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Animal and Plant Health Inspection Service

7 CFR Parts 300 and 319

Importation of Grapefruit, Lemons, and Oranges From Argentina; Final Rule

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Parts 300 and 319

[Docket No. 97–110–5]

RIN 0579–AA92

Importation of Grapefruit, Lemons, and Oranges From Argentina

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the citrus fruit regulations by recognizing a citrus-growing area within Argentina as being free from citrus canker. Surveys conducted by Argentine plant health authorities in that area of Argentina since 1992 have shown the area to be free from citrus canker, and Argentine authorities are enforcing restrictions designed to protect the area from the introduction of that disease. We are also amending the fruits and vegetables regulations to allow the importation of grapefruit, lemons, and oranges from the citrus canker-free area of Argentina under conditions designed to prevent the introduction into the United States of two other diseases of citrus, sweet orange scab and citrus black spot, and other plant pests. These changes will allow grapefruit, lemons, and oranges to be imported into the continental United States from Argentina subject to certain conditions.

EFFECTIVE DATE: June 15, 2000. The incorporation by reference provided for by this rule is approved by the Director of the Federal Register as of June 15, 2000.

FOR FURTHER INFORMATION CONTACT: Mr. Wayne D. Burnett, Import Specialist, Phytosanitary Issues Management Team, PPQ, APHIS, 4700 River Road Unit 140, Riverdale, MD 20737–1236; (301) 734–6799.

SUPPLEMENTARY INFORMATION:

Background

The regulations in ''Subpart—Fruits and Vegetables'' (7 CFR 319.56 through 319.56–8, referred to below as the fruits and vegetables regulations) prohibit or restrict the importation of fruits and vegetables into the United States from certain parts of the world to prevent the introduction and dissemination of plant pests, including fruit flies, that are new to or not widely distributed within the United States.

The regulations in ''Subpart—Citrus Fruit'' (7 CFR 319.28, referred to below as the citrus fruit regulations), restrict the importation of the fruit and peel of all genera, species, and varieties of the subfamilies *Aurantioideae, Rutoideae,* and *Toddalioideae* of the family *Rutaceae* into the United States from specified countries in order to prevent the introduction of citrus canker disease (*Xanthomonas campestris* pv. *citri* (Hasse) Dye). The citrus fruit regulations also restrict the importation of the fruit and peel of all species and varieties of the genus *Citrus* into the United States from specified countries, including Argentina, in order to prevent the introduction of the citrus diseases sweet orange scab (*Elsinoe australis* Bitanc. and Jenkins) and the B strain of citrus canker, which is referred to in the citrus fruit regulations as ''Cancrosis B.''

On August 12, 1998, we published a proposed rule in the **Federal Register** (63 FR 43117–43125, Docket No. 97–110–1) to amend the citrus fruit regulations by recognizing a citrus-growing area within Argentina as being free from citrus canker. In that document, we also proposed to amend the fruits and vegetables regulations to allow the importation of grapefruit, lemons, and oranges from the citrus canker-free area of Argentina under conditions designed to prevent the introduction into the United States of two other diseases of citrus, sweet orange scab and citrus black spot, and other plant pests.

The proposed rule was followed by three notices regarding the comment period and public hearings for the proposed rule. Specifically, on October 16, 1998, we published in the **Federal Register** (63 FR 55559, Docket No. 97–110–2) a notice advising the public that we were extending the comment period for the proposed rule by 120 days and that we had scheduled a public hearing in Thousand Oaks, CA, to give interested persons the opportunity for the oral presentation of data, views, and arguments regarding the proposed rule. On December 4, 1998, we published in the **Federal Register** (63 FR 67011, Docket No. 97–110–3) a notice advising the public that we had changed the date and location of the public hearing in Thousand Oaks, CA. Finally, on January 13, 1999, we published in the **Federal Register** (64 FR 2151, Docket No. 97–110–4) a notice advising the public that we had scheduled an additional public hearing to be held in Orlando, FL.

With the extension granted in the October 16, 1998, notice, we solicited comments for a total of 180 days ending on February 11, 1999. We received 332 comments by that date, including 63 comments received at the public hearings held in Orlando, FL, and Thousand Oaks, CA. The comments were from foreign and domestic producers, handlers, packers, and processors of citrus fruit; Members of the U.S. Congress and elected representatives of State and local governments; State plant protection officials and officials from Argentine's national plant protection organization, the Servicio Nacional de Sanidad y Calidad Agroalimentaria (SENASA); and representatives of the U.S. Citrus Science Council (USCSC), a group formed specifically to respond to the proposed rule.

Seventeen of the comments were letters requesting that we extend the comment period for the proposed rule, and 3 comments simply stated that any decision should be based on sound science. Two hundred and fifty comments, 148 of which were form letters offering support for the position of the USCSC, raised concerns or made suggestions regarding the proposed rule. Those comments are addressed in detail later in this document. The remaining 62 comments offered support for the proposed rule as it was written. Those commenters who supported the proposed rule noted the mutual benefits of trade, recognized the scientific basis of the proposed rule, stated that Argentine imports would provide competition for citrus imports from other countries, saw an opportunity to increase citrus exports to Argentina, noted that Argentine citrus has been exported to markets in other countries—including citrus-producing countries—without incident, and noted the positive economic effects that Argentine citrus imports would have on consumers, wholesalers, distributors, and ports of entry.

The comments that we received in opposition to the proposed rule focused largely on the scientific basis and support for the proposed mitigation measures and on the execution and conclusions of the risk assessment that was used by the Animal and Plant Health Inspection Service (APHIS) in reaching the decision to initiate the proposed rule. These comments, as well as the numerous comments that we received on other particular aspects of the proposed rule and its supporting documentation, are reported and addressed in this final rule.

With regard to the proposed mitigation measures, several commenters questioned whether the systems approach to phytosanitary security explained in the proposed rule would provide an adequate measure of protection against the introduction of the diseases and insect pests of concern, especially given their understanding that APHIS had never before used a systems approach to mitigate the risks presented by a pest complex that included both insects and pathogens. Other commenters questioned the volume, adequacy, and accuracy of the scientific data provided by Argentina to support the efficacy of the proposed mitigation measures contained in the systems approach. As we discuss in detail below in response to specific comments, we believe that the information furnished by Argentina, when considered in conjunction with the body of information available in the scientific literature regarding the insects and diseases of concern, provides the necessary rational basis for our determination that individual and cumulative mitigative effects of the systems approach serve to reduce the risks presented by Argentine grapefruit, lemons, and oranges produced and imported in accordance with this rule to a negligible level.

With regard to the pest risk assessment prepared by APHIS, several commenters disagreed with the manner in which we prepared the risk assessment, questioning basic choices made by the risk assessors concerning issues such as independence in the model and our use of a shipping box as the risk unit. Other commenters questioned whether APHIS offered sufficient justification for the estimates used in section II.8 (Likelihood of Introduction) of the risk assessment. In this final rule, we discuss, in our responses to specific comments on these and other related issues, the manner in which we prepared the risk assessment and how we arrived at our estimates. Our experience in examining the risks presented by agricultural commodities produced around the world has led us to select the model that we used as the framework for estimating those risks. This model has proven itself over the years and for several commodity/pest combinations to be an efficient means of estimating phytosanitary risk, and we (and others, including the Harvard Center for Risk Analysis) believe our guidelines are valid. While we acknowledge that there are alternative ways of estimating this type of risk, we do not believe that using a different model would result in a substantively different outcome.

Distribution Limitations

In the proposed rule, we discussed the importation of grapefruit, lemons, and oranges into the entire United States. However, the risk assessment that was prepared prior to the preparation of the proposed rule only examined the risks presented by the importation of that fruit into the continental United States (the 48 contiguous States, Alaska, and the District of Columbia). Although we have no reason to believe that the risk associated with importing Argentine citrus into Hawaii, Guam, the Northern Mariana Islands, Puerto Rico, or the U.S. Virgin Islands would differ in any significant way from the risks associated with the importation of that fruit into the continental United States, the fact remains that the risk assessment did not consider the risks associated with the importation of Argentine citrus into destinations outside the continental United States. Therefore, in this final rule we have narrowed the area into which the grapefruit, lemons, and oranges may be imported by limiting the distribution of the fruit to the continental United States. If we were requested to do so by Argentina or other interested parties, we would undertake to assess the risks associated with the entry of Argentine citrus into areas outside the continental United States and initiate rulemaking to provide for the entry of the fruit into those additional areas if our risk assessment supported such an action.

We continue to have confidence in the efficacy of the systems approach for Argentine citrus and in the conclusions of our pest risk assessment, which found that the risk presented by grapefruit, lemons, and oranges imported in accordance with that systems approach is negligible. However, in response to comments from the domestic citrus industry and others voicing concern over the use of a systems approach in a situation where both diseases and insect pests exist in a foreign production area, we will institute a limited distribution plan that will delay the entry of Argentine citrus into citrus-producing areas in the continental United States until 2004. This delay will provide an opportunity for the efficacy of the systems approach to be demonstrated under actual production and distribution conditions before Argentine citrus imports are allowed to enter citrus-producing areas of the continental United States. The limited distribution plan would involve a three-stage phase-in of Argentine citrus imports:

- *Stage 1 (the 2000 and 2001 shipping seasons).* Upon the effective date of this final rule, fruit that meets the requirements of the export program will be eligible for entry into 34 States in the continental United States that are neither buffer States nor commercial citrus-producing States.
- *Stage 2 (the 2002 and 2003 shipping seasons).* When Argentina begins shipping fruit in May or June of 2002, the fruit will be eligible for entry into the 34 ''Stage 1'' States as well as the 10 buffer States (Alabama, Arkansas, Colorado, Georgia, Mississippi, Nevada, New Mexico, Oklahoma, Oregon, and Utah) that share borders with one or more commercial citrus-producing States, leaving only 5 commercial citrus-producing States (Arizona, California, Florida, Louisiana, and Texas) as prohibited destinations in the continental United States.
- *Stage 3 (the 2004 shipping season).* When Argentina begins shipping fruit in May or June of 2004, the fruit will be eligible for entry into all areas of the continental United States.

These ''rolling effective dates'' are built into the final rule, which precludes the need for APHIS to initiate rulemaking in 2002 and 2004 to expand the area into which the fruit may be imported. If it is determined that the requirements of the export program are not being observed routinely or uniformly, APHIS will be able to act quickly to suspend the rolling effective dates or even the entire program, if warranted. The export program provides for the detection of diseased fruit at any point in the pathway, with that detection leading to the rejection of the shipment containing the diseased fruit and the removal of the grove that produced the fruit from the export program for the remainder of the shipping season. Thus, the detection of diseased fruit will not, by itself, result in the suspension of all or part of the export program.

To determine whether the requirements of the export program are being observed routinely or uniformly and to ensure that the distribution restrictions of this rule are being observed, APHIS personnel will be involved in monitoring activities in both the United States and Argentina:

Monitoring—United States. To help ensure that importers and distributors of Argentine citrus are aware of the distribution limitations of this rule, those limitations will be included as one of the conditions of the permit that importers must obtain in order to import grapefruit, lemons, or oranges from Argentina. APHIS personnel, as well as personnel with State regulatory agencies and the Department's Agricultural Marketing Service, will be enlisted to enforce the distribution limitations of the rule. This will be accomplished through market visits, inspections, and outreach efforts directed at importers, shippers, distributors, and retailers. The infrastructure needed to support these efforts is already in place.

Monitoring Argentina. The rule does not require direct APHIS involvement in the supervision of the export program in Argentina; that direct supervision is the responsibility of SENASA, Argentina's national plant protection organization, which is regarded by APHIS (and internationally) as an efficient and capable organization. A recent (April 24 to 28, 2000) site visit to citrus groves and packinghouses in Argentina by APHIS bears out this perception. In order to evaluate whether it is appropriate to allow each stage of the phased-in distribution plan to occur as scheduled, and to provide for the ongoing evaluation of the export program, APHIS will be conducting inspection visits to the Argentine production area and will maintain contact with SENASA throughout each year to monitor their administration of the export program. Further, APHIS and SENASA are currently finalizing the details of the annual operational work plan that will address the administration of the program during the current season and that will serve as the basis for future annual work plans. That work plan will include provisions for active and direct monitoring of the export program by APHIS personnel who will conduct frequent oversight visits to the growing areas and packinghouses. APHIS' monitoring activities will include:

- Inspections of groves following the removal of leaves and other litter,
- Review of the timing and application of fungicidal sprays,
- Accompanying SENASA inspectors as they conduct preharvest grove inspections and collect samples of fruit for laboratory examination,
- Visits to the SENASA-approved laboratories that will be examining the sampled fruit to review the procedures for, and results of, the fruit incubation protocol,
- Observing the harvesting of fruit, its transport to the packinghouses, and the entry control systems in place at the packinghouses, and
- Ensuring that the required handling, treatment, inspection, identification, and packing requirements of this rule are being observed in the packinghouses.

These monitoring activities carried out by APHIS and SENASA personnel will provide us with a clear confirmation of the practicability of the systems approach under actual production conditions, its efficacy in preventing disease in export groves, and the ability of the required inspections and laboratory examinations to detect diseased fruit. Additional evidence of the success or failure of the export program will be gained through the inspections that will be conducted at U.S. ports of entry following the arrival of the fruit and the application of any required cold treatments. Should APHIS, as a result of these activities or any other assessments of the program, conclude that the requirements of the export program are not being observed uniformly and routinely, the program will be reviewed; should APHIS determine that there are deficiencies in the program that cannot be remedied, the phased-in expansion of distribution, or even the export program itself, may then be suspended or terminated.

Specific Regulatory Changes Regarding Limited Distribution

To implement the limited distribution plan, we have made several changes to this final rule. These changes are explained below and pertain to the distribution limitations themselves, box marking, stickering, and ports of entry.

Limitations on Distribution.

We have added a new § 319.56–2f(g) to this final rule to incorporate the distribution limitations into the requirements of the rule. That paragraph states that the distribution of the grapefruit, lemons, and oranges is limited to the continental United States (the 48 contiguous States, Alaska, and the District of Columbia.). That paragraph also states that during the 2000 through 2003 shipping seasons, the distribution of the grapefruit, lemons, and oranges is further limited as follows:

- During the 2000 and 2001 shipping seasons, the fruit may be distributed in all areas of the continental United States except Alabama, Arizona, Arkansas, California, Colorado, Florida, Georgia, Louisiana, Mississippi, Nevada, New Mexico, Oklahoma, Oregon, Texas, and Utah.
- During the 2002 and 2003 shipping seasons, the fruit may be distributed in all areas of the continental United States except Arizona, California, Florida, Louisiana, and Texas.

For the 2004 shipping season and beyond, the fruit may be distributed in all areas of the continental United States.

Box Marking

As was presented in the proposed rule, § 319.56–2f(c)(6) of this final rule requires the boxes in which the fruit is packed to be marked with the SENASA registration number of the grove that produced the fruit. This final rule requires that the boxes also be marked with a statement indicating that the fruit may not be distributed in Hawaii, Guam, the Northern Mariana Islands, Puerto Rico the U.S. Virgin Islands (*i.e.,* destinations outside the continental United States), or in any State (each of which must be individually listed) into which the distribution of the fruit is prohibited under the limited distribution plan. To account for the possibility that the fruit might have to be repackaged following its entry into the United States, new paragraph § 319.56–2f(i) states that any new boxes in which the fruit is packed must also be marked with the limited distribution statement required under § 319.56–2f(c)(6).

Stickering

APHIS has found that the marking of individual fruit is necessary for the limited distribution scheme to be enforceable; otherwise it would be difficult to distinguish Argentine grapefruit, lemons, or oranges from domestically produced fruit or fruit imported from other sources. Therefore, we have amended § 319.56–2f(c)(5) in this final rule to require that the grapefruit, lemons, and oranges be individually labeled with a sticker that identifies the packinghouse in which they were packed. We understand that Argentina's citrus producers routinely label their fruit with stickers identifying the packinghouses in which the fruit was prepared for distribution, and we believe that those packinghouse labels would serve to adequately identify the fruit since we would be able to provide examples of each packinghouse's sticker to our inspectors and cooperators. Therefore, we do not believe that this stickering requirement will impose a significant additional burden on Argentine growers, packers, or exporters.

Ports of Entry

New § 319.56–2f(h) states that the grapefruit, lemons, and oranges may enter the United States only through a port of entry located in a State where the distribution of the fruit is authorized under § 319.56–2f(g), which, as explained above, is the section of the regulations that provides for the limitations on the distribution of the fruit. The port-of-entry restrictions of § 319.56–2f(h) apply to both the limited distribution plan's staged phase-in of imports into the continental United States and the prohibition on the distribution of the fruit outside the continental United States.

As noted above, we believe that this limited distribution plan will provide an opportunity for the efficacy of the systems approach to be demonstrated under actual production and distribution conditions before Argentine citrus imports are allowed to enter citrus-producing areas of the continental United States.

