective service provider must fulfill the following requirements:

- a. Availability of technical staff with specific training in the field of pest management and in the recognition of pests of apple and pear trees;

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- b. Be included among the authorities of the Regions or Autonomous Provinces for the provision of technical advisory services to fruit processors;
- c. The prospective technicians must possess the requirements of impartiality with respect to the APU or APF. Technicians and inspectors cannot inspect an APU or an APF that is managed or owned by people to whom they are related or with whom they share financial interests;
- d. The authorized technicians must possess High School Diploma or Degree in the field of agriculture or an equivalent qualification and have gained at least five years of experience in scientific and technical frameworks operating in the phytosanitary field or Technical Consultancy;
- e. In cases where the prospective service provider is an organization, the organization shall report the names of the prospective technicians that will perform the phytosanitary service in the APU and APF to the Regional PPO and to the Cooperator.

The ASP can make field inspections within an Approved Production Unit (APU), in an Approved Processing/packing facility (APF) and can cooperate with the preclearance inspection, complying with the provisions of the OWP and of this SOP Operational Manual. The reports of the field activities and memorandum will be sent to the Regional Phytosanitary Service of MiPAAF.

Procedures for various phytosanitary services

- a. Survey and monitoring of APUs and APFs can be executed by ASP technicians;
- b. Phytosanitary measures shall be executed according with the procedures described in the workplan and in this manual; the results of said phytosanitary measures shall be recorded through a specific approved form by the Phytosanitary Service (attachment 1);
- c. In case of serious non-compliances, which can result in the exclusion of an APU from the preclearance program, these non-compliances have to be reported immediately to the responsible Regional Phytosanitary Service;
- d. The reports shall be filed and sent by e-mail to the relevant Regional Plant Protection Service by the day after or at least within five days from the field activity, so that it can be transmitted to the Central Plant Protection Service.

II. ASP Competencies:

ASP technicians must have specific knowledge in the following subjects:

- a. Recognition of quarantine insects and the symptoms their presence causes;

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- b. Knowledge of the OWP and of the procedures defined in this "Operational Manual" (SOP);
- c. Knowledge of the integrated production system;
- d. Procedures for phytosanitary measures in the APU;
- e. Procedures for phytosanitary measures in APF;
- f. Procedures of reporting;
- g. Appropriate actions based on inspection results;
- h. Traceability.

III. Procedures to certify and approve production units for participation in the preclearance program:

To participate in the export program, prospective production units shall apply to the Italian NPPO. To certify and approve prospective production units applying for participation in the export program, the NPPO shall use check list, Attachment 2, to verify that necessary phytosanitary requirements are met. Only the Italian NPPO can certify and approve production units. Recognition shall be granted by specific Executive Decision of the Supervisor of the relevant MiPAAF Regional Phytosanitary Service. By 15th May 2013, the National Phytosanitary Service will send to APHIS the list of the Approved Production Units.

To meet the certification requirements and be approved by the Italian NPPO for participation in the preclearance program, the prospective production unit must:

- a. Be enrolled in the "integrated production" program made in accordance with the "National Quality System of Integrated Production";
- b. In the case of production units consisting of several contiguous sub-units, each sub-unit must be enrolled in the "integrated production" program made in accordance with the "National Quality System of Integrated production";
- c. In the case of productions units or production sub-units associated in Consortia or operatives, the participation in the program may take place through the Consortium or Cooperative membership;
- d. Be identifiable through clearly defined boundaries using an aerial photograph systems such as Google maps;
- e. Be identified with a unique number which defines the location at regional and/or provincial level;

- f. Provide adequate warranties for the traceability of the product;
- g. In the case of production units certified for European (PDO/PGI, Organic), National (NSQIP), Regional or Provincial quality systems that require traceability, the traceability requirement is automatically met;
- h. Maintain a system of record keeping for all controls and treatments performed;
- i. The managers of the production units or sub-units must have the proper technical expertise or prove to be members of a system of technical advice;
- j. In the case in which the production units or production sub-units are parts of producers' organizations recognized by the State according to the provisions of the EC Regulation 1234/2007 (OCM), the technical expertise requirement is automatically met;
- k. Each production unit has to indicate a contact person. The contact person may perform the same role for more than one production unit;
- l. The "contact person" must have proven experience in the phytosanitary sector, in the "Integrated Production" and, in case of production units belonging to Cooperatives or Consortia, the contact person must demonstrate his/her knowledge of traceability's procedures implemented by the Cooperative or Consortium.