Miscellaneous Comments

Comment: In 1995, APHIS denied Argentina's petition to export citrus to the United States due to the risks that were posed by the fruit. The proposed rule does not set forth the information and experimentation that transpired between 1995 and 1996 that led APHIS to reverse its position. It is only appropriate that the U.S. citrus industry have the opportunity to evaluate the basis for APHIS' decision to reverse its position.

Response: In our proposed rules, we usually focus on describing and justifying the specific regulatory changes or additions that we are proposing, so we do not routinely provide the sorts of historical or evolutionary details that the commenter mentions. In the case of the Argentine citrus proposed rule, we concentrated on explaining the proposed citrus export program set forth in the regulatory text of the proposed rule; we did not believe it was necessary to examine the differences between that program and any earlier Argentine petitions that we had rejected. However, the process of data gathering, experimentation, and negotiation that led to the proposed rule is documented in the material contained in the rulemaking record, and we provided that material to several interested parties who requested it, including representatives of the U.S. citrus industry.

Comment: Two documents in the rulemaking record—a trip report prepared after APHIS' 1994 trip to northwestern Argentina and a memorandum dated May 27, 1994, that discusses the status of Argentina's request to export citrus both raise questions and concerns regarding the Argentine petition. The May 1994 memorandum recommended two actions: (1) That the Government of Argentina request a thorough risk assessment be completed, and (2) that an expert group of pathologists from APHIS and the Agricultural Research Service determine what research was needed before a regulatory decision was made, establish tolerances for diseased fruit in an export program and how these can be measured, and make an assessment of Argentina's citrus canker survey. While the call for a risk assessment in point number one may have been addressed by APHIS' original 1995 risk assessment, the recommendations on point number two appear to have gone unaddressed. We believe that all those questions must be answered before APHIS takes any further action on Argentina's petition. To that end, the proposed rule should be withdrawn to allow for a full scientific discussion of the questions found in those documents.

Response: Both of the actions recommended in the May 1994 memorandum were completed prior to the development of the proposed rule. As noted by the commenter, APHIS did prepare a preliminary qualitative pest risk assessment in 1995, and that 1995 assessment was followed up by the 1997 quantitative pest risk assessment used as support for the proposed rule.

In September 1994, our expert group of pathologists identified to Argentina the areas in which we believed additional research was needed and requested another year's worth of data to substantiate their proposed mitigation measures; that data was received in the spring of 1996. Further, as evidenced by the provisions of the proposed rule and this final rule, we established tolerances for diseased fruit in the export program (*i.e.,* the detection of a single diseased fruit will result in the grove in which the fruit was grown being removed from the export program, and the fruit from that grove being prohibited entry into the United States, for the remainder of that year's growing and harvest season). We have also included inspection provisions to detect diseased fruit and prevent its entry into the United States. Finally, we completed our review of Argentina's citrus canker survey program and have full confidence in the efficacy of its methodology and the accuracy of its findings. Given that all the issues raised in the May 1994 memorandum were addressed prior to the preparation of the proposed rule, we do not believe it is necessary to withdraw the proposed rule for the reasons stated by the commenter.

Comment: In 1994, Argentina proposed a systems approach to suppress citrus black spot and sweet orange scab that was based on individual farms performing the suppression treatment. At the time, APHIS stated that individual farms were too small a unit for sufficient disease suppression and that a larger area with clearly defined geographic boundaries encompassing all citrus grown in the region would be necessary. Why is APHIS now proposing a system based on individual farms performing the suppression treatment?

Response: The original Argentine proposal did not include several of the aspects of the systems approach required by this rule, such as the preharvest surveys, laboratory analysis of sampled fruit, and post-harvest treatments. When those aspects of the systems approach were included in later proposals and data were made available to support their efficacy, we concluded that a grove-level approach to the plant pests of concern would be appropriate.

Comment: The 1994 trip report posits that one possible step that could be taken in order to permit Argentine citrus to enter the United States would be to limit exports to Northeastern ports. A limited distribution requirement similar to the restrictions on the importation of avocados from Mexico would not be a sufficient or enforceable mitigation measure for Argentine citrus. If the market provides an economic reason to ship the citrus to other States, parties with an economic motivation to do so will find a way to make that happen. It is not realistic to say that APHIS has sufficient resources to "police" this requirement. The result would be the spread of devastating diseases to citrus growing regions. Indeed, APHIS has had recent experience in dealing with illegal shipments of Mexican avocados by a large retailer. Once Argentine citrus enters the United States, it must be assumed that the fruit will reach every market in the continental United States. Thus, any potential restriction on where the fruit can be shipped is unrealistic.

Response: That suggestion was indeed offered during discussions that preceded the preparation of the proposed rule, but the proposed rule did not include limitations on distribution. This final rule does, however, limit the importation of the fruit to the continental United States and incorporates a three-stage phase-in of imports that limits the distribution of the fruit during the 2000 through 2003 shipping seasons. These aspects of this final rule are explained above under the heading "Distribution Limitations." As noted in that section, we continue to have faith in the efficacy of the systems approach and in the findings of the risk assessment, thus we continue to believe that citrus fruit imported from Argentina in accordance with this rule presents a negligible risk of introducing diseases or insect pests into any area of the continental United States.

APHIS personnel, as well as personnel with State regulatory agencies and the Department's Agricultural Marketing Service, will be enlisted to enforce the distribution limitations of the rule. This will be accomplished through market visits, inspections, and outreach efforts directed at importers, shippers, distributors, and retailers, and the infrastructure and resources needed to support these efforts are already in place. Given the experience we have gained through the Mexican avocado program and through the implementation of our expanded smuggling interdiction program, we believe that we have the ability to enforce the distribution restrictions of this rule.

Comment: We requested a 1-year extension of the comment period for the proposed rule, then shortened the requested length of the extension to 6 months. By granting only a 4-month comment period extension and subsequently denying our request for a 2-month postponement of the scheduled public hearing, APHIS has denied the affected public a fair opportunity to comment on the proposed rule.

Response: With the original 60-day comment period and the 120-day extension noted by the commenter, the proposed rule was open for public comment from August 12, 1998, through February 11, 1999, a total of 6 months. We believe that this 180-day comment period afforded the affected public a fair opportunity to comment on the proposed rule. Further, in denying the commenter's request for a 2-month postponement of the California public hearing, which we had already postponed once, the Department made it clear that it was willing to review any new information that might surface following the close of the comment period. Specifically, the APHIS hearing officer at the Thousand Oaks, CA, hearing—which was attended by the commenter—read the following statement from Deputy Secretary Richard Rominger: ''Following the close of the comment period, we will thoroughly analyze and review the available material and all comments in the record to determine how best to proceed in the rulemaking process. However, if any new scientific information comes to light after the close of the comment period on February 11, 1999, which has a material and significant bearing on this rulemaking proceeding, such information will be thoroughly considered by the Department, and the Department will take such further action as is appropriate.''

Comment: We informed APHIS on October 2, 1998, that our group was organizing to comment on the proposed rule and had selected a delegation of university scientists from California, Texas, and Florida to travel to Argentina in order to gather information. By failing to provide timely assistance to our group in arranging that trip, APHIS has denied our group and other interested parties a meaningful opportunity to conduct critical scientific analysis.

Response: We believe that the correspondence exchanged between APHIS and the commenter concerning a site visit indicates that APHIS cooperated with the commenter's group in its efforts to arrange a visit to Argentina:

- After receiving the commenter's letter dated October 2, 1998, APHIS informed the Argentine Ministry of Agriculture of the commenter's desire for a site visit by university scientists. Argentine officials responded by requesting APHIS' endorsement of the visit prior to granting their consent for a site visit.
- In a letter dated November 6, 1998, APHIS informed the commenter of Argentina's response. In that letter, we stated that we were prepared to endorse the visit and asked for a specific description of its objectives so that we could pass that information along to Argentina.
- In a letter dated December 1, 1998, the commenter responded with the requested information and indicated its eagerness to work with APHIS to arrange the trip.
- In a letter dated December 7, 1998, we informed the commenter that we would endorse the visit and attempt to arrange a visit in the second week of January 1999.
- In a letter dated December 17, 1998, the commenter rejected the idea of a January visit, stating that the notice was too short and that January was not a ''biologically relevant'' time for a visit. In that letter, the commenter's group informed APHIS that it wished to make a visit in April or May, and perhaps make another visit in July or August.
- No further progress was made on the issue of a site visit following that December 17, 1998, letter. In subsequent correspondence, the commenter's group informed us that they would attempt to ensure that the comment period was extended or the record otherwise held open in order to provide for APHIS' consideration of any information collected during possible future site visits by their scientists.

We believe that the timeline provided above shows that APHIS did in fact provide timely assistance to the commenter, and we disagree with the commenter's assertion that APHIS denied interested parties a meaningful opportunity to conduct critical scientific analysis.

Comment: On September 22, 1998, we filed a Freedom of Information Act (FOIA) request with APHIS in which we asked for any background materials and correspondence relating to the 1997 risk assessment. APHIS' FOIA office acknowledged that request on September 29, 1998, but did not provide any material or acknowledge our follow-up request before the end of the comment period. APHIS has, therefore, withheld or failed to disclose relevant information that would allow the public to interpret and understand the findings in the risk assessment.

Response: Due to our FOIA staff's large workload, we were unable to fulfill the commenter's FOIA request before the February 11, 1999, close of the comment period. However, we did forward the requested documents to the commenter shortly after the close of the comment period. As indicated in the response to a previous comment, we informed the commenter prior to the close of the comment period that we are willing to thoroughly consider, and address as appropriate, any new scientific information that comes to light that has a material and significant bearing on this rulemaking proceeding.

Comment: At the February 5, 1999, public hearing, a member of the APHIS panel stated that APHIS was relying on a 1986 Plant Protection and Quarantine (PPQ) study to support its position that it was highly unlikely that citrus black spot would become established by the spores produced on infected fruit. We believe that APHIS is using this PPQ study as the pivotal foundation for the proposed rule. APHIS' failure to disclose its reliance on this pivotal 1986 study until extremely late in the proposed rule's comment period is a violation of proper administrative procedures. APHIS has denied the affected public the opportunity to comment on the Agency's rationale for the proposal; the lack of disclosure of this one study, in and of itself, is a compelling reason why this proposal must be withdrawn by APHIS.

Response: APHIS did not use the cited 1986 study as ''the pivotal foundation for the proposed rule.'' Most of the APHIS employees involved in the preparation of the proposed rule were either unaware of or had forgotten the 1986 study. It was not until the panel that represented APHIS at the two public hearings was preparing for the February 5, 1999, hearing in Orlando, FL, that one of the panel members recalled the existence of that study; this was more than 5 months after the proposed rule was published. Further, the official transcript of the February 5, 1999, hearing indicates that the APHIS panel member simply quoted from the 1986 study; she did not state that APHIS was ''relying on'' the study. Because we did not rely on the study or its findings in the preparation of the proposed rule, we do not believe the fact that it was not mentioned until late in the comment period is grounds for the withdrawal of the proposed rule.

Comment: APHIS did not comply with its obligations under Executive Order 12866 in developing the proposed rule. In particular, section 6(a) of the Executive Order provides that each agency should engage the impacted public with an opportunity for informal dialogue prior to issuing a proposed rule. For this reason alone, APHIS should withdraw the proposed rule to permit the required consultations to begin.

Response: The portion of the executive order cited by the commenter reads in part: ''Each agency shall (consistent with its own rules, regulations, or procedures) provide the public with meaningful participation in the regulatory process. In particular, before issuing a notice of proposed rulemaking, each agency should, where appropriate, seek the involvement of those who are intended to benefit from and those expected to be burdened by a regulation.'' Consistent with our standard procedures, APHIS did in fact informally contact representatives of the domestic citrus industry regarding the Argentine proposal in October 1997, and indications at that time were that the domestic citrus industry supported the concept of Argentine citrus imports. Further, a new pest list based on the 1995 risk assessment and updated with information provided by Argentina was sent for comment to the State plant regulatory officials (SPRO's) in the citrus-producing States of Florida, Louisiana, Texas, Arizona, and California in the fall of 1996, and a draft of the 1997 quantitative pest risk assessment was sent to those SPRO's in the spring of 1997. Each of the SPRO's was encouraged by APHIS to circulate those documents as they saw fit. We do not believe, therefore, that the proposed rule must be withdrawn in order to comply with Executive Order 12866.

Comment: If APHIS allows Argentine citrus to enter the United States without adequate protective measures in place, and the U.S. citrus industry is then economically injured, APHIS' actions would rise to the level of a ''taking'' of private property by an arm of the U.S. Government.

Response: Because this rule places no limitations or restrictions whatsoever on the U.S. citrus industry or individual U.S. growers or their property, we do not believe that this rule constitutes a regulatory taking.

Comment: In failing to establish quarantine-level treatments for citrus black spot and sweet orange scab in the proposed rule, APHIS is failing to meet its responsibilities for pest exclusion under the Plant Quarantine Act and the Federal Plant Pest Act, which clearly charge the Secretary of Agriculture with the responsibility for preventing the entry of pests that are new to or not widely established in the United States.

Response: Neither the Plant Quarantine Act nor the Federal Plant Pest Act state that quarantine-level treatments are the only means through which the Secretary may meet his responsibilities for pest exclusion under those acts. Rather, 106 of the Federal Plant Pest Act (7 U.S.C. 150ee) authorizes the Secretary to promulgate regulations requiring the inspection of articles imported into the United States and may impose ''other conditions upon such movement, as he deems necessary to prevent the dissemination into the United States, or interstate, of plant pests * * *.'' Quarantine-level treatments are not available for all commodity/pest combinations; in the absence of such treatments, we must consider whether alternative measures are available that will provide a comparable level of quarantine security, and we expect other nations to do the same with respect to U.S. agricultural exports. In this rule, we require the use of tiered and overlapping measures that, when combined with specified cold treatments or host resistance, will reduce the pest risks associated with the importation of Argentine citrus to a negligible level. We believe, therefore, that we have met our responsibilities under the acts cited by the commenter.

Comment: APHIS' fruits and vegetables regulations only address the importation of fruits and vegetables from countries where insect pests are present; diseases are not addressed. It appears that APHIS does not have the authority under its regulations to permit the entry of fruits or vegetables from countries where one or more diseases exist. Therefore, given that citrus diseases exist in Argentina, it appears that APHIS does not have the authority under its regulations to promulgate a regulation that allows the importation of grapefruit, lemons, and oranges from that country.

Response: Our regulations are not the source of our authority to regulate the importation of fruits and vegetables; rather, they are a means through which we exercise the authority derived from statutes such as the Federal Plant Pest Act and the Plant Quarantine Act. The Secretary of Agriculture is provided with the authority in the Plant Quarantine Act to restrict the importation of fruits and vegetables because of ''injurious plant diseases or insect pests'' or to prohibit such importation because of any ''disease or of any injurious insect'' (7 U.S.C. 159, 160). Therefore, we have clear statutory authority to regulate the importation of fruits and vegetables because of diseases as well as insect pests. With respect to our regulations implementing the Secretary's authority under those acts, the commenter is correct in noting that the fruits and vegetables regulations contain no general provisions regarding diseases. However, the regulations in ''Subpart—Citrus Fruit'' (§ 319.28), which we are amending in this rule and which was discussed in the proposed rule, do in fact contain specific restrictions on the importation of fruit of citrus and citrus relatives from specified countries due to the presence of citrus diseases in those countries.

Comment: The April 1992 pest risk analysis that APHIS completed for its rulemaking regarding the importation of citrus from South Africa states that ''[i]mportation of all plant parts, except seed, of *Citrus* spp. should be prohibited from countries where the disease [black spot] occurs'' (Pest Data Sheet on Black Spot of Citrus, p. 62). Yet, neither the risk assessment nor the proposed rule for Argentine citrus mentions that serious concern that the Agency had so recently expressed about citrus black spot. It appears that APHIS is now proposing to make an abrupt change in its position regarding this disease and the danger that it poses without either articulating the reasons for this change or including in the record substantial evidence that could support such a divergence from longstanding agency policy.

Response: We disagree with the commenter's contention that we are making an abrupt change in policy with regard to the risks presented by citrus black spot. More importantly, our position regarding the phytosanitary significance of citrus black spot has not changed as drastically as the commenter suggests. We still consider citrus nursery stock and plant parts other than fruit to pose a high risk as pathways for the introduction of citrus black spot. It is only our position relative to citrus fruit—specifically, citrus fruit that has been subjected to the measures required by this rule—that has changed since the April 1992 pest risk analysis for South African citrus. The pest data sheet cited by the commenter was completed more than 5 years before we prepared the Argentine citrus analysis and did not consider the tiered and overlapping measures used in the systems approach to mitigate the risk of citrus black spot; thus, the data sheet's recommendations were made in the context of an importation scenario in which no measures short of prohibition were offered to mitigate the risk of citrus black spot.

APHIS' reading of the relative risks presented by citrus plants, fruit, and other plant parts is consistent with the current research into the epidemiology and control of citrus black spot and the evolving scientific understanding of the disease. For example, Professor J.M. Kotze of the University of Pretoria (South Africa) reports in a Department of Microbiology and Plant Pathology summary of plant pathology research focus areas that: ''We have shown that the disease [citrus black spot] spreads to new areas through leaves of nursery trees. The importance of the inoculum sources was already demonstrated, especially the fact that fruit presents no danger to importers of citrus in Europe.'' Fruit has been shown to be a poor pathway for the introduction of citrus black spot, and, as explained in the proposed rule, the required systems approach acts to reduce any remaining risk to a negligible level.

Trade-Related Issues

Comment: In the proposed rule, APHIS stated: ''Maintaining a prohibition on the importation of grapefruit, lemons, and oranges from the Argentine States of Catamarca, Jujuy, Salta, and Tucuman in light of those State's [sic] demonstrated freedom from citrus canker would run counter to the United States' obligations under international trade agreements and would likely be challenged through the World Trade Organization'' (WTO). This is simply not true. Even if the four involved Argentine States are free from citrus canker, there are other potentially devastating citrus diseases and pests present. Under the Uruguay Round WTO agreement, the United States has no obligation to permit the introduction and spread of quarantine diseases and pests in this country. Any country is free to adopt a ''zero risk'' standard as its appropriate level of protection; we submit that the current U.S. prohibition on fruit that is infected with sweet orange scab and citrus black spot is entirely consistent with the Uruguay Round's ''Agreement on the Application of Sanitary and Phytosanitary Measures'' (the ''S&P Agreement''). Argentina has not shown that the importation of fruit from an indisputably infected region poses no risk that sweet orange scab, citrus black spot, or both, may be introduced into the United States.

Response: We understand that we are not required to allow diseased or infested fruit to be imported into the United States; indeed, this rule does nothing to alter the ''current U.S. prohibition on fruit that is infected with sweet orange scab and citrus black spot'' noted by the commenter. However, we also recognize that we are obliged to use health requirements only to the extent necessary to meet our ''appropriate level of protection.'' In the case of grapefruit, lemons, and oranges from Argentina, we believe that the tiered and overlapping safeguards contained in this final rule will reduce the pest risk associated with their importation to a negligible level. If the United States had deemed ''zero risk'' to be its appropriate level of protection, then it is unlikely that Argentine citrus—and many other commodities, for that matter—would ever be approved for importation into the United States. There will always be some degree of pest risk associated with the movement of agricultural products; APHIS' goal is to reduce that risk to a negligible level.

While the one sentence quoted by the commenter from the proposed rule mentioned only citrus canker, we believe that it is evident from the content of the entire proposed rule that we did indeed consider the presence of other diseases and insect pests in Argentina. It should be noted that the sentence quoted by the commenter was preceded by another sentence in the proposed rule: ''We have rejected that alternative [*i.e.,* to make no changes in the regulations and continue to prohibit the importation of grapefruit, lemons, and oranges from Argentina] because we believe that Argentina has demonstrated that the citrus-growing areas of the States of Catamarca, Jujuy, Salta, and Tucuman are free from citrus canker and because we believe that the systems approach offered by Argentina to prevent the introduction of other plant pests reduces the risks posed by the importation of grapefruit, lemons, and oranges to a negligible level.''

Comment: We submit that APHIS should consult with the U.S. Congress on the issue of the ''appropriate level of protection'' in this situation, especially given that the world trading community has yet to settle the issue of what constitutes an appropriate level of protection. The citrus industry is far too important to the United States economy and trade interests for APHIS to make critical economic and foreign policy decisions on its own, particularly when no international standard dictates a particular result.

Response: The provisions of the WTO SPS Agreement provide that it is the sovereign right of each member to set its own level of protection, thus it would be inappropriate for the ''world trading community'' to make such a determination. In this instance, APHIS, as the recognized regulatory authority, is establishing a system of phytosanitary measures that reflect the level of protection deemed appropriate. It is our intent to allow fresh grapefruit, lemons, and oranges to be imported into the continental United States from Argentina only if they are grown, packed, and shipped under specified phytosanitary conditions designed to mitigate the risk of plant pest introduction. We are confident that the phytosanitary measures required by this rule will mitigate the risk presented by Argentine citrus. Given that confidence, we do not believe that the level of protection afforded by this rule is a departure from the level of protection we demand in other commodity import situations.

Comment: Article 6 of the S&P Agreement recognizes that countries can have regions that are pest- or disease-free or have areas of low pest or disease prevalence. However, it is envisioned that each country claiming to have such regions has the burden of proving that such areas have no pests or diseases or have low levels of pests or disease. Argentina has not provided any information to APHIS as to the levels of pests or diseases that are present in the four States that are proposed for export.

Response: Argentina claims that the citrus-growing regions identified in this rule are free from citrus canker, and we believe that they have provided sufficient documentation to support that claim. We also believe that Argentina submitted sufficient documentation to support its position that the remaining pests and diseases were of low enough prevalence that the chemical, cultural, and other controls of the systems approach would prevent their introduction into the United States on fruit imported under the requirements of this rule.

Comment: APHIS' regulations in § 319.56–2 refer to ''without risk,'' yet the proposed rule seems to have a standard on ''negligible risk.'' Even if APHIS does have the statutory authority to adopt a ''negligible risk'' standard, the standard is undefined and impossible to determine. This is not acceptable. The standard should be capable of being independently validated and should be set only after rigorous peer review, in accord with standards and guidelines adopted by WTO with the advice of International Plant Protection Convention (IPPC).

Response: The ''without risk'' provision selected by the commenter is found in § 319.56–2(e) and is used in the context of importing a fruit or vegetable from a definite area or district of a country that is free from some or all of the injurious insects that attack the fruit or vegetable when that area or district meets the criteria for pest freedom found in § 319.56–2(f). Section 319.56–2(e) is not applicable to this rulemaking because the Argentine Government has made no claims with regard to the freedom of northwestern Argentina with regard to injurious insects *i.e.*, fruit flies in this case. The risk of diseases is addressed under the regulations in § 319.28 (Subpart—Citrus Fruit), which contains no such ''without risk'' standard. In any event, we do not believe that a policy of requiring imports to be ''without risk'' or to present ''zero risk'' could be sustained by any country that wishes to engage in international trade. There will always be some degree of pest risk associated with the movement of agricultural products; APHIS' goal is, and always has been, to reduce that risk to a negligible level. This goal is entirely consistent with the standards and guidelines of the WTO and the IPPC.

Comment: In the proposed rule, APHIS does not offer any ''reasoned analysis'' for departing from its longstanding policy of not permitting the importation of fruit from diseased regions. In its two recent rulemakings regarding the importation of citrus from South Africa and Australia, APHIS stated that it would deny the entry of citrus from each of those countries if the citrus was found to be infected with citrus black spot. It appears that it was clear to APHIS in those cases that citrus black spot was so troubling and dangerous that the only way to protect the United States against importation of this disease was to disallow the importation of any fruit from diseased areas. The inconsistency of APHIS' proposed approach to Argentine fruit with its prior, recent positions regarding fruit from South Africa and Australia is never mentioned or explained in the proposed rule or the risk assessment. Further, the differences in the approaches applied to Argentine citrus on one hand, and Australian and South African citrus on the other, leaves the United States open to challenges from Australia and South Africa under article 2.3 of the S&P Agreement, which requires that member countries do not discriminate with respect to other member countries where ''similar conditions prevail.''

Response: In the two rulemakings cited by the commenter regarding the importation of citrus from Australia and South Africa, the freedom of the production areas from citrus black spot formed part of the basis for allowing the importation of citrus from those countries. Because the importation protocols were based largely on that area freedom, it follows that we would prohibit the importation of citrus from either country if it was found to be infected with citrus black spot. In the case of Argentine citrus, no such claim of area freedom is made, which is why this rule requires control and detection measures for citrus black spot. Because of these differences in the bases for the three rules in question, we do not believe that this final rule arbitrarily or unjustifiably discriminates between countries where similar or identical conditions prevail. Further, it is important to note that this final rule, like the Australian and South African citrus fruit regulations, prohibits the importation of any fruit found to be infected with citrus black spot.

Comment: The rate of importation of fruit into the United States should be consistent with the rate of production of a normal lemon farm as if trees were planted today. If I planted a lemon tree today, I wouldn't receive any production for 3 years, and then production would increase gradually through the tenth year. Regardless of current Argentine production available for importation, no lemons should be allowed into the United States during the first 3 years, and then only 15 percent the fourth year, 30 percent in the fifth year, *etc.*, until full production is allowed.

Response: APHIS has no authority to impose the quotas suggested by the commenter.

Comment: APHIS should calculate the cost per field box to the American farmer of the cost of U.S. Government regulation and adopt a temporary tariff in that amount on all imported Argentine fruit. The amount collected by the temporary tariff would be distributed to the American lemon farmer based on each farmer's field box production until Argentina adopts the same laws and regulations that the American farmer must obey. The minimum-wage law, Labor Standards Act, and all environmental and health safety laws are examples of such laws and regulations.

Response: APHIS has no authority to impose the tariff suggested by the commenter.

Comment: APHIS has no regulations that govern the procedure and standards for consideration of import petitions filed by foreign governments. Nor does the website maintained by APHIS provide any information on the process for, or standards which are applied to, such petitions. We submit that APHIS has an obligation to establish its procedures and standards when dealing with plant diseases in such a way as to provide the affected industry with confidence that agency decisionmaking is being conducted in a ''reasoned'' way based upon substantial evidence in the record and meaningful opportunity for public comment.

Response: Foreign governments most often broach the subject of exporting new fruits or vegetables to the United States through formal negotiations or informal contacts with APHIS officials. These requests and any subsequent detailed proposals are reviewed by APHIS staff experts. After that review, APHIS staff may either recommend approval of the petition or contact the petitioning government with a request for additional research, proposed safeguards, etc. As noted by the commenter, this government-to-government contact is not the subject of any procedural regulations in part 319. However, the public is provided the opportunity to review the Agency's basis for any change in the regulations proposed as a result of a foreign government's import petition. Each time we propose to amend our regulations to address an import request that involves a new commodity/region combination, we prepare a proposed rule that is commented upon by the public. In each case, the proposed import program, including mitigation measures, is clearly described in the proposed rule, and the rationale underlying the proposed import program is explained. The public, which includes any potentially affected industry, then has the opportunity to review the proposed rule and its supporting information and may provide comments that must be considered and addressed by APHIS before any final action on a foreign government's import petition may be taken.

Systems Approach

Comment: APHIS' regulations contain no discussion, definition, or description of what constitutes a ''systems approach,'' or what treatment or treatments will qualify as an acceptable systems approach. There are no standards in APHIS regulations that permit affected parties to understand or judge the Agency's actions to approve or disapprove such an approach. This is unacceptable. An agency is obligated to set forth the standard the agency is applying or how it is applying that standard to the factual situation.

Response: The standard that we apply to any potential import situation is clear and has been well-established over the course of numerous APHIS rulemakings dealing with the importation of agricultural commodities: Does the importation of a particular commodity from a particular region present a risk of introducing pests into the United States, and, if so, can that risk be reduced to a negligible level through the application of phytosanitary measures? These considerations are addressed each time we propose to amend our regulations to address an import request that involves a new commodity/region combination. In each case, the proposed mitigation measures, which can range from something as basic as inspection at the port of entry to a more complicated systems approach of tiered and overlapping measures, are clearly stated in the proposed rule, and the rationale for their proposed use is explained. So, while the general provisions of our regulations do not discuss, define, or describe what constitutes a systems approach or what treatment or treatments qualify as an acceptable systems approach, we do not believe that the lack of such a discussion in the regulations detracts from the public's ability to understand, assess, and comment upon the mitigation measures proposed for a particular commodity/region combination.

Comment: Applying a systems approach to disease suppression for the purpose of allowing imports from a region with a disease that does not exist in the United States is a fundamental change in APHIS policy. Previously, APHIS has always demanded that the area in which the crop is grown be completely free of disease and geographically separated from regions with the disease. This principle is applied to citrus canker in the northwestern region of Argentina, but is not the case with sweet orange scab or citrus black spot. There has not been a full scientific discussion of the principles that need to be fulfilled before moving forward with such a fundamental change in the standards for U.S. quarantine pest protection. Therefore:

• APHIS should identify and cite the studies that have been used to determine that a systems approach provides sufficient safety from all kinds of plant pests when importing fresh produce into the United States;

• APHIS should establish basic standards for the kind of data and experiments that are needed to provide confidence in applying the systems approach to disease control;

• APHIS should establish standards by which the information used to determine the effectiveness and practicality of the systems approach are to be judged; and

• There needs to be a public discussion of what level of risk is appropriate.

Response: We believe that the commenter is incorrect in asserting that APHIS is fundamentally changing its policy by not demanding that a growing area be completely free of disease and geographically separated from regions where disease exists. A long-standing precedent for the local freedom concept is found in the citrus fruit regulations in § 319.28(b)(1), which allow Unshu variety oranges to be imported into certain areas of the United States from Japan and South Korea if the oranges are grown in citrus-canker-free export areas that are surrounded by 400-meter buffer zones. While the Unshu orange program differs from the Argentine citrus program in many respects, the fact remains that the Unshu orange program stands as an example of a successful approach to importing fruit from regions where a disease exists.

As noted in the response to the previous comment, it is true that the general provisions of our regulations do not discuss, define, or describe what constitutes a systems approach or what treatment or treatments qualify as an acceptable systems approach. However, we do not believe that the lack of such a discussion in the regulations detracts from the public's ability to understand, assess, and comment upon the mitigation measures proposed for a particular commodity/region combination because, in each case where we propose to allow the entry of a new commodity, we explain the proposed mitigation measures and provide the scientific rationale underlying their proposed use. Thus, the public has the opportunity to judge each proposed importation according to the criteria suggested by this commenter.

The commenter states that ''APHIS should identify and cite the studies that have been used to determine that a systems approach provides sufficient safety from all kinds of plant pests when importing fresh produce into the United States.'' We are unaware of any studies that examine the use of systems approaches as broadly or definitively as the commenter suggests; there are simply too many possible combinations of pests and hosts on one hand, and biological, physical and operational factors that could be integrated into a systems approach on the other, to allow for such a conclusive determination. Thus, while it is acknowledged that systems of practices and procedures can be assembled to provide quarantine security in many cases, each proposed use of a systems approach must be evaluated individually. We will, however, consider the commenter's suggestion that we establish, to the extent possible, general standards for the preparation and evaluation of data that serve to support the establishment of systems approaches. Finally, the commenter states that there needs to be a public discussion of what level of risk is appropriate; we believe that the comments received in response to our proposed rule are one indication that such a discussion of the level of risk that APHIS has determined to be approporiate is already open and ongoing. Given the numerous, evolving, and unpredictable factors affecting the perception of, and tolerance for, risk, it appears that the ''public discussion of what level of risk is appropriate'' will, by necessity, be an ongoing exchange rather than a discrete deliberation.

Comment: APHIS has never before proposed using a systems approach for a combination of diseases and insect pests. What is particularly troubling about the approach APHIS is proposing in the Argentine rule is that the Agency has issued this proposal with no specific discussion of its rationale; its only stated justification is the previous use of system approaches. However, previous systems approaches are similar in only the most remote of ways and are not at all similar in execution or in impact. Thus, the Agency must set forth a detailed justification supported by sound scientific evidence for this fundamental shift in regulatory approach. Further, we submit that APHIS should have adopted this expanded use of a systems approach only after conducting a notice and comment process, with rigorous scientific peer review to determine whether a systems approach can be an effective tool when addressing diseases.

Response: It is not true that we sought to justify the use of a systems approach for Argentine citrus by pointing to previous uses of systems approaches; indeed, the proposed rule did not mention the use of a systems approach in any context other than that of Argentine citrus. Further, we disagree with the commenter's contention that we issued the proposed rule ''with no specific discussion of its rationale.'' Our rationale for the use of a systems approach for Argentine citrus was stated early in the proposed rule, at the end of the first paragraph under the heading ''Importation of Grapefruit, Lemons, and Oranges,'' where we stated ''To prevent the introduction into the United States of those diseases [*i.e.,* sweet orange scab and citrus black spot] and fruit flies, the Government of Argentina, with the cooperation of APHIS, has formulated a systems approach of tiered and overlapping measures that, when combined with specified cold treatments, would reduce the risks presented by those pests to a negligible level.'' The proposed rule then explains in detail each of the phytosanitary measures that would be required in order for citrus to be exported to the United States from Argentina. That explanation, we believe, constitutes the ''detailed justification'' requested by the commenter. We do not believe that our application of systems approach principles to the importation of Argentine citrus is in any way a departure from our policy of allowing the importation of fruits and vegetables when the risks presented by those commodities can be mitigated to a negligible level.