IV. Phytosanitary measures for approved production units (APUs):

The workplan stipulates how the Italian NPPO ensures the absence of detectable *Leucoptera malifoliella*, *Grapholita (Cydia) funebrana*, *Adoxophies orana* and *Argyrotaenia pulchellana*.

Non-detectable levels of *Leucoptera malifoliella* must be guaranteed through adequate monitoring activities. Any preventive treatments if required must be certified using at least two official field surveys during the growing season. The first survey is to be carried out after the flowering and two to three weeks prior to harvest under the supervision of the Regional Phytosanitary Services.

The absence of detectable *Grapholita (Cydia) funebrana*, *Adoxophies orana* and *Argyrotaenia pulchellana* must be guaranteed through adequate monitoring activities, any preventive treatments or focused treatments pursuant to the United States Code of Federal Regulations 7 CFR 319.56-22 (c) (1) and has to be certified using at least two field official inspections during the growing season, to be carried out after the flowering and before harvest under the supervision of the Regional Phytosanitary Services.

The "contact person" of each APU will have to guarantee and demonstrate the observance of the provisions of this "Operational Manual" with regard to the proper execution of any

treatment provided for the control of quarantine pests. A well maintained Field Activity Notebook is mandatory for the members of the "National Quality System of Integrated Production" and can be used as a document controls and treatments.

The Regional Phytosanitary Services of MiPAAF will supervise the ASP activities and will spot-check orchards registered in the official list of Approved production Units.

For the implementation of inspection activities, the ASP technician in charge has to respect the provisions in the "Instructions for Field Inspections" (Attachment 3) and has to use standard inspection report (Attachment 4).

V. Procedures to certify and approve processing/packing facilities (APF) for participation in the preclearance program:

To participate in the export program, prospective processing/packing facilities shall apply to the Italian NPPO. To certify and approve prospective processing/packing facilities applying for participation in the export program, the Italian NPPO shall use check list (Attachment 5), to verify that necessary phytosanitary requirements are met. Only the Italian NPPO can certify and approve processing/packing facilities. Recognition shall be granted by specific Executive Decision of the Supervisor of the relevant MiPAAF Regional Phytosanitary Service.

Before each marketing campaign, the competent Regional Phytosanitary Service will verify the eligibility requirements of the processing/packing facilities included in an official list submitted annually to APHIS by the National Phytosanitary Service. The list of Approved Processing/packing Facilities will be submitted to APHIS by the 1st of August 2013. In particular the competent Phytosanitary Service or the ASP will ensure that the packing facilities comply with the following parameters:

- a. Facilities' cleaning and disinfection;
- b. Appropriate storage chambers for fruit stocking, in good conditions of temperature and modified atmosphere;
- c. Existence of proper selecting line for fruit selection or pre-selection;
- d. Ability to dedicate a specific line for the selection and packaging of program fruit;
- e. Proper controls to prevent harmful organisms from causing re-infestations e.g. insect nets on the windows automatic doors or rubber or air barriers at the plants' entrance or at the entrance of the plant's section used for the preclearance program controls;
- f. Implementation of a system that guarantees the traceability in the APU and APF of program fruit;

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- g. Each APF has to indicate a "contact person". The same person may perform the same role for more than one APF;
- h. The "contact person" must have proven experience in the phytosanitary sector, in the integrated production, about the fruit conservation and selection procedures:
- i. In the case of Production Units and APS belonging to Cooperatives or Consortia, the contact person has to demonstrate his/her knowledge of traceability procedures implemented by the Cooperative or Consortium. The "contact person" has to guarantee and demonstrate the right implementation of the procedures of this operational manual.

VI. Transportation, storage, selection, processing/packaging and phytosanitary measures for approved processing facilities (APF):

a. Transportation

Each bin or box with the fruit coming from the APU must be identified in the field and at the time of delivery and marked with a label with a specific barcode encoding the following information:

- The Name of the delivering producer;
- The Date of delivery;
- Fruit Variety;
- Fruit Quality;
- The APU and subunit when applicable;
- The APF where initial grading of fruit takes place, when applicable;
- The APF where final grading, packing and official inspection will take place.

All fruit must be accompanied by a document signed by the technician listed in the APU registration declaring all the information stated above. In addition this document must declare the quantity of fruit being transported.