Comment: The systems approach is premised upon the layering of several risk reduction measures. An effective verification and enforcement system is essential for the layering of risk reduction measures to result in the desired outcome. What will be done when one or more of these layers beaks down? APHIS should have a response plan for action when a risk reduction measure fails.

Response: The systems approach contained in this rule, as is the case with all systems approaches contained in APHIS' regulations, is indeed premised upon the layering of several risk reduction measures. The tiered and overlapping nature of any systems approach ensures that even if any one of the elements of the systems approach is omitted or fails, and that omission or failure remains undetected, adequate measures will remain to provide the necessary level of phytosanitary security. Further, we agree that an effective verification and enforcement system is essential to the success of any systems approach. To achieve that success, this rule requires that SENASA actively participate in or supervise each step of the process in Argentina to verify and document each step's successful completion or application, and the required documentation must be made available to APHIS. Further, as discussed earlier in this document in the paragraph titled ''Monitoring—Argentina,'' the operational work plan that addresses the administration of the export program will include provisions for active and direct monitoring of the program by APHIS personnel who will conduct frequent oversight visits to the growing areas and packinghouses in order to observe each step of the program in Argentina. Further, each shipment of fruit must be accompanied by a phytosanitary certificate issued by SENASA that verifies that the fruit was produced and handled in accordance with the requirements of § 319.56–2f(a) through (c) and that the fruit is apparently free from citrus black spot and sweet orange scab. Fruit that fails to meet those requirements will not be eligible for importation into the United States. At the port of entry in the United States, APHIS will inspect the fruit and its accompanying phytosanitary certificate and will confirm that any required cold treatment has been properly applied. Finally, the detection of citrus black spot or sweet orange scab on any grapefruit, lemons, or oranges at any time in Argentina, during transport, or in the United States will result in the grove in which the fruit was grown or is being grown being removed from the SENASA citrus export program for the remainder of that year's growing and harvest season, and the fruit harvested from that grove being ineligible for importation into the United States from the time of detection through the remainder of that shipping season.

Comment: For a systems approach to be effective, it is essential to know the biological interactions between the pest and its host to understand how these interactions affect production, shipment, and marketing of commodities. There is very little current knowledge about citrus black spot or sweet orange scab, and virtually no work has been done on the question of how the diseases would respond if brought into the United States. Thus, there is a substantial threshold question of whether a systems approach can even be designed to deal with citrus black spot or sweet orange scab.

Response: As neither of those diseases is present in the United States, it is not unusual that most researchers in this country who study citrus crops and their pests have directed their efforts to other, more immediate concerns. However, in countries where citrus black spot or sweet orange scab is present and where citrus is an economically important crop, those diseases have been, and continue to be, the subject of focused research. We believe that the information on the prevention, control, and detection of these diseases that has been collected over the years, combined with the results of the field trials conducted in Argentina, provides the necessary degree of scientific support for the systems approach described in this rule.

Comment: APHIS has not used a systems approach previously in a situation where the intended result of the treatments is simply suppression of the symptoms of the disease(s) in a proposed export area. Thus, proposing to rely on an approach which admittedly only results in suppression of the symptoms of the diseases is a fundamental policy shift by APHIS. The proposal also stands in stark contrast to the goal of complete eradication of a disease, which has been and remains the objective in every situation in the United States where a plant disease or pest does exist. As such, any contemplated use of such an approach should be subjected to the most rigorous, exhaustive, and comprehensive level of scientific peer review.

Response: The intended result of the treatments, particularly the oil-copper oxychloride sprays during the growing season, as well as measures such as grove cleaning to remove inoculum, is the prevention of infection, and not simply the suppression of symptoms as stated by the commenter. Other required measures are specifically designed to detect the presence of diseased fruit and prevent its importation into the United States. Given that the goal of this rule is to provide for the importation of disease—free and not simply asymptomatic—grapefruit, lemons, and oranges, we do not believe that this rule represents a departure from our policy of allowing the importation of fruits and vegetables when the risks presented by those commodities can be mitigated to a negligible level.

Comment: A publication titled *Quarantine Treatment for Pests of Food Plants* (edited by Jennifer L. Sharp and Guy J. Hallman, Westview Press, 1994), includes a discussion of systems approaches that stresses the importance of determining the level at which a pest or disease exists in order to design an effective systems approach. Nothing on the record of the Argentine proposed rule indicates the ''level of infestation'' of the host fruit by any of the diseases or pests at issue. This infestation information must be known before APHIS can even consider the possibility of designing a systems approach. Only when this infestation level is known can the efficacy of the proposed system be judged. Without this information, interested parties are unable to conduct any meaningful review of the proposed systems approach.

Response: The ''level of infestation'' passage noted by the commenter is found on page 226 of the cited publication and states ''* * * [S]ystems recognize that the commodity in question is a host, the level of infestation in the host being the key component in the design of the overall system. Systems rely on knowledge of the infestation level of the host and measure the impact of the various operational procedures on removing infested hosts, thereby reducing the risks that infested hosts will be shipped.''

For the fruit flies of concern in Argentina, a single quarantine treatment—cold treatment—is available and is required by this rule, which leaves citrus black spot and sweet orange scab as the ''diseases or pests at issue.'' Surveys produced by Argentina show that disease incidence—*i.e.,* the ''level of infestation'' referred to in the cited publication—varies from season to season, depending on the prevailing environmental conditions, and can be high in untreated groves. The results of those surveys were reported in the risk assessment that accompanied the proposed rule, so there is in fact information on the record indicating our knowledge of disease incidence in Argentina. Because of the known seasonal variations in disease incidence, the design of the systems approach for Argentine citrus began with the assumption of a potentially high ''level of infestation'' and set out, through biological and operational factors such as buffer zones, inoculum removal, inspections, testing, and treatments, to reduce the risks of infected fruit being shipped to the United States.

Comment: It is not possible to properly assess the adequacy of a systems approach in preventing the introduction of pests into an importing nation without detailed knowledge of the circumstances under which a pest occurs, and the frequency with which it occurs, in the export region. APHIS' current risk assessment is based on a poor body of knowledge of insect species present or potentially present in Argentina, particularly the *Anastrepha* species present in northwestern Argentina. Further, the level of pesticide use there could be masking the presence of lesser-known pests that could emerge as a problem if newer, more specific pesticides are used in Argentina. Therefore, extensive taxonomic research and population surveys on fruit flies and other insect species present in northwestern Argentina, as well as data on other potential hosts in that region, are necessary in order for a proper risk assessment to be completed on Argentine citrus and for the systems approach to be fully evaluated.

Response: Citrus is an economically important crop in Argentina, and as such has been, and continues to be, the subject of well-supported and vigorously pursued research into its production and factors affecting that production, including pests. We are confident, therefore, that the pest list produced by SENASA, which was reviewed by APHIS and by agricultural officials in the four main citrus-producing States of this country and compared against reports from various international sources and the scientific literature, accurately addressed the range of citrus pests present in Argentina. Further, we believe that the risks posed by those pests were adequately considered in the risk assessment and addressed by the provisions of this rule.

Comment: What is the goal of the systems approach for citrus black spot and sweet orange scab? Some of the statements in the rulemaking record imply that the goal is to have disease-free groves, while the proposed rule seems to seek the suppression of disease symptoms in export groves. Recent statements by APHIS imply that it would be acceptable for diseased fruit to enter the United States.

Response: The goal of the systems approach is to reduce the plant pest risks associated with the importation of Argentine citrus to a negligible level. With regard to citrus black spot and sweet orange scab, the systems approach is designed to accomplish that goal through both prevention and detection; the grove cleaning and growing season spraying requirements are designed specifically to prevent fruit from becoming infected in the first place, and subsequent surveys, inspections, and testing provide multiple opportunities for the detection of infected fruit. If a single infected fruit is found at any point in the process, including inspections conducted after the fruit has arrived in the United States, the grove in which that fruit was grown will be removed from the SENASA citrus export program and the fruit harvested from that grove may not be imported into the United States from the time of detection through the remainder of the shipping season. Thus, the commenter's impression that we would find it acceptable for diseased fruit to enter the United States is incorrect.

Comment: The record of data supplied by Argentina, as provided to the public by APHIS, is completely inadequate to assess the efficacy of the individual measures, let alone the systems approach, for citrus black spot and sweet orange scab. Either APHIS has not maintained a complete record of the information Argentina supplied, or the Agency is basing its risk estimates on ambiguous data because of inadequate reporting by Argentina.

Response: We have, in fact, maintained a complete record of the information supplied by Argentina, and we did share that information with the commenter, although we were unable to provide the information that was the subject of the commenter's FOIA request until after the close of the comment period. Further, it is important to note that our assessment of the risks presented by Argentine citrus and of the efficacy of specific measures was not based solely on the material provided by Argentina; information gathered from other sources and the expert judgment of subject matter specialists also played a role. This is the norm when conducting probabilistic assessments to inform decisions regarding importation of agricultural commodities. When data that represent ''direct evidence'' do not exist, which is often the case in probabilistic risk assessments, available information is reviewed and applied through the use of professional judgment. APHIS bases the estimates needed for its probabilistic commodity risk assessments on pest interception records, the known biology of the organism being assessed (or the known biology of related taxa) as represented in the scientific literature, expert judgment based on laboratory experience with the pest or related organisms, expert judgment based on field experience with the pest or related organisms, expert judgment based on experience conducting commodity inspections at ports of entry or in the exporting country, and experience working with export programs and export-quality commodities. Thus, we believe that the entire body of information available is, in fact, sufficient to support the efficacy of the measures required by this rule and our analysis of the risks associated with Argentine citrus.

Comment: The following items are examples of the type of data or information that appear to be missing from the rulemaking record. No information is provided as to what the climatic conditions were in the tested groves during the spraying program. Similarly, no information is provided on how the spraying program would be affected by different climatic conditions in different growing areas, such as the northwestern versus the southern part of Tucuman, and Tucuman as compared to Salta, etc. Accordingly, it was impossible to answer many critical questions: Was it a year of light incidence of the disease, and thus the spraying was very effective? What would happen in a year of heavy incidence? What were the ages and varieties of the trees in the program? What was the protocol that was followed? How would different climatic conditions affect the spraying program? Would the same results have been achieved if the trees had been 10 years older? Neither the risk assessment nor the rulemaking record addresses or answers any of these questions. APHIS must require much more extensive tests covering multiple variables before further considering the Argentine petition. Variables that should have been included in tests before approving the Argentine petition would include, but are not limited to: Multiple and differing climatic situations (*i.e.,* drier versus more humid areas; more humid years versus drier years); differing ages of trees, since citrus black spot is more often seen in older trees and in ripe fruit; differing sizes of groves; whether the grove was virtually surrounded by untreated groves; whether the trees had been under any type of stress; etc.

Response: The bioecological factors affecting citrus black spot development that were considered in the design of the field testing conducted in Argentina, the protocols for the field tests, and the results of those tests are among the material provided to the commenter in Note S.P. 338 of December 5, 1995, and its three annexes (''Biecology of Black Spot in Citrus,'' ''Field Assays for the Control of Black Spot in Citrus,'' and ''Results of the Postharvest Assays Carried Out up to the Present''). These documents demonstrate that Argentina recognized, and took into account, that factors such as climate, humidity, fruit susceptibility, and the presence of inoculum have an effect on the presence of the disease. The Argentine field tests were conducted during growing seasons marked by both dry conditions with light disease incidence in control trees and prolonged rainy conditions with a heavy incidence of disease in control trees. This information, which was used in the design of the systems approach, was also considered by the experts who prepared the risk assessment. As noted elsewhere in this document, the systems approach is designed to mitigate the risk of citrus black spot during years in which the disease is likely, which is why this rule requires in part that the timing of the fungicidal sprays be determined by SENASA using an expert system that takes climatic data, as well as fruit susceptibility and the presence of disease inoculum, into account. We believe that the body of information contained in the rulemaking record, including the research and testing data provided by Argentina, provides the necessary scientific and rational basis for our regulatory decisionmaking.

Comment: The evidence that APHIS has made available to date is inadequate to support the proposed rule. The Secretary should appoint an independent scientific team to travel to the proposed Argentine production area when climatic conditions are appropriate, and that team should be given access to the production and packing facilities, as well as to the transportation and port operations that would be utilized for the export program. The Secretary should direct that team to report its findings to the Department and Congress.

Response: APHIS, under the authority of the Plant Quarantine Act and the Federal Plant Pest Act, has reviewed the Argentine petition and has made the determination that phytosanitary measures that comprise the systems approach reduce the pest risk to a negligible level. The systems approach that is the subject of this rule was developed in Argentina by that country's plant health officials and citrus interests and was presented, along with its supporting data, to APHIS for review. APHIS rejected Argentina's initial proposal on the grounds that it did not sufficiently mitigate the pest risk presented by Argentine citrus. It was only after Argentina included additional phytosanitary measures in its systems approach and provided what we determined to be an adequate amount of additional efficacy data that APHIS accepted the Argentine proposal. The Secretary is not required to appoint an independent scientific team as suggested by the commenter, nor do we believe that one is needed in light of the review already conducted by APHIS.

Comment: The 1997 risk assessment states that the level of visible incidence of citrus black spot can be extremely high in Argentina—as high as 82 percent and can vary greatly year to year. This level of disease incidence is disturbingly high. Further, this data does not address the phenomenon of symptoms that remain latent. Based on the current state of science, we submit that no fruit from such highly diseased areas should be allowed to enter the United States.

Response: The section of the risk assessment cited by the commenter stated that in untreated export-area orange groves, field surveys for citrus black spot in 1994 and 1995 found 14 percent and 82 percent, respectively, of sampled fruit were infected with the citrus black spot fungus, and a similar 1996 survey found that 56 percent of the sampled trees in an untreated lemon grove bore fruit with citrus black spot symptoms. The risk assessment further states, however, that in the 1994 survey, citrus black spot incidence was reduced from 14 percent in control groves to 0 percent in treated orange groves; in the 1995 survey, citrus black spot incidence was reduced from 82 percent to 11 percent; and in the 1996 lemon survey, none of the trees sampled in treated groves bore fruit with citrus black spot symptoms. These tests show that the incidence of citrus black spot can be significantly reduced by orchard treatments, which is just one aspect of the systems approach, even when the level of disease in the area is high. The issue of asymptomatic, latently infected fruit is addressed by the rule's requirement that a sample of fruit collected according to a statistically valid sampling protocol be held for 20 days under conditions that are ideal for producing symptoms in infected fruit. We believe that this rule provides an array of effective measures to reduce to a negligible level the risk of introducing citrus black spot into the United States.

APHIS Involvement

Comment: The proposed rule does not provide for APHIS personnel to perform any of the required inspections in Argentina. APHIS personnel should inspect all groves according to a detailed protocol, and the Argentines should pay all costs associated with such inspections.

Response: APHIS routinely relies upon the national plant protection organizations of exporting countries to provide the supervision or certification of phytosanitary measures that might be required for specific agricultural commodities, just as other countries rely upon APHIS to provide such services. We have had the opportunity to work with SENASA on numerous phytosanitary issues in the past and, as a result, we have every confidence in SENASA's ability to administer and supervise the citrus export program established by this rule. SENASA, as the national plant protection organization of Argentina, has a well-established infrastructure in place throughout the country. Also, SENASA personnel were involved at every step in the development of the systems approach, so they are as familiar as APHIS with its requirements. Further, SENASA personnel possess a level of familiarity with Argentine groves, growers, and citrus production that APHIS personnel do not. Given these considerations, we do not believe that any appreciable advantage would be gained, from a plant protection/risk reduction perspective, by requiring Argentina to pay for APHIS to establish a new operational presence in that country. However, as discussed earlier in this document in the paragraph titled ''Monitoring—Argentina,'' the operational work plan that addresses the administration of the export program will include provisions for active and direct monitoring of the program by APHIS personnel who will conduct frequent oversight visits to the growing areas and packinghouses in order to observe each step of the program in Argentina.

Comment: APHIS does not have a sufficient number of employees stationed in Argentina to provide an adequate level of monitoring for the proposed export program.

Response: As noted in the response to the previous comment, we have every confidence in SENASA's ability to administer and supervise the citrus export program established by this rule. Accordingly, this rule does not require direct APHIS supervision of the activities of the citrus export program carried out in Argentina, so APHIS staffing in that country is not an issue. While APHIS personnel will travel to the production areas in order to monitor the progress of the export program, especially during the first season, this rule provides for the direct supervision of the measures required in Argentina to be carried out by SENASA.

Origin Requirement

Comment: The proposed rule does not provide for annual surveys on citrus canker. Such surveys should be made, records should be kept, and audits should be required.

Response: Argentina has an ongoing monitoring program, as well as quarantine protection systems, for citrus canker that have been in place since 1992. Because Argentina's monitoring program is conducted in accordance with United Nations' Food and Agriculture Organization (FAO) standards, which include reporting and recordkeeping requirements, we do not believe that it is necessary for this rule to impose additional or redundant requirements regarding citrus canker surveys.

Comment: If APHIS allows the importation of Argentine citrus, it should impose movement restrictions on Argentine citrus similar to those of its domestic citrus canker regulations.

Response: Our domestic citrus canker regulations apply to fruit grown or packed in areas that are quarantined due to the presence of citrus canker. Because it has been established in accordance with international standards that northwestern Argentina is free of citrus canker, such movement restrictions are neither necessary nor justifiable.

Comment: According to the risk assessment, the median chance of citrus canker becoming established in the United States with no pest mitigation program is estimated as 1 chance in 4 trillion per year. The extremely low value for this risk estimate can partially be attributed to the fact that northwestern Argentina is assumed to be free of citrus canker. However, even if it is assumed that 100 percent of the boxes of fruit were initially infected (instead of the average of 0.05 percent assumed in the risk assessment), the likelihood of citrus canker establishing itself in the United States would be 1 in 2 billion per year, according to the analysis performed by APHIS. If it is really this improbable that citrus canker will become established in the United States, why does the risk assessment even address citrus canker? Why does the United States currently prohibit the importation of citrus fruit from countries where citrus canker occurs and regulate the interstate movement of citrus fruit from infested areas of the United States? On the one hand, APHIS states that no outbreak of citrus canker has ever been traced to the importation of fruit, and hence estimates a very low probability that citrus canker will occur. In contrast, the risk assessment's pest data sheet indicates that citrus canker can potentially move long distances on diseased fruit, that at least three outbreaks of citrus canker have occurred in the United States within the past 100 years, and that there is currently citrus canker in Florida. This information seems to indicate a risk greater than 1 in 2 billion per year, and suggests that the quantitative estimate is incorrect.

Response: The fact that northwestern Argentina has been demonstrated to be free of citrus canker in accordance with international standards was an important factor in our assigning an ''extremely low value for this risk estimate.'' Another important factor in that risk estimate is the evidence that the long-distance spread of citrus canker has occurred primarily through the movement of infected planting and propagating materials. The commenter reports that the pest data sheet indicates that the pathogen could potentially move long distances on diseased fruit, but omits the second half of the sentence in which that statement appears, wherein we report that there is no authenticated example of a disease outbreak that initiated from diseased fruit. Given the preponderance of evidence and expert opinion that long-distance spread occurs primarily through the movement of infected planting and propagating materials, and given the absence of documented cases of citrus canker outbreaks attributable to the movement of infected fruit, we believe that the probability calculated by the commenter is actually not unreasonable and our assessment of the risk posed by citrus fruit from the citrus-canker-free States of northwestern Argentina is appropriate. The larger question of whether citrus canker may be spread long distances on diseased fruit has not been answered to the satisfaction of some in the citrus production and research communities, which accounts for our continuing restrictions on the importation and interstate movement of citrus fruit from areas where the disease occurs.

Comment: If the fruit from northwestern Argentina passes through that country's eastern regions, which are not free from citrus canker, it is possible that the fruit could be contaminated by airborne citrus canker bacteria during transport.

Response: As stated in the pest data sheet for citrus canker provided in the risk assessment, short-distance dispersal of the pathogen in groves occurs primarily by wind-driven rain (rain and wind in excess of 6—8 m/sec) that causes the water soaking in leaves necessary for infection and causes entrance wounds when shoots are injured by wind whipping. The pest data sheet also notes that overhead irrigation may also play a role in short distance spread, as may mechanical equipment used in grove maintenance (Ferguson, *et al.*, 1985; Swings & Civerolo, 1993). Given that citrus fruit traveling from the packinghouses in the production areas will be boxed, with those boxes being protected from the elements to prevent damage, we do not believe that there is any appreciable risk of the fruit being contaminated by airborne citrus canker bacteria during transport.

Comment: In a 1994 report that is part of the rulemaking record, APHIS personnel who visited Argentina stated that they had concerns regarding an apparent lack of inspection at the local airports with regard to citrus canker. Has this issue been satisfactorily addressed?

Response: This issue was addressed following APHIS' 1994 trip. Argentina has established quarantine control stations at all main entrances to the citrus-canker-free States, including quarantine checkpoints at local airports.

Comment: Although it is claimed that the four States of northwestern Argentina listed in the proposed rule are free from citrus canker, it may be that citrus canker does actually exist in those States but is inhibited by warm temperatures and dry climate.

Response: Argentina's monitoring system for citrus canker consists of inspections and systematic sampling carried out annually in all production areas as well as in urban areas and nurseries. The collected samples are analyzed at university and research center laboratories using a high-sensitivity immunofluorescence serologic technique. Since this monitoring system was implemented in

1992, no evidence of citrus canker has been found. We are, therefore, confident that citrus canker is not present in the four northwestern Argentine States.

Grove Requirements

Comment: The 150-meter buffer zone appears to be inadequate for mitigating the spread of citrus black spot spores dispersed long distances by the wind.

Response: The buffer zone is designed to reduce to an insignificant level the possibility that ascospores from an infected grove would reach a grove producing fruit for the U.S. market. The ascospores are the only wind-dispersed propagule of black spot and are produced in leaves on the ground, usually under the tree canopy. Environmental conditions must be correct for ascospores to be dispersed (*i.e.*, rain to promote the release of the ascospores followed by sufficient wind to move the ascospores from under the overhanging canopy of the tree). The combination of the prevention of long-distance movement by the canopy itself and the presence of a 150-meter buffer that, like the export area of the grove, must be cleaned of all fallen leaves and other debris before blossom, will significantly reduce the unlikely possibility that ascospores from outside the area of production will reach the production area. Additionally, because environmental conditions are monitored and control methods are utilized during periods when the developing fruit is susceptible to infection, the likelihood of successful infection is negligible.

Comment: The risk assessment claims all new citrus stock in the canker-free area must originate within the zone (which we assume to mean the canker-free area) or be tissue culture that has passed through quarantine, whereas the proposed rule only requires new citrus stock planted within the export groves to meet those requirements. Does the risk assessment therefore overestimate the protection offered by this measure?

Response: The citrus stock origin requirements referred to by the commenter as being in the risk assessment are existing requirements established and enforced by SENASA as part of that agency's program to maintain the citrus-canker-free status of the northwestern Argentine States. SENASA's citrus stock origin requirements apply to all groves in the citrus-canker-free area of Argentina; therefore, the risk assessment's characterization of those requirements is correct and does not overestimate the protection offered by those requirements. Because the requirements of this rule pertain only to groves that produce fruit for export to the United States, the rule does not extend those requirements to other groves producing fruit for other export markets or for domestic consumption within Argentina.

Comment: The proposed rule provides that any new citrus planting stock used in a certified grove must originate from one of the four States or from a SENASA-approved propagation center (§ 319.56–2f(b)(3)). It is not clear whether this requirement goes only to citrus canker, or whether it also applies to citrus black spot and sweet orange scab. If it does not apply to citrus black spot and sweet orange scab, what precautions will be taken to insure that planting stock does not carry these diseases from within the approved areas? Evidence must be included in the record that such precautions will be effective.

Response: As explained in the response to the previous comment, the citrus stock origin requirements are part of SENASA's program to maintain the citrus-canker-free status of northwestern Argentina. Thus, those requirements apply only to citrus canker, and not to citrus black spot or sweet orange scab. Because this rule is not based on the four northwestern Argentine States being a free area for citrus black spot or sweet orange scab, it was not necessary to include provisions for the freedom of planting stock from those two diseases.

Comment: The preamble to the proposed rule states that domestic-origin citrus plants must meet ''strict phytosanitary requirements'' before they may enter the four States that will be allowed to export. Is this reference to the SENASA requirements for a propagation center?

Response: Yes. The requirements referred to in the preamble of the proposed rule pertain to the testing and grow-out regimen conducted at SENASA-approved citrus stock propagation centers for citrus stock that has been imported into Argentina and for any domestic-origin citrus plants from outside the four citrus-canker-free States. As stated in the proposed rule, citrus plants from sources outside the citrus-canker-free area ''must meet strict phytosanitary requirements before they may enter the States of Catamarca, Jujuy, Salta, or Tucuman. Under SENASA supervision, such citrus plants are officially tested to ensure their freedom from quarantine pests and diseases, and are grown in quarantine before being released for use in the citrus canker-free area of Argentina.''

Comment: The preamble implies that nursery stock will be ''tested.'' However, citrus black spot is a latent disease. Can it be successfully detected years in advance of when it appears? If tests cannot be carried out, what precautions will be taken to ensure that stock that may be from groves infected with sweet orange scab or citrus black spot is not planted in noninfested groves? Answers to these questions do not appear in the rulemaking record. Without such answers, APHIS should not proceed with the proposed rule.

Response: As noted previously, SENASA's requirements, and the requirements of this rule, pertaining to planting stock are intended to prevent the introduction of citrus canker into the citrus-canker-free area of northwestern Argentina; because the four Argentine States are not a free area for citrus black spot or sweet orange scab, those measures are not intended to provide protection against citrus black spot or sweet orange scab introduction via nursery stock. The risks presented by those two diseases are instead mitigated by the pre-and post-harvest treatment and inspection requirements of this rule.

Comment: The risk assessment speaks only of the removal of fallen fruit and leaves in the grove, but implies immediate and continuous removal. The proposed rule considers fallen fruit, leaves, and branches in both grove and buffer zone, but specifies removal only before blossoming in the grove (but not necessarily before blossoming in the buffer zone, or in any regions outside the buffer zone). If the buffer zone contains fruit blossoming earlier than the grove, the fruit is more likely to become infected if there is contaminated material remaining on the ground, but such infection is less likely to be observed/reported.

Response: The buffer zone immediately surrounds the grove—indeed, it would be part of the grove if the owner was not producing fruit for export to the United States—so it is not likely that the trees in the buffer area will be blossoming any earlier or later than the trees in the export portion of the grove.

Comment: The proposed requirement for the removal of all fallen fruit, leaves, and branches from the orchard floor and the buffer area is not a biological, well-justified safeguard. Research on attempts to decrease incidence in other, similarly dispersed diseases through cleaning of groves indicated that, while leaf and fruit removal could remove about 90 percent of the inoculum, the 10 percent of inoculum still present was more than sufficient to maintain the presence of the disease. It is very likely that ascospore inoculum will remain in the ground and any out-of-season or late-hanging fruit will supply additional inoculum.

Response: The removal of fruit, leaves, and branches from the orchard floor and buffer area is a biologically justified safeguard. Because the ascospores of citrus black spot are produced only in fallen leaves, the removal of this debris will significantly reduce the inoculum level. This is a part of a control strategy that is used by plant pathologists for diseases for which inoculum is produced in fallen debris. Because this is only one part of a systems approach, it is designed to reduce the likelihood of infection, not prevent it entirely. Therefore, we have taken into account in the risk analysis the possibility that debris may remain on the ground or in late season fruit.

Comment: The proposed rule requires that export groves be cleaned of debris, leaves, and fallen fruit before bloom to remove the main sources of disease inoculum. Argentine researchers monitored leaf fall during a whole season and found that for all three citrus species in Salta, the majority of leaves fell between August and November, while fruit set occurred from September to October. Thus, the maximum leaf fall is occurring during bloom and fruit set. Furthermore, the summer rains, which are needed for development of citrus black spot on the dead leaves, tend to start in October. If decreasing inoculum through removal of fallen leaves is the goal to protect the developing fruit, then there must be continuous cleaning of the grove throughout the maximum leaf fall period, otherwise fruit will be developing in the presence of leaf litter as a potential source of inoculum.

Response: A thorough cleaning of the grove and buffer area prior to blossom will remove a significant amount of potential inoculum. Any ascospores on leaves that fall after the cleaning of the grove will not form ascocarps until 40 to 180 days after blossom, depending on the frequency of wetting; by that time, the preventive oil-copper oxychloride sprays will be in use to protect the developing fruit from infection. If the removal of fallen fruit, leaves, and branches was the only measure employed to reduce the risk of citrus black spot infection during the growing season, additional cleaning would likely be advisable, but given the additional requirements of this rule, we do not believe that is necessary.

Comment: The proposed requirement for the removal of all fallen fruit, leaves, and branches from the orchard floor and the buffer area would be difficult, if not impossible, to satisfy. We suggest that the word ‘‘substantially’’ be inserted before the word ‘‘all’’ to make this requirement more realistic.

Response: Although the grove/buffer sanitation requirement may be difficult to meet, SENASA and the growers in northwestern Argentina have indicated their willingness to comply with that requirement. Further, it would likely prove difficult to establish a standard for what is meant by ‘‘substantially all.’’

Comment: The proposed grove-cleaning would be a difficult, if not impossible, task to complete. The proposed rule does not explain what criteria will be used to verify the orchard floor cleaning and how it can be verified at a later date.

Response: The proposed rule and this final rule state that SENASA must inspect the grove and buffer area before blossom to verify that all fallen fruit, leaves, and branches have been removed from the ground. In the phytosanitary certificate required by paragraph (d) of the regulations, SENASA must confirm that the fruit was produced in accordance with the requirements of the regulations; the grove and buffer area sanitation measures are one of those requirements. SENASA will keep records regarding its inspection of each export grove and buffer area, and APHIS may request to review those records. Further, as noted previously in this final rule, the operational work plan governing the administration of the export program will provide for the active and direct monitoring of the export program by APHIS personnel; that monitoring will include verification of the required grove sanitation measures.

Comment: The risk assessment states that groves are inspected for disease symptoms prior to fungicide applications, and fruit with possible disease symptoms is sent to a laboratory for analysis. The timing of fungicide applications is determined by ‘‘an expert system.’’ In section 8.f. P1 of the risk assessment, it indicates that the export groves would have a ‘‘minimum of two or three additional applications’’ of fungicide, as opposed to the total of at least two specified in section 8.a. of the risk assessment and in the proposed rule. The proposed rule states that SENASA will determine timing of fungicide applications ‘‘during the growing season,’’ based on monitoring of climatic data, fruit susceptibility, and the presence of disease inoculum, and will monitor for correct fungicide application. There is no requirement in the proposed rule for inspection of the groves for pests at times of fungicide application, nor for laboratory analysis of suspect fruit at this time (if there is any fruit at the times of spray application). There is no discussion of what is meant by ‘‘presence of disease inoculum.’’ There is no requirement that the fungicide treatment include any fruit, leaves, or branches on the ground that have not been removed. It is not required by the proposed rule that SENASA use an expert system to determine fungicide application times.

Response: After the risk assessment was prepared, and before the provisions that formed the basis of the proposed rule were fully developed, SENASA suggested that the inspections be conducted after the fungicide treatments, when there is a better chance of detecting the disease; this accounts for the difference between the risk assessment (which speaks to inspection before fungicide treatment) and the proposed rule on this subject. The oil-copper-oxychloride treatments will be applied during the period of greatest susceptibility of the fruit to infection (*i.e.*, from the time that three quarters of the petals have fallen to the time the fruit have reach 3 cm in diameter). Given that disease symptoms are unlikely to be manifested at that stage of fruit development, the proposed rule did not, and this final rule does not, call for inspections prior to the application of those treatments or the laboratory inspection of suspect fruit at that time.

With regard to the number of oil-copper-oxychloride applications, section 8.f P1 of the risk assessment did, as noted by the commenter, state that groves would receive ‘‘a minimum of two or three additional applications of fungicide,’’ while elsewhere in the risk assessment and in the proposed rule the number of applications was characterized as ‘‘two or more’’ and ‘‘at least twice.’’ However, the way in which the number of applications was characterized did not have any effect on our estimation of the mitigation value of the fungicidal sprays. Our estimates were not based on any finite, predetermined number of sprays; rather, the risk assessment assumed that the timing and number of sprays would be determined using SENASA’s expert system, with the optimal number of sprays being applied to prevent infection.

With regard to the term ‘‘expert system,’’ which was used in the risk assessment, we chose to describe the components of the system in the proposed rule (*i.e.*, monitoring of climatic data, fruit susceptibility, and the presence of disease inoculum) rather than simply use the term itself. The risk assessment and the proposed rule are, therefore, referring to the same thing. We have included the term ‘‘expert system'' in § 319.56–2f(b)(5) of this final rule to make that clear.

With regard to what is meant by ''presence of disease inoculum,'' SENASA's monitoring of the presence of disease inoculum considers both the presence of fallen leaves within the grove, as leaves have been identified as the primary source of inoculum, as well as the incidence of disease in the area surrounding each grove.