If the final grading, packing and official inspection of fruit is performed in a shed other than the one used for initial grading and storage transportation must take place by means of conveyance cleaned, closed with appropriate doors, and used only for the transportation of fruits to USA, in order to eliminate the possibility of contact with other lots of fruit.

During activities involving loading and unloading operations must be done in area used exclusively for program fruit.

b. Fruit Storage

The storage of apples and pears for the USA market will have to take place in rooms specifically identified and registered so as to guarantee the best preservation of fruits. The

registration can be manual or automatic. The storage will take place in cold storage rooms in optimal conditions of temperature and modified atmosphere.

The bins or boxes with fruit destined to the US market will have to be separated from bins with fruits with other destinations. The separation can take place by placing the bins in homogeneous stacks or by positioning the bins in the upper part of the cell, or any other arrangement that allows the precise identification of the product intended for export in the USA.

The selection, pre-selection and/or packaging and storage may take place in the same APF or in a specially approved facility. Only the Italian NPPO may approve the facility.

c. Fruit Selection

Sizing and selection of the fruits must be carried out under the supervision of the competent staff identified by the APS or the competent Regional Phytosanitary Service or ASP technician.

The bins of apples and pears have to be taken from the storage rooms and placed in the selecting or pre-selecting line while keeping the distinction among the different APUs of origin.

The fruit will be selected at least for variety, color, homogeneous category by size or weight, and for any possible defects. The international standard of reference is the UNECE FFV-50 standard.

At the end of the processing cycle the fruits from each APU will be re-placed in bins on which a label will be tagged, showing at least:

- Processing date;
- Variety;
- Category;
- APU or sub-unit of origin.

In the case of automated traceability, information will be available by a bar code; in case of manual system, information will be reported on a special label and recorded in a special register available for inspection.

d. Processing/packaging and phytosanitary measures

The processing and packaging operations have to be done under the supervision of the competent staff identified by the APF or the competent Regional Phytosanitary Service or ASP technician.

Processing and packaging area near to the selection line has to be cleaned, well identified and temporarily delimited from other processing areas. In this specific area only the fruits

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from an APU that have passed the necessary field surveys will be inspected and processed.

While waiting for processing or for loading into the sealed containers to the US, the storage will take place in identified, conditioned, closed and separated rooms.

The lots to be exported to the US must be separately processed from the other lots of fruits not destined to USA and, in each phase of the process, the full traceability (from the APU of origin) must be guaranteed. The fruit processing and selection have to be performed by specially trained staff which knows how to process, how to detect and identify the signs, symptoms caused by the presence of quarantine pests, and how to act in this case.

Crop residues, such as leaves, twigs or earth must be removed from packaging shipments destined to the United States.

The selected or preselected fruits will be placed for packaging on a properly cleaned (with water and/or compressed air) processing line, separated from other processing lines and temporarily dedicated exclusively to the processing of program fruit.

Along the processing line, the second pre-inspection will take place, in accordance with the workplan and section VII.b of this manual. Each fruit that shows typical damage caused by quarantine pests will be separated and evaluated to verify the presence of possible viable quarantine pest.

Apples will be packaged in try pack of 18 kg each; pears will packaged in single or double layer box of 7 or 13 kg each.

Each package or pallet must be marked externally by a label indicating, in addition to other compulsory information, the APU identification and APF code.

Following the official preclearance inspection the cartons with fruit approved for export must be marked with specific system (e.g. labels, stickers...) approved by the Phytosanitary Service in order to distinguish them from non-program fruit.

VII. Inspection and certification of fruit:

The three levels of pre-inspection are carried out in an APF pursuant to the United States Code of Federal Regulations 7 CFR 319.56-22, the workplan and this manual. The APU and APF must ensure that fruits are delivered in clean bins and are of a good quality. Specifically, the following good practices and regulations are defined.

- a. The first pre-inspection will be made upon the delivery of program fruit, before selection and sizing or while fruit is stored in conservation rooms (cold storage) prior to packaging. Quarantine pest interceptions must be reported immediately to the

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Regional Phytosanitary Service. Fruits showing symptoms of quarantine pest activity shall be properly discarded.

The facilities' staff involved in the first pre-inspection has to be selected from the most experienced employees specifically trained in the inspection activities of this program. The training can be carried out by the "contact person" of the facility, by a technician from an ASP or by a technician with a diploma or degree in agricultural subjects. Documents of the training must be produced and made available to the Regional Phytosanitary Service. The training must include at least the following topics:

- Basic knowledge of the export program;
- Techniques adopted by the participant in the export program on the traceability of the product;
- Identification of the signs and symptoms caused by quarantine pests.
- Procedures following the identification of quarantine pests.