We did not include provisions for the spraying of fruit, leaves, or branches that may be on the ground because the oil-copper-oxychloride treatment is intended to prevent infection in the developing fruit itself and because the required grove sanitation measures are intended to leave the ground in the grove free of such debris.

Comment: Eureka-type lemons, which are commonly planted in Argentina, do not have a very distinct start and finish of flowering, depending on climatic conditions. Under mild winter conditions, flowering can occur year round; indeed, some reports indicate that lemons are harvested year round in Tucuman province. In one report, Argentine researchers observed both immature and mature lemons on the sampled trees at the same time in Salta and noted that the presence of different aged fruit provides for an additional risk of fruit infection. How can a grove be certified as having been cleaned prior to bloom when bloom is not specifically seasonal?

Response: While there may be multiple blooms in a year under mild winter conditions, Argentina reports that there is, as occurs in the United States, a main spring flush during which most of the trees will bloom, and it is the fruit from those trees that will be exported to the United States. Therefore, the blossoming period in the Argentine production areas is distinct enough to allow for the cleaning and inspection of the groves and buffer areas prior to blossom.

Comment: The timing of flowering in not necessarily distinct in some common lemon varieties, and it is not clear how the timing of the oil-copper-oxychloride treatments will be determined when flowering and fruit set occur over several months. The efficacy studies of the fungicide treatments need to provide for careful testing of timing of the treatments to deal with the different bloom lengths, fruit set, rainfall patterns, and disease incidence in the different citrus species and the different regions.

Response: The timing of each treatment application will be determined by SENASA using an expert system that considers climatic data (including temperature and rainfall patterns), fruit susceptibility (which is dictated in part by the timing and length of bloom, when fruit set occurred, and the relative disease susceptibility of each species), and the presence of disease inoculum (which takes into account both the presence of fallen leaves within the grove, as leaves have been identified as the primary source of inoculum, and the incidence of disease in the area surrounding each grove). The goal of the expert system is to maximize the effectiveness of the oil-copper-oxychloride treatments in preventing the fruit from becoming infected. Whether or not that goal has been met will become apparent during the laboratory incubation and examination of the 20-day preharvest sample, as well as through the grove and packinghouse inspections.

Comment: The proposed rule fails to require that certified groves keep detailed records of the various blooms and required program steps (*e.g.*, when the spraying and debris-clearing programs are carried out). Any program which APHIS develops should be subject to further public comment.

Response: There is no need for APHIS to develop a recordkeeping program as suggested by the commenter. As stated in the proposed rule and in this final rule, SENASA is responsible for inspecting the registered groves prior to blossom to ensure that the required sanitation measures have been accomplished, as well as for determining the timing of the oil-copper-oxychloride treatments and monitoring their application. SENASA will maintain records of these activities as part of its citrus fruit export program, and will make those records available to APHIS during program reviews or when otherwise necessary.

Comment: From the APHIS–SENASA correspondence, it is clear that APHIS had wanted an inspection of the orchard prior to the fungicide treatments. However, SENASA requested that the inspection for disease occur after the treatments. APHIS must explain its reasoning for why the inspection of a grove for disease before fungicide applications was not included in the proposed rule.

Response: Until the fruit has matured somewhat and has begun to color, the symptoms of citrus black spot will not be apparent. Since the fruit would be too small and would not have colored yet prior to the fungicide applications, we concurred with SENASA's suggestion that the inspections be conducted after the treatments, when there is a better chance of detecting the disease.

Comment: No specific rate for the copper oxychloride sprays is provided in the proposed rule. It appears that the Argentine researchers found that a rate of 0.36 percent was more effective in preventing the disease, but SENASA has stated that a rate of 0.18 percent would be used for the export program, which may be ineffective at least some of the time or on some fruit, according to the information in the record. APHIS should determine why the lower copper oxychloride rate was chosen by SENASA, even though the data showed the higher rate to be more effective.

Response: The lower oil-copper-oxychloride application rate was recommended by SENASA based on its studies that showed that the 0.36 and 0.18 percent application rates were both effective in preventing disease in test plots when the disease was evident in the control plots. Given that the 0.18 percent application rate was shown to be effective in preventing disease, and given that this rule requires at least two applications of the fungicide during the growing season, we have accepted SENASA's recommendation that the 0.18 percent application rate be used.

Comment: It appears that Argentine researchers performed only one test to assess the effectiveness of the in-season fungicide treatments for sweet orange scab and that only one test was conducted using both in-season fungicide treatments and post-harvest chemical treatments. This limited testing is not sufficient to determine the effectiveness of the proposed measures. APHIS should provide or cite efficacy data for the proposed copper oxychloride sprays on the incidence of sweet orange scab.

Response: The American Phytopathological Society's Citrus Compendium (Whiteside *et al.*, 1988), which was cited in the body of the risk assessment (p. 57) and in the pest data sheet for sweet orange scab (p. 101), indicates that copper sprays are effective protectants to prevent the infection of susceptible fruit by sweet orange scab.

Comment: While the risk that sweet orange scab might be introduced into the United States may be reduced by timely, reliable, and negative surveys, there are still some unresolved taxonomic issues surrounding the *Elsinoe* species complex. The less than distinct differentiation between possible strains/biotypes strongly suggests that additional systematic research is needed to fully understand this pest complex.

Response: While there may be room for additional systematic research in order to fully differentiate between possible strains/biotypes of *Elsinoe* spp., we do not believe that any of those taxonomic issues need to be resolved in order for the survey, inspection, and treatment provisions of this rule to be effective in reducing the risk of sweet orange scab being introduced into the United States.

Comment: A more detailed description of how an orchard will be inspected or sampled (location in grove, timing, *etc.*) for sweet orange scab is necessary.

Response: The freedom of the fruit from sweet orange scab will be verified through the inspections required by this rule, *i.e.*, the visual inspection of the grove and buffer area required by § 319.56–2f(b)(6) and the packinghouse inspections required by § 319.56–2f(c)(4) and (c)(5). Given that the symptoms of sweet orange scab are readily detectable on infected fruit, and given that the detection of the disease in a single fruit will result in a grove's losing its ability to export fruit to the United States for the remainder of the current growing and shipping season, we believe that the 20-day preharvest survey and the subsequent packinghouse inspections will effectively mitigate the risk of fruit infected with sweet orange scab being imported into the United States.

Comment: Copper-based fungicides are preventative, *i.e.*, they only prevent new infections and do not stop already established infections. Thus, timing is extremely critical to ensure that developing fruit is continuously protected from infections. Other fungicides, such as preharvest applications of Benomyl (benlate), not only prevent, but also stop infections that are already present, and newer chemistry fungicides (triazoles, strobilurins, *etc.*) may provide better control of already infected fruit and allow rotation of fungicides.

Response: Copper oxychloride is a well-established preventative treatment for citrus black spot and sweet orange scab, and its efficacy has been demonstrated in a variety of studies on the control of these diseases (for example, as referenced in Whiteside *et al.,* 1988, as cited in the risk assessment). We would, however, certainly consider allowing the use of other fungicides if the Argentine growers or SENASA were to request that we do so and were to provide information supporting the efficacy of the alternative treatments.

Comment: Since the packinghouse treatments have little or no impact on citrus black spot infections, any citrus black spot present in the fruit must have been prevented or detected by the time of harvest. The keys to the proposed program for Argentina are successful prevention and successful detection of any infection. The proposed preventative fungicide treatments are not 100 percent effective, so the successful detection of treatment failures is critical, but the latency of citrus black spot makes that detection very difficult. Given that difficulty, it appears there is a near certainty that latently infected fruit will be imported into the United States.

Response: As explained in detail later in this document, we have modified the protocol for sampling the grove and buffer area in response to comments on the subject. This final rule requires the sampling of 4 fruit from each of 298 randomly selected trees in each 800 hectares of grove and buffer area, which yields at least a 95 percent confidence level of detecting an infection rate of 1 percent or greater. In addition, the modified sampling protocol requires that the fruit be chosen from the portion of the tree most likely to have infected fruit. Given those requirements, there is almost no chance that infection could exist in a grove without infected fruit being included in the sample subjected to laboratory examination. Further, during the required 20-day sample holding period, the fruit will be held under conditions that are ideal for the expression of symptoms in any infected fruit (*i.e.*, 27 °C, 80 percent relative humidity, and permanent light). Finally, this rule requires that the detection of symptoms in a single fruit will result in a grove being removed from the export program and all fruit from that grove being prohibited from entering the United States. Given those considerations, we believe that the risk of latently infected fruit being imported into the United States is negligible.

Comment: The risk assessment claims the buffer zone receives the same ''treatment, inspections, sanitation, *etc.*'' as the grove, but the proposed rule only calls for full inspections of fruit from the grove, not from the buffer zone. Thus if citrus black spot or sweet orange scab is detected on fruit from the buffer zone at or after harvest, there is strictly no requirement to remove that grove from the program. Indeed, there are no requirements in the proposed rule for any inspection or reporting on diseases in the buffer zone after the 20 days preharvest inspection.

Response: This final rule, as did the proposed rule, calls for the removal of fallen fruit, leaves, and branches from both the grove and the buffer area, inspection of both the grove and the buffer area to ensure the cleaning requirements have been met, spraying of oil-copper oxychloride in both the grove and the buffer area, and a visual inspection of both the grove and the buffer area 20 days before harvest. While the proposed regulations did not specifically state where the sample of fruit for laboratory examination was to be collected, the samples must be taken from both the grove and the buffer area. (This is made clear in § 319.56–2f(b)(6)(ii) in the regulatory text of this final rule.) This is consistent with the risk assessment's statement that the buffer zone will receive the same ''treatment, inspections, sanitation, *etc.*'' as the grove. After harvest, the packinghouse treatments and inspections are limited to the fruit from the grove itself because, as stated in § 319.56–2f(b)(2), no fruit from the buffer zone may be offered for importation to the United States.

Comment: There is no definition of ''laboratory,'' or any requirement for certification of such laboratories, nor is there any requirement that the laboratory examination be certified or carried out by SENASA.

Response: The laboratory testing required by § 319.56–2f(b)(6)(ii), as is the case with the other surveys and inspections that must be conducted in Argentina under this rule, must be conducted under the direct supervision of SENASA, and records relating to testing and test results will be available for review by APHIS.

Post-harvest Requirements

Comment: The risk assessment (8.a.) claims that packinghouses will be used for export to the United States only. The preamble of the proposed rule states that packinghouses cannot accept fruit from ''nonregistered export groves during the time that fruit intended for export to the United States is being handled in the packinghouse.'' The proposed rule requires that ''[d]uring the time that a packinghouse is used to prepare grapefruit, lemons, or oranges for export to the United States, the packinghouse may accept fruit only from groves that meet the requirements of paragraph (b) of this section.'' The risk assessment (8.a.) requirement is stricter than the proposed rule, and the preamble of the proposed rule indicates that packinghouses could accept nonregistered, nonexport fruit. The proposed rule allows for some possibility of admixture, since no time-scale is specified; one could alternately process nonexport and export fruit in separate batches.

Response: While the risk assessment's narrative description of the systems approach and the proposed rule's description of packinghouse requirements differed in their approach, we do not believe that the two documents contradict one another. The statement in the risk assessment that packinghouses in the program will only be used for export to the United States reflected the risk assessors' understanding that there would be no commingling of fruit from registered and nonregistered groves in the packinghouses. This is entirely consistent with our statement in the preamble of the proposed rule that ''[b]arring the entry of fruit from nonregistered groves into the packinghouse would ensure that the fruit intended for export is not commingled with or potentially infected by fruit that was grown in a grove that has not been subject to the same sanitation, inspection, and treatment measures that would be required for export groves.'' This statement from the proposed rule's preamble also makes it clear that we were not indicating, as the commenter asserts, that packinghouses would be able to accept fruit from nonregistered groves during the time that fruit was being prepared for export to the United States.

To address the commenter's concerns that ''no time-scale is specified'' with regard to when batches of export fruit and nonexport fruit could be processed, we have modified the wording in § 319.56–2f(c)(2) to reflect our intent that there be no commingling of fruit from registered and nonregistered groves in the packinghouse. That paragraph now states: ''During the time that any grapefruit, lemons, or oranges from groves meeting the requirements of paragraph (b) of this section are in the packinghouse, no fruit from groves that do not meet the requirements of paragraph (b) of this section may enter the packinghouse.'' To support this requirement, and to prevent the ''possibility of admixture'' raised by the commenter, a SENASA-registered technician will be present at each packinghouse to verify the origin of all fruit entering the packinghouse. In its correspondence with APHIS during the development of the proposed rule, SENASA had stated that a registered technician would be present at each packinghouse for that purpose, but this consideration was not explicitly set forth in the text of the proposed rule. We also are amending § 319.56–2f(c)(2) to make it clear that a packinghouse technician registered with SENASA must verify the origin of all fruit entering the packinghouse.

Comment: What steps will be taken to ensure there is no commingling of fruit from certified and uncertified groves at the packinghouse? For example, records would have to be kept of the arrival of each load. These records would have to be available for auditing.

Response: As noted in the response to the previous comment, a technician responsible for the packinghouse, who will be approved by and registered with SENASA, will be on hand to verify the origin of all lots of fruit entering the packinghouse. These technicians are required by SENASA to maintain accurate records, and SENASA will make those records available to APHIS upon request.

Comment: The proposed rule and risk assessment do not mention the need for measures to prevent the contamination of export groves, packinghouses, or storage facilities by workers or equipment that have been in untreated groves or that have been in contact with untreated fruit. Such measures are necessary to prevent the artificial spread of disease inoculum. APHIS should consider establishing sanitation measures for workers and equipment moving between nonregistered groves and those producing fruit destined for export to the United States. The requirements would have to be set forth in detail in the regulation, and strict audit and inspection procedures would have to be implemented to ensure that disease is not transmitted to export groves. If such requirements are not established, APHIS should discuss why such measures are not needed, given the characteristics of the two diseases of concern. Similarly, APHIS should establish sanitation measures for packinghouses and storage facilities to use between runs of U.S.-bound citrus and fruit bound for other markets.

Response: The spores produced in fruit infected with sweet orange scab and citrus black spot are nonpigmented and are thus short-lived when removed from their host tissue. It is, therefore, unlikely that any ''free'' spores that might be found on workers or equipment moving from an untreated grove into an export grove, packinghouse, or storage facility would remain viable long enough to cause infection. Similarly, because of the short-lived nature of ''free'' spores, there is little risk that export fruit would become contaminated during processing at a packinghouse that had previously handled fruit from nonregistered groves. In any event, that export fruit will be mature fruit, and thus not susceptible to infection. Furthermore, that fruit will be surface-sterilized and waxed in the final processing steps before being packed in boxes, thereby rendering nonviable any spores contaminating the surface of the fruit. That surface-sterilization and waxing is a routine measure applied to all fruit in Argentine packinghouses, including nonexport fruit, so it is unlikely that export fruit would be contaminated after packing even if it was stored with nonexport fruit.

Comment: The proposed rule does not specify what happens to other fruit in the packinghouse if infected fruit from some other grove that simultaneously or recently went through the same packinghouse is detected.

Response: We believe that it is unlikely that infected fruit would proceed undetected as far as the packinghouse, given this rule's requirements for the removal of potential sources of inoculum from the groves, the treatment of developing fruit, and the sampling and testing of mature fruit prior to harvest. However, if infected fruit was identified in the packinghouse or at a later time, we believe that the non-susceptibility of the mature fruit that will be handled in the packinghouses, when combined with the short-lived nature of ''free'' spores and the required surface-sterilization and waxing, make it unlikely that fruit will be contaminated as a result of contaminated fruit having recently passed though the same packinghouse. This rule's requirement that the identity of the origin of the fruit be maintained during its time in the packinghouse will prevent fruit from two different groves being processed simultaneously.

Comment: The risk assessment claims that at the prepacking inspection stage, any blemished fruit are culled. There is no requirement in the proposed rule for culling of blemished fruit, although that presumably would be a commercial necessity; the proposed rule only requires SENASA to examine fruit for any evidence of disease.

Response: The commenter is correct in presuming that the culling of blemished fruit is a commercial consideration. As such, our proposed rule did not include a requirement for the culling of blemished fruit, *per se,* but instead focused on SENASA inspecting the fruit prior to packing to verify its freedom from citrus black spot and sweet orange scab. However, as explained in the response to the next comment, we have included the culling of blemished fruit in the provisions of this rule set forth in § 319.56–2f(c)(4) relating to the 4-day packinghouse holding period.

Comment: The proposed rule called for the holding of all harvested fruit for 4 days at room temperature before sorting and packing, but there is no evidence in the record that this is an adequate time for latent citrus black spot symptoms to develop. The Argentine researchers stated that they held sampled fruit for 20 days at 27 °C, 80 percent relative humidity, and in permanent light in order for latent citrus black spot infections to develop enough for detection. In addition, the risk assessment assumes that the fruit sampled from the orchard shortly before harvest will be held for 20 days at room temperature, which would allow latent citrus black spot infections to show up in the samples. However, the proposed regulations do not explicitly state a 20-day holding period at room temperature, nor do they define what constitutes ''room temperature.'' APHIS should conduct studies to determine the optimum time, temperature, and other environmental conditions for detection of the latent citrus black spot infections; if APHIS cannot provide data that demonstrates the effectiveness of the 4-day holding period, a longer holding period should be required. Further, steps must be taken to ensure that all packinghouses are able to hold the harvested fruit at the required temperatures for citrus black spot development in order to assess the practicability of this measure. Finally, the requirements for Argentine citrus should explicitly state that fruit sampled from the grove 20 days before harvest must be held under conditions conducive to citrus black spot development.

Response: We acknowledge that the proposed rule did not fully explain the procedure to be used during the 20-day laboratory examination period of the sampled fruit. We further acknowledge that the proposed rule incorrectly stated that the purpose of the 4-day holding period was to allow for symptom expression of citrus black spot in the event that latent infection exists in the fruit. We have corrected both of these issues in the text of the final rule.

As noted by the commenter, the laboratory procedure to be used to promote the expression of symptoms in the fruit sampled 20 days prior to harvest will be to hold the fruit for 20 days at 27 °C, 80 percent relative humidity, and in permanent light. These conditions have been shown to be ideal for latent citrus black spot infections to develop enough for detection. Although this protocol was omitted from the proposed rule, the protocol was, as evidenced by the commenter's remarks, explained fully in documents made available following the publication of the proposed rule.

If none of the sampled fruit manifest symptoms of citrus black spot during the 20-day laboratory examination period, the remaining fruit in the grove will be harvested and taken to the packinghouse, where it will be held at room temperature—*i.e.,* not refrigerated—for 4-days. This 4-day holding period is a standard practice in the Argentine citrus industry that provides sufficient time for bruises or other damage on the fruit to become plainly evident, thus providing an opportunity for that blemished fruit to be culled. For the purposes of this rule, that 4-day holding period will also provide an opportunity for SENASA inspectors to examine the harvested fruit for signs of infection.

We have, therefore, amended the requirements set forth in the rule portion of this document in order to fully explain these requirements. The requirements pertaining to the laboratory examination are set forth in § 319.56–2f(b)(6)(ii), and the provisions relating to the 4-day holding period and the culling of damaged fruit in the packinghouse are set forth in § 319.56–2f(c)(3) and (c)(4).

Comment: Section 8.a of the risk assessment claims 4–5 days holding time (for all fruit) to allow expression of citrus black spot. Section 8.f P3 of the risk assessment claims a ''20-day preharvest sample and incubation period'' that may have been derived from the 20-day preharvest inspection, or may be a confusion between inspection and this packinghouse holding time. Section 8.f P3 of the risk assessment also confuses matters since it refers to a ''sample'' holding time, but then refers to the likelihood of packinghouse detection, but the fruit in the packinghouse would not have had the 20-day holding time. The preamble and proposed rule require just 4 days holding time at room temperature, followed by SENASA inspection.

Response: The commenter has identified that, like the proposed rule, the risk assessment's narrative description of the systems approach (Section 8.a) incorrectly characterizes the purpose of the 4-day holding period. The intended purpose of both the 4-day holding period and the 20-day laboratory examination period are explained in the response to the previous comment and in paragraphs (b)(6), (c)(3), and (c)(4) of § 319.56–2f in this final rule. In light of that explanation, it can be seen that the reference to ''a 20-day preharvest sample and incubation period'' in section 8.f P3 of the risk assessment accurately portrays what is required by this rule. Section 8.f P3 of the risk assessment links the sample holding time and the likelihood of packinghouse detection (which the commenter states ''confuses matters'') because that node P3, ''Pathogen not detected at packing house inspection'' is the portion of the risk assessment where the 20-day holding period is addressed. As stated in Section 8.f. P3: ''Also considered in making our estimates for this node in the mitigated scenario, was the orchard sampling 20 days prior to harvest and the incubation of this sample at room temperature to observe post harvest symptom development.''

Comment: The risk assessment claims in section 8.a that blemished fruit are culled during harvest and claims in section 8.f. P2 that diseased fruit would be detected and culled at harvest; section 8.f P2 also stated that this detection would be improved for citrus black spot ''under the proposed workplan'' due to its ''more rigorous export standards and [the] reduced frequency of latent infection,'' although no specific measures are mentioned for harvest time. The preamble and proposed rule have no harvest requirements whatever, and it appears from the correspondence on the record that the Argentines do not know what ''blemished fruit'' means.

Response: As noted in our response to a previous comment, the culling of blemished fruit was not specifically addressed in the proposed rule, but requirements for the culling of blemished fruit in the packinghouse have been added to this rule. While pickers can be expected to cull obviously blemished fruit during harvest, the best opportunity for the removal of blemished fruit will come after the fruit has been held for 4 days at room temperature. Given that the 4-day holding period will provide an opportunity for bruises and other damage on the fruit to become more readily apparent, we consider this post-harvest culling to be an improvement over the reliance on pickers to cull blemished fruit that was envisioned in the risk assessment. Finally, we have explained to SENASA what we mean by the term ''blemished fruit.''

Comment: The proposed systems approach envisions chemical treatment after the 4-day holding period, followed by a further inspection before packing. Does APHIS believe such treatment will have any impact on citrus black spot? If so, what is the evidence? The literature on citrus black spot would indicate that such treatment would have no impact. We believe that the data provided by Argentina demonstrates the chemical treatment envisioned in the proposed systems approach, to be applied prior to packing of the fruit, will not have any impact on the virulence of the citrus black spot spores.

Response: The post-harvest treatment is designed to render nonviable any spores contaminating the surface of the fruit, and these post-harvest treatments are mainly to prevent post-harvest decay. In the risk assessment, our estimates took into account the fact that post-harvest treatments have little effect on citrus black spot infections (a reduction from 0.64 to 0.50).

Comment: The proposed rule does not specify any concentrations or other conditions for the immersion in orthophenilphenate of sodium, nor any application rate for the spray with imidazole or application of 2–4 thiazalil benzimidazole and wax. Thus, it appears that any concentrations or application rates—including ineffective ones—would meet the requirements of the proposed rule.

Response: Argentina's environmental protection authority, like our Environmental Protection Agency, requires that products such as those called for in this rule be applied in accordance with their label instructions. For orthophenilphenate of sodium, the concentration is 200 L per 2,000 L of water; for imidazole, it is 200 cm^3 per 100 L of water; and for 2–4 thiazalil benzimidazole, it is 0.5 L per 200 L of water. By not including these concentrations in the text of the rule itself, we avoid the need for future amendments to the rule should the label instructions change.

Comment: The risk assessment (8.f. P4) states that the treatment program incorporates a dip in 200 parts per million sodium hypochlorite for 2 minutes. The preamble and rule portions of the proposed rule spell out the required chemical treatments, but do not include any mention of time for the sodium hypochlorite immersion.

Response: The commenter is correct; the proposed rule should have stated that the immersion in sodium hypochlorite be for 2 minutes as described in the risk assessment. We have corrected that omission in § 319.56–2f(c)(4)(i) of this final rule.

Comment: There is no explicit mention that the packed boxes of fruit may not contain any plant parts other than the fruit to be exported. Leaves and twigs are suitable vectors for diseases and several insects pests (e.g., brown citrus aphid). While a prohibition on inclusion of leaves, twigs, or other plant parts in packing boxes is included as a general requirement for imported fruits and vegetables in 7 CFR 319.56–2(a), the requirements for Argentine citrus should explicitly prohibit any plant parts other than the fruit itself.

Response: The commenter is correct in noting that § 319.56–2(a) requires that ''[a]ll importations of fruits and vegetables must be free from plants or portions of plants, as defined in § 319.56–1.'' *Plants or portions of plants* is defined in § 319.56–1 as ''[l]eaves, twigs, or other portions of plants, or plant litter or rubbish as distinguished from clean fruits and vegetables, or other commercial articles.'' We agree that this is an important requirement and have added language to the requirements in § 319.56–2f(c)(5) to make it clear that SENASA inspectors must ensure that all stems, leaves, and other portions of plants have been removed from the fruit prior to packing.

Comment: All packing boxes sent to commercial citrus-growing areas of the United States should be required to be destroyed upon reaching their destination, and records of such destruction should be kept.

Response: We are unaware of any risks presented by packing boxes used to ship citrus fruit produced in accordance with this rule that would make it necessary to require their destruction, and we do not believe that any meaningful reduction in risk would be realized by imposing such a requirement.

Fruit Flies, Other Pests, and Treatments

Note: On May 19, 2000, we received a letter from the California Citrus Research Board (CCRB) informing APHIS that the CCRB had contracted with U.S. Department of Agriculture's (USDA's) Agricultural Research Service (ARS) to conduct a research program to determine the suitability of lemons as a host of tephritid fruit flies. The CCRB letter reported that the preliminary results of the initial tests call into question the current regulatory assumption that lemons at any stage of maturity are not a viable fruit fly host. When contacted by APHIS for additional information, ARS reported that the preliminary results were similar to the results published in 1984 by ARS scientists (*i.e.,* the Spitler, et al. research discussed below) in which a limited number of Medfly pupae were recovered in similarly conducted tests. ARS reports that, at the present time, it is reluctant to extend the findings of these preliminary laboratory cage studies to lemons in a commercial field setting where there might be other, more preferred fruit fly hosts present. Further, ARS points out, some species of fruit are known to be much more infestable after harvest than before as a result of a rapid ripening process initiated when the fruit is separated from the tree; ARS states that fruit that can be stored on the tree, such as citrus, may fall into this category. ARS has stated that they will provide APHIS with a full report upon the conclusion of the studies. If the results of the studies lead to a recommendation that quarantine measures such as cold treatment should be required for lemons, we will take action to amend both our foreign and domestic quarantine regulations to require that the appropriate treatment be applied to lemons as a condition of importation or interstate movement.

Comment: APHIS should require a fruit fly trapping program in the export area and should require spraying of the groves if population levels exceed a set threshold. If the spraying proves ineffective at eradicating the fruit flies, exports should be cut off, even with cold treatment.

Response: Argentina reports that populations of Medfly and the South American fruit fly *(Anastrepha fraterculus)* are not present at economically important levels and periodically confirms their low population levels through trapping. Further, Argentina maintains that *A. obliqua* and *A. serpentina* are not present in Argentina despite reports to the contrary, and that both species of fruit fly are considered quarantine pests in Argentina. Given the economic importance of the citrus industry in Argentina, it is in that country's best economic interests to ensure that fruit fly populations remain low. The lack of significant fruit fly population pressure, combined with the nonhost status of smooth-skinned lemons and this rule's requirement for a probit 9 level (99.997 percent mortality or 1 survivor per 33,333) cold treatment for grapefruit, oranges, and lemons other than smooth-skinned lemons, has led us to conclude that trapping and spraying provisions are not a necessary element of the Argentine citrus export program.

Comment: There is no discussion in the proposed rule of fruit fly detection in Argentina, nor what, if any, prevalence of fruit flies would be sufficient to prevent import. Thus, any analysis must take account of the possibility of very high prevalence of fruit flies.

Response: Our risk assessment did take into account the presence of fruit flies in Argentina and concluded that the nonhost status of smooth-skinned lemons and the post-harvest cold treatments for other citrus fruit would reduce the risk of Argentine citrus introducing fruit flies into the United States to a negligible level.

Comment: The proposed rule, the risk assessment, and the PPQ Treatment Manual (which is used by APHIS personnel as a guide for the application of quarantine treatments) do not consider the issue of ''preconditioning phenomenon,'' which could render cold treatment ineffective in preventing the transmission of fruit fly pests into the United States via Argentine citrus. Research indicates that fruit fly larvae and eggs can develop increased tolerance to quarantine cold treatment if the infested fruit is exposed to sublethal temperatures in the field or in storage prior to the initiation of an approved cold treatment. In order to preclude the possibility of preconditioning phenomenon, the PPQ Treatment Manual should explicitly state that the fruit should not be held at sublethal chilling temperatures prior to initiation of cold treatment. In addition, further research should be conducted to determine whether it may be necessary to require fruit subjected to cold field or storage conditions to undergo longer quarantine chilling periods.

Response: In a publication titled *Temperature Sensitivity in Insects and Application in Integrated Pest Management* (edited by Guy J. Hallman and David L. Denlinger, Westview Press, 1998), it is noted that any technique used to reduce chilling injury (*e.g.,* holding the fruit for several days at temperatures several degrees above the quarantine treatment temperature, which is referred to as ''pretreatment'' or ''preconditioning'') can also be suspected of favoring the survival of the pest inside the fruit. However, Dr. Guy Hallman, one of the editors of that publication, indicated to APHIS that no references in the literature were found for this ''preconditioning phenomenon'' with regard to quarantine pests, although it has been demonstrated with flesh flies, house flies, *Drosophila,* and other laboratory species. It was Dr. Hallman's opinion that because cold treatments are so extreme and infestation rates in commercial fruit are so low, the issue of ''preconditioning phenomenon'' is not likely to be a serious practical concern. This opinion is borne out by the consistently successful use of quarantine cold treatments around the world over many years on numerous commodity/pest combinations.

Comment: APHIS's position that lemons cannot be a host to Mediterranean fruit fly is not consistent with published scientific literature on the subject, which demonstrates clearly that lemons can become a host to this pest in certain circumstances. While lemons are not a preferred host to the Medfly, they have been found to be a host when insect pressure is applied to ripe or damaged fruit. If tree-ripe fruit is shipped to the United States, this increases the risk of Medfly introduction into the United States dramatically. The studies APHIS cites to support the nonhost status of lemons (Spitler *et al.* 1984) are based on lemons picked green to partially ripe, which is how lemons are picked in commercial production in the United States. It is not clear from the proposed rule at what stage the Argentine lemons will be picked for export to the United States, but we believe the Argentines pick lemons by maturity, since much of their fruit goes to processing and currently they do not have the ''curing'' facilities to ripen lemons during storage. APHIS should establish maximum maturity standards for lemons for export, in the absence of cold treatments. If the maturity standard is exceeded, then either a cold treatment should be required or the shipment of ripe lemons should be rejected for export. Further, APHIS needs to consider the impact of harvesting lemons at earlier stages on the ability to detect any citrus black spot infections.

Response: While the commenter refers to lemons in general, it is only smooth-skinned lemons that are exempted from the cold treatment requirements of this rule. In the research conducted by Spitler *et al.* (J. Econ. Entomol. 77: 1441–1444, 1984), both green and yellow Eureka and Lisbon variety smooth-skinned lemons were used. In their discussion of the results of the study, the researchers report: ''Although maturity of the lemon (green or yellow) had no noticeable effect on the number of flies collecting on the fruit, more punctures (707 green vs. 805 yellow per 10 fruit) and eggs (23 [green] vs. 46 [yellow]) per egg cavity were found in the more mature yellow fruit. Even in a thin-skinned lemon with 57 ovipositor wounds, no larvae or pupae (*i.e.,* our criterion of survival) were recovered.'' So, while the researchers did observe that oviposition was more likely in the more mature yellow fruit, they found that in only one case—in which the ripest fruit used in the study was left in the infestation cage for 3 days in an attempt to have egg survival—did any larvae or pupae survive (5 survivors out of a very conservatively estimated population of 31,800). In the other 12 lots tested, in which the percentage of yellow lemons ranged from 50 to 100 percent in all lots but 1 (which was 100 percent green lemons), there were no survivors out of a very conservatively estimated population of 484,182. The results of this study, coupled with our experience with both domestically produced and imported lemons, has led us to conclude that the probability of a Medfly infestation resulting from the importation of commercial shipments of smooth-skinned lemons is extremely low. Thus, because we do not believe that it is necessary to establish maximum maturity standards for smooth-skinned lemons imported under this rule, we do not believe that it is necessary to consider the impact of harvesting lemons at earlier stages on the ability to detect any citrus black spot infection.

Comment: APHIS must consider the effects that fruit fly population pressure and environmental stress on fruit trees may have on the nonhost status of lemons. The existence of a large fruit fly population in any given year or at any particular time of year substantially increases the likelihood that the fruit flies will infest citrus fruit, especially if other hosts are not available at that time, even if the fruit is considered a poor host for fruit flies. Similarly, the effect of plant stress on host resistance must be taken into account. Therefore, APHIS should integrate on-site field inspections, trapping programs, and/or possible field control programs for all species of fruit flies into the systems approach for Argentine citrus, and should require monitoring to ensure that no conditions arise that overwhelm the lemons' resistance to fruit flies. Further, the effect of citrus tree health on susceptibility should be included in the risk assessment.