- b. The second pre-inspection will be made along the processing line between two specific points strategically located to allow effective second pre-inspection. Between these two points the staff will randomly pick the fruits from the conveyor belt and inspect them with care, in particular to check the absence of *Cemiosoma (Leucoptera malifoliella)* in the stem and calyx ends. Quarantine pest interceptions must be reported immediately to the Regional Phytosanitary Service. Fruits showing symptoms of quarantine pest activity shall be properly discarded.

The facilities' staff involved in the second pre-inspection has to be selected from the most experienced employees and specifically trained inspection activities. The training can be carried on by the "contact person" of the facility, by a technician from an ASP or by a technician with a diploma or degree in agricultural subjects. Documents of the training must be produced and made available to the Regional Phytosanitary Service. The training must include at least the following topics:

- Basic knowledge of the export program;
- Identification of the signs and symptoms caused by insect quarantine;
- Procedures following the identification of insect quarantine.

- c. The third pre-inspection will take place during the palletization of fruit packed in export cartons and has to be conducted by inspectors of the Regional Phytosanitary Service or their ASP, as specified in the workplan.

The packing facility shall, upon request, provide sufficient staff to assist the inspectors in the selection of the fruits to be inspected. The inspection will be conducted in a safe location, properly equipped and lighted.

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The official pre-clearance inspection shall be jointly conducted by the Regional Phytosanitary Service inspectors and by the APHIS inspectors, in accordance with the workplan. The inspection may take place in the processing and packaging facility or designated location.

The inspection has to be made in a properly prepared, equipped and well lighted room. In case the inspection takes place in a location different from the APF, the transport of the lot's sample to the inspection location will be made in a cooled, closed and properly cleaned conveyance.

Only packaged fruits coming from the authorized APU can be transported and exported, even if they come from different APFs. In any case the full traceability of the product must be maintained.

The responsible phytosanitary inspector together with the APHIS inspector perform the inspection of the fruits to be exported, aiming specifically to verify, through a visual inspection, the absence of *Leucoptera malifoliella*, *Grapholita (Cydia) funebrana*, *Adoxophies orana* and *Argyrotaenia pulchellana*.

The "Operational Work plan" (OWP) establishes an inspection rate pursuant to the hypergeometric distribution in ISPM 31, Methodologies for Sampling of Consignments, using a two percent level of detection tolerance and 95% confidence level. The inspection unit can be no less than 1,000 cartons. Reference the procedure in **Appendix #** of the workplan.

The specific fruits and packages' inspection for the certificate issuance will take place at the end of the pre-inspections and will be completed before loading the containers. Each inspected pallet shall be marked with a tag showing the name of the Service. All shipments with solid wood packing material must comply with the requirements of the ISPM 15 International Standard.

VIII. Phytosanitary certificate and other documents:

The responsible phytosanitary inspector of the Italian NPPO issues a phytosanitary certificate for the fruits free from the quarantine pests and destined to the USA. The certificate must declare the following information:

- Container and seal's number;
- Date of issue
- APU of origin
- APS of origin
- Any additional information specified by the workplan

IX. Non-compliance and corrective actions:

Non-compliance and corrective actions shall be executed pursuant to the United States Code of Federal Regulations 7 CFR 319.56-22 and the workplan.

a. Pre-inspection

The presence of live larvae or cocoons of *Leucoptera malifoliella* determines the “non-compliance” of the lot.

The presence of live larvae or cocoons of *Grapholita (Cydia) funebrana* or *Adoxophies orana* or *Argyrotaenia pulchellana*, if authorized treatments are not available, determines the "non-compliance" of the entire Inspection Unit.

The APU, from which the non-compliant batch comes from, will be excluded from the export program for the rest of marketing season.

b. Official pre-clearance inspection

The presence of live larvae or cocoons of *Leucoptera malifoliella*, *Grapholita (Cydia) funebrana* or *Adoxophies orana* or *Argyrotaenia pulchellana* determines the "non-compliance" of the entire Inspection Unit (IU).

If non-program fruit declared to be from an APU is found not to have been grown in the APU, the APU will be suspended from the program for the 2013/2014 marketing season. Fruit in the preclearance IU from different APUs will remain eligible for the export program.

Reconditioning of a rejected inspectional unit is not permitted.

X. Precooling, cold treatment and official seals:

a. Precooling of Fruit

If the cold treatment is done “in transit” all fruit must be precooled to a pulp temperature not to exceed the maximum prescribed in treatment schedule T107-a and with the instructions listed in the PPQ Treatment Manual, Chapters 3,7,2.

b. Cold treatment

The pest risk caused by *Ceratitidis capitata* is mitigated by the cold treatment. The cold treatment can be conducted only in USDA certified facilities, containers or vessels. Cold treatment must be initiated by the Italian NPPO. For 2013/2014 Marketing Season the treatment is provided “in transit”, made by specialized transport companies, in containers or vessels certified by USDA.

The cold treatment against the “Mediterranean Fruit Fly” (*Ceratitidis capitata*) has to be made in accordance with treatment schedule T107-a of the PPQ Treatment

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Manual. For more details about cold treatment procedures see treatment schedule T107-a of the PPQ Treatment Manual.

c. Official seal

Following initiation of the cold treatment the Italian NPPO will seal each maritime container with a strap seal provided by APHIS. The number of the strap seal associated with each container will be communicated to the APHIS inspector for inclusion in the PPQ Form 203.

XI. Duration and review:

This Manual (SOP) will be valid for the 2013 – 2014 commercial campaign.

Attachment 1. APU Certification and Approval Form

Regional Phitosanitary Service

Attachment 1 – rev. 01-2013

<u>INSPECTION REPORT</u>	
“Preclearance operational Workplan” for the export to the USA of apples and pears from “Production Units” approved by.....	
Date	Phitosanitary Inspector
<u>APU/TN/</u> _____	
MUNICIPALITY CADASTRAL MUNICIPALITY Land Unit: Area: Variety: Installation year:	
Notes: _____ _____ _____ _____ _____	

Phitosanitary Inspector's Signature _____

Attachment 2. APU Inspection Checklist**APU INSPECTION - CHECK LIST**

Attachment 2 Rev. 01-2013

APU Number		Date	
Product:		Variety	
Area (ha)			

N°	Check Points	YES	NO
1	Are the units production or the sub-units enrolled in the "integrated production" program made in accordance with the "National Quality System of Integrated production"?		
2	The production unit is managed by a producer associated with a Cooperative		
3	Cooperative or Consortium's name		
4	The cooperative is recognized as Producers Organization in accordance with the Reg. EC 1234/2007		
5	The Production Unit is identifiable with clearly defined boundaries		
6	The Production Unit is managed in a professional way		
7	Systems of aerial photogrammetric are available (e.g. Google map)		
8	Producers or Consortia can provide guarantees about the product traceability		
9	The production Unit belongs to certified European (PDO/PGI, Organic), national (NSQIP) or regional and provincial quality systems.		
10	A register of controls and treatments is available		

11	The manager has a proper technical experience.		
12	The manager is a member of a system of technical advice		
13	The "contact person" has been named		
14	The "contact person" has proven experience in the "Integrated production" and traceability.		
15			
16			
Notes			

Attachment 3. Instruction for APU Inspection

Implementation modalities

For each single APU or single plot of an APU, in case this is composed of several not neighbouring plots, 25 plants have to be inspected, by selecting 12 on the perimeter, 3 for each side, substantially equidistant, not on the external row or header, but 1 or 2 rows inside the plot borders and the second or third in the header (see simplification scheme attached). The other 13 plants have to be selected on a diagonal plot, substantially equidistant each other.

The plants have to be **clearly, univocally and easily identified**. Unless otherwise specified in the APHIS inspectors' considerations after their visit at the end of June, the same plants will be used for the first and second inspection. The two inspections are mainly implemented in order to verify the absence of **live species** of *Leucoptera malifoliella*, but, at the same time, the Inspector or the IVA Agents also have to verify the eventual presence of tortrix included in the APHIS quarantine list or *Cydia funebrana*.

Regulated pests:

Leucoptera malifoliella

Adoxophyes orana

Argytaenia pulchellana (or *ljungiana*)

Cydia funebrana

Ceratitis capitata

1° Inspection (in June)

The control has to be implemented on the leaves. For each selected plant, a random selection of **12** leaves around the whole plant has to be analyzed (in case of spindle trellising system). In case of palmette or more extended trellising system, 6 on each side, both on the right and the left of the plants. In case of detection of mine of *Leucoptera malifoliella*, a sample has to be taken, by noting the plant from which it is taken and delivering it to the SFR entomology laboratory within the day.

As well as the *Leucoptera malifoliella* control, the presence of the two tortrix *Adoxophyes orana* and *Argytaenia pulchellana* (or *ljungiana*) has to be verified concurrently, even on leaves different from those analyzed for *Leucoptera malifoliella* (or eventually also in the specific traps, if installed).

The eventual presence of the above-mentioned phytophagous has to be immediately signalled to SFR, since it is necessary to call for a therapy in the APU and the neighbouring orchards within 1 km range.

The memoranda of control have to be archived and sent to the competent Phytosanitary Service by email within the day after and not later than 5 days later in case of negative results; in case of presence of one or more quarantine pests, the memoranda have to be sent in the shortest possible time.

2° Inspection (before the harvest)

The control has to be implemented on leaves and fruits. For each selected plant, a random selection of **12** leaves around the whole plant has to be analyzed (in case of spindle trellising system). In case

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of palmette or more extended trellising system, 6 on each side, both on the right and the left of the plants. For each plant, 4 fruits have to be analyzed, selected with the same modalities as the leaves, that means randomly around the plant in case of spindle, 2 for each side, on the right and left, in case of palmette or more extended trellising system.

In case of detection of live larvae within the mine of *Leucoptera malifoliella* on the leaves or of cocoons within the calix cavity of the fruit, a sample has to be taken, by noting the plant from which it is taken and delivering it to the SFR entomology laboratory within the day. As well as the *Leucoptera malifoliella* control, the presence of the two tortrix *Adoxophyes orana* and *Argyrotaenia pulchellana* (or *ljungiana*) has to be verified concurrently, even on different leaves than those analysed for *Leucoptera malifoliella* (or eventually also in the specific traps, if installed). The eventual presence of the above-mentioned phytophagous has to be immediately signalled to SFR, since it is necessary to call for a therapy in the APU and the neighbouring orchards within 1 km range.

The memoranda of control have to be archived and sent to the competent Phytosanitary Service by email within the day after and not later than 5 days later in case of negative results; in case of presence of one or more quarantine pests, the memoranda have to be sent in the shortest possible time.

Attachment 4. Inspection Report

APU – INSPECTION REPORT

Check list – Attachment 4

APU Number		Date:	
Product:	APPLE () PEAR ()	Variety	
Area:		Row Number :	

N°	Plant's position	Leaves* Inspection Outcome	Fruits* Inspection Outcome
1	North	0	
2	North	0	
3	North	0	
4	East	0	
5	East	0	
6	East	0	
7	West	0	
8	West	0	
9	West	0	
10	South	0	
11	South	0	
12	South	0	

13	Row ____ Plant ____	0	
14	Row ____ Plant ____	0	
15	Row ____ Plant ____	0	
16	Row ____ Plant ____	0	
17	Row ____ Plant ____	0	
18	Row ____ Plant ____	0	
19	Row ____ Plant ____	0	
20	Row ____ Plant ____	0	
21	Row ____ Plant ____	0	
22	Row ____ Plant ____	0	
23	Row ____ Plant ____	0	
24	Row ____ Plant ____	0	
25	Row ____ Plant ____	0	

- Leaves: 12 leaves/plant
- Fruits: 12 fruits/plant

Attachment 5. APF Checklist

Date		Nome APS	
Product	Apple () Pear ()	Address	
		Organization of Producers	

N°	Checks Points	YES	NO
1	The shed is equipped with temperature-controlled and adequate capacity storage cells		
2	The shed is equipped with selecting and packaging lines		
3	Is it possible to select fruits coming from different APUs?		
4	Is it possible to identify and separate the processing and packaging line from other lines?		
5	Is it possible to identify two points along the packaging line to do the second pre-inspection?		
6	For the third pre-inspection, is there an available room properly equipped and organized?		
7	For the preclearance inspection, is there an available room, properly equipped and organized?		
8	Is there a traceability system from the APU to the packaged product?		
9	Are there any devices to prevent re-infestation of the inspected lots to the U.S. market (insect nets, doors)?		
10	Has a contact person been named?		
11	Does the "contact person" have proven experience, as provided for in the Operational Manual at the point 5 letter h)?		

12	Do the shed have processing certification?		
	If yes, which one?	ISO 9001	
		Global Gap	
		BRC	
		IFS	
		Others	
13			
14			
15			
Notes			