Response: In the research conducted by Spitler *et al.* discussed in the previous comment, Eureka and Lisbon variety smooth-skinned lemons were exposed to a high population pressure of 7,500 adult medflies per 3.6 m^3 in the infestation cage, a population level unlikely to be attained in the field. With that high population pressure in the infestation cage, the researchers estimated that a total of 516,000 eggs were laid in the 13 lots of lemons used in the study, with only 5 pupae surviving, a mortality rate that exceeds the probit 9 security level of 99.997 percent mortality (*i.e.,* 1 survivor per 33,333). In the last of the 13 lots tested, a total of 34 yellow lemons were placed in the infestation cage for 1 day, after which the eggs in each lemon were counted (rather than estimated). These 34 lemons yielded a total of 126,997 eggs, an average of 3,735 eggs per lemon. Despite this exceedingly high per-fruit egg population, no larvae or pupae were recovered from the lemons. The commenter further suggests that we assess the effect of citrus tree health on host resistance. Official records reflecting the host resistance of commercial smooth-skinned lemons date back as far as 1914 (Quayle, H.J., ''Citrus fruit insects in Mediterranean countries,'' USDA Bulletin 134, 1914), yet we have been unable to find any records or other published material documenting cases in which plant stress or other environmental conditions led to a breakdown in that resistance.

Comment: Fruit flies in many cases prefer other hosts that are not limited to subtropical or Mediterranean climates. For example, the South American fruit fly and Medfly will lay eggs in stone fruit, apples, or pears, which are grown commercially in many areas of the United States. While it is unlikely that the fruit flies would survive during the winter in northern regions of the United States and become established permanently in these regions, their introduction could still ruin local fruit crops for one season, and fruit from temporarily infested regions could be transported into more hospitable climates where the fruit flies could become established. Therefore, APHIS' risk assessment should consider the full range of environments in the risk assessment in which fruit flies, if introduced, can cause significant damage to agricultural crops and should develop confirming data on fruit fly distributions using insect phenology models, such as those developed by plant protection authorities in Australia (*e.g.,* CLIMEX).

Response: The remote chance of the occurrence suggested by the commenter is addressed in the risk assessment's node for ''pest finds suitable host.'' We believe that it would be exceedingly unlikely that fruit flies would be introduced in commercial shipments of Argentine citrus fruit in such numbers that their populations would reach outbreak levels in a matter of a few months. With regard to the use of CLIMEX, we have found that this computerized climate matching system can be overly conservative and often does not identify the full range of areas into which we know a pest could spread. What we do in most cases, and did do in the Argentine citrus risk assessment, is ask what are all the locations that have both suitable hosts (not part of CLIMEX) and suitable habitat (we consider additional factors not considered by CLIMEX). Our results typically indicate that a pest could spread to more areas than indicated by CLIMEX.

Comment: Having gone through two Medfly quarantines in the last 10 years because the USDA considers lemons a host to the Medfly, we find it difficult to understand why Argentina is exempt from the same rules that apply to our country. Similarly, California spends hundreds of thousands of dollars per year on Medfly trapping, survey, and exclusion activities, yet the proposed rule does not require any fruit fly trapping in Argentina.

Response: Smooth-skinned lemons harvested for packing by commercial packinghouses are not regulated articles under our domestic Medfly regulations in §§ 301.78–2, and it is those varieties of lemons that are exempted from the cold treatment requirements of this rule. Thus, there is no disparity between the provisions of this rule and our domestic Medfly regulations in this regard. Any Medfly-related measures that were applied to smooth-skinned lemons in California during Medfly quarantines in that State were not due to APHIS regulations, but were applied at the request of nations to which California growers sought to export their product. The Medfly survey and exclusion activities carried out by California are designed to maintain that State's freedom from Medfly; similar requirements were not made part of this rule for the export areas of northwestern Argentina because that region has not been represented as a Medfly-free area.

Comment: Lemons have been stated to be nonhosts of fruit flies, but during the Medfly eradication program in Ventura County, CA, and other parts of California and in Hawaii, lemons have, in fact, been found that were infested with Medfly larvae.

Response: Smooth-skinned lemons harvested for packing by commercial packinghouses are not regulated articles under our domestic Medfly regulations in §§ 301.78–2, and this rule is consistent with our domestic Medfly regulations. Neither the risk assessment nor proposed rule stated that lemons in general were considered to be nonhosts of fruit flies. Instead, both documents, as well as the supporting research such as that conducted by Spitler *et al.* (1984), indicate that it is only smooth-skinned varieties of lemons that are considered nonhosts of fruit flies. Accordingly, this rule requires all lemons other than smooth-skinned varieties to undergo specified cold treatments to mitigate the risk presented by fruit flies, a consideration reflected in the risk assessment. Considerable research and investigations into anecdotal reports such as those cited by the commenter have not uncovered any documented cases of Medfly attacking smooth-skinned varieties of lemons.

Comment: No information appears to be available on what pesticides are used or registered for use in Argentina. What assurances can the USDA give that pesticide residues on imported fruit will not threaten public health?

Response: The U.S. Food and Drug Administration (FDA) samples and tests imported fruits and vegetables for pesticide residues. If residue of a pesticide unapproved in the United States is found in a shipment of imported fruit or vegetables, the shipment is denied entry into the United States by the FDA.

Comment: APHIS has an obligation to the U.S. citrus grower community to assess whether Argentine growers currently use pesticides (for the control of pests or diseases) that cannot legally be used in the United States. Further, APHIS should assess whether there would be any substance that could be used in the United States to control a pest or disease, should such a pest or disease be brought in that is not currently present in the United States. If no substances are registered in the United States that would replace those used in Argentina, APHIS should not allow the citrus to be imported.

Response: As noted in the response to the previous comment, the FDA samples and tests imported fruits and vegetables for pesticide residues. The U.S. Government does not have any control over what pesticides are approved for use in foreign countries. The Environmental Protection Agency has regulations that address the exportation from the United States of pesticides that are not registered for use in this country and works with foreign environmental protection agencies and agricultural producers to promote safer pesticide use and food production practices. In response to the second part of the commenter's remarks, there is a variety of fungicides and other pesticides available for use in the United States in the unlikely event that a plant pest is introduced into this country via citrus imported from Argentina in accordance with this rule.

Comment: The proposed rule and risk assessment do not address the legitimate concern that a pest that exists in one U.S. citrus-growing region could be introduced by imported Argentine citrus into another U.S. citrus-growing region that is free of that pest. For example, brown citrus aphid (Toxoptera citricidus), a quarantine actionable pest that is a vector of the tristeza virus, is listed as existing in Florida in the 1997 Risk Assessment. Currently, Arizona and California, which have limited occurrences of tristeza, have measures in place to prevent the introduction of brown citrus aphid from Florida; Texas has not had any serious tristeza outbreaks due to the lack of good vectors for the virus. APHIS should address the possibility that pests established in one part of the United States could be introduced into free areas of this country via imported Argentine citrus. We suggest that APHIS should require country-of-origin/lot number labeling of individual fruit in order to address this concern and to allow for the tracking of Argentine fruit if it becomes necessary. Further, APHIS should develop an overall policy, consistent with WTO rules, for dealing with this situation.

Response: The commenter raises the concern that pests established in one part of the United States could be introduced into free areas of this country via imported Argentine citrus, and then suggests that country-of-origin/lot number labeling of individual fruit to allow for the tracking of Argentine fruit could be used to address that concern. To address the commenter's first concern, in preparing our risk assessment, we identified all pests of citrus known to be present in Argentina, examined the available information regarding those pests, then focused our analysis on any pests that were identified as quarantine actionable pests that could reasonably be expected to follow the pathway, *i.e.,* be included in commercial shipments of citrus. With regard to the commenter's second concern, this rule, in § 319.56–2f(c)(6), requires that Argentine fruit be packed in boxes that bear the SENASA registration number of the fruit's grove of origin, so we will have the ability to track shipments of imported Argentine fruit after they enter the United States. Although the requirement was not added in response to this commenter's suggestion, this final rule does, as explained earlier in this document under the heading ''Specific Regulatory Changes Regarding Limited Distribution,'' contain a requirement for the stickering of individual Argentine fruit.

The commenter also urged APHIS to develop an overall policy, consistent with WTO rules, for dealing with the issue of pests of limited distribution. We believe that the new revised text of the IPPC, which was approved by the FAO Conference at its 29th Session in November 1997, provides the kind of overall policy sought by the commenter. (The WTO SPS Agreement identifies the IPPC as the organization providing international standards for measures implemented by governments to protect their plant resources from harmful pests.) Specifically, Article VI, ''Regulated pests,'' provides that: ''Contracting parties may require phytosanitary measures for quarantine pests and regulated non-quarantine pests, provided that such measures are: (a) no more stringent than measures applied to the same pests, if present within the territory of the importing contracting party; and (b) limited to what is necessary to protect plant health and/or safeguard the intended use and can be technically justified by the contracting party concerned.'' Under the Federal Plant Pest Act and the Plant Quarantine Act, APHIS has the authority to take action against pests of limited distribution in the United States when such pests are found present in imported plants or plant products. Such action would be in accord with WTO rules.

Comment: The risk assessment states that leprosis is found in Florida, but an expert states that leprosis has been eradicated in Florida since the early 1960's. Leprosis is not present in California or Arizona. False spider mites (Brevipalpus spp.) are present in Argentina and vector the virus for leprosis; these mites and their eggs are difficult to detect through visual inspection, and the usual post-harvest treatments have no effect on their presence. Although several Brevipalpus spp. are present in the United States, the lack of leprosis has made them less of a threat to U.S. agriculture. If the vectoring mites and leprosis occur together in the northwest region of Argentina—and there is evidence that leprosis is a serious disease in Misiones Province in northern Argentina—then additional treatments of all the fruit for the mites is required. APHIS should consider the risk associated with Brevipalpus spp. remaining with the fruit through post-harvest treatment and shipping and the risk of the mites carrying the leprosis virus. If a risk is identified, then measures need to be taken to prevent the mites from transmitting leprosis to the United States via citrus, even if that disease exists in Florida.

Response: The expert mentioned by the commenter has not published his findings regarding leprosis, whereas Alfieri, *et al.* (1994) and Brunt, *et al.* (1996) both list leprosis as present in the United States. As both leprosis and Brevipalpus spp. mites occur in the United States and are not subject to official restrictions or regulations (*i.e.*, they are not listed as actionable and are not under an official control program), these organisms do not meet the geographical and regulatory definition of a quarantine pest.

Comment: The risk assessment does not account for the possibility that a number of insect and mite species may be transmitted under the calyx (button) of citrus fruits, thus allowing for the possibility of transmission of such pests into the United States via Argentine citrus. The calyx of citrus fruit can harbor a large number of insects and mites or their eggs. These contaminant species are not easily visible unless the button is removed (which leads to more rapid fruit decay) and are resistant to cold treatment, surface washes, and insecticide treatments. APHIS' risk assessment should address the issue of all types of insect pests that may inhabit the calyx of Argentine citrus, and calyx inspection should be a routine part of the inspection of Argentine citrus at the port of first arrival.

Response: As indicated in an earlier response, in preparing our risk assessment, we identified all pests of citrus known to be present in Argentina, examined the available information regarding those pests, then focused our analysis on any pests that were identified as quarantine actionable pests that could reasonably be expected to follow the pathway, *i.e.*, be included in commercial shipments of citrus. In examining the information regarding citrus pests present in Argentina, we did not identify any insect or mite species that could be transmitted under the calyx of citrus fruit that were quarantine actionable pests that could reasonably be expected to follow the pathway. Thus, we do not believe that it is necessary to include provisions in this rule to require the routine calyx inspection at the port of first arrival. However, this does not preclude our inspectors from conducting calyx inspections, even on a routine basis, when they believe such a measure might be necessary.

Disease Detection

Comment: The proposed rule states: ''If, during the course of any inspection or testing required by this section or § 319.56–6 of this subpart, citrus black spot or sweet orange scab is detected on any grapefruit, lemons, or oranges, the grove in which the fruit was grown or is being grown shall be removed from the SENASA citrus export program for the remainder of that year's growing and harvest season * * *.'' It is currently unclear how much disease detection is needed to cause SENASA to remove the grove from the export program. Does a single infection on a single fruit disqualify an orchard from the export program? The presence of the diseases can be detected in the litter and occasionally the tree without obvious fruit infections. Would that be grounds for the removal of a grove? A much clearer definition of when a grove must be removed from the export program, and an explanation of why that threshold for removal was chosen, needs to be established in order to minimize the risk that latently infected fruit will reach the United States. Further, the proposed rule contained no discussion of whether any special criteria or measures need to be met for a grove to re-enter the export program after it has been disqualified for a season due to disease incidence.

Response: Paragraph (f) of § 319.56–2f clearly states that if citrus black spot or sweet orange scab is detected on any grapefruit, lemons, or oranges, the grove will be removed from the export program. So, in response to the commenter's first question, a single infection on a single fruit, will result in a grove's removal from the export program. That paragraph does not, however, call for the removal of a grove from the export program upon the detection of either disease in litter or in the tree if the infection is not detected in the fruit, since there are no requirements for the testing of litter or parts of the tree other than the fruit. The commenter's statement that the presence of citrus black spot and sweet orange scab ''can be detected in the litter and occasionally the tree without obvious fruit infections'' is true to a certain extent; the fungi can be isolated from leaf litter and leaves on the tree. However, the presence of these diseases cannot be reliably detected through the visual inspection of plants or plant parts other than the fruit. So, while § 319.56–2f(b)(6)(i) does provide that a grove's freedom from citrus black spot and sweet orange scab shall be verified through visual inspection of the grove and buffer area, that visual inspection will necessarily be limited to fruit on the trees. The diseased fruit threshold was chosen because it will be the fruit itself, and not any leaves, branches, or litter, that will be imported into the United States. We did not include any special criteria or measures for a previously disqualified grove to re-enter the export program because we believe that the testing, treatment, and inspection requirements that must be satisfied by any grove seeking to export fruit to the United States make such additional measures unnecessary.

Comment: In the proposed rule, § 319.56–2f(f) refers to ''growing,'' ''harvest,'' and ''shipping'' seasons, with no definition of what is meant by such terms.

Response: We regard the ''growing season'' as the period between bloom and fruit maturity, the ''harvest season'' as the period during which the mature fruit are picked, and the ''shipping season'' as beginning at roughly the same time as the harvest season and continuing until shortly after the harvest ends. As we are using those terms in their generally understood sense, we see no reason to specifically define them in the regulations.

Comment: In § 319.56–2f(f) of the proposed rule, it states that fruit must pass ''any inspection or testing required by this section or § 319.56–6 of this subpart.'' Thus, if fruit is observed to be infected before fungicide application, or at some random time (but not during an inspection), or by non-SENASA personnel, there is strictly no requirement to remove the grove from the export program, since these inspections are not ''required.'' There is no overall catchall requirement that any detection is sufficient to remove a grove from the export program.

Response: We believe that the official inspections and tests called for by this rule will be sufficient to detect the diseases of concern should they be present in a grove or in harvested fruit. However, in order to address the concerns raised by this commenter, we have added the words ''or at any other time'' to § 319.56–2f(f).

Comment: While the proposed rule specifies that any detection of sweet orange scab or citrus black spot during required inspections shall result in a grove's removal from the export program, it provides no mechanism by which this shall happen. For example, there is no requirement for SENASA to be notified, and no requirement for SENASA to notify APHIS.

Response: In response to this comment, we have amended § 319.56–2f(f) in this final rule to require that both SENASA and APHIS be notified in the event that citrus black spot or sweet orange scab is detected.

Comment: While the proposed rule specifies that any detection of sweet orange scab or citrus black spot during required inspections shall result in a grove's removal from the export program, it does not state what would occur if citrus canker was discovered in a grove or within a particular growing region.

Response: As stated in the proposed rule, we believe that Argentina has demonstrated, in accordance with FAO guidelines for pest-free areas, that the citrus production areas in Catamarca, Jujuy, Salta, and Tucuman are free from citrus canker. Should citrus canker be detected in any of those States in the future, those same FAO guidelines require that Argentina report that detection. Because the citrus fruit regulations in § 319.28 prohibit the importation of the fruits and unprocessed peel of all species and varieties of the genus Citrus from areas where citrus canker exists, the detection of citrus canker in an area within the citrus-canker-free region of northwestern Argentina would result in a prohibition on the importation into the United States of grapefruit, lemons, and oranges from that area.

Comment: The proposed systems approach for citrus black spot and sweet orange scab provides only suppression of symptoms and reduction of the inoculum in the area proposed for export. So the question the risk assessment must answer is will this provide the United States with an appropriate level of protection against the introduction and establishment of one or both of these diseases when it is clear that infected, though symptomless, fruit will be certified for export to the United States?

Response: The risk assessment provides the decisionmaker with the information he needs to determine whether certain phytosanitary measures provide ''an appropriate level of protection'' in a particular situation; it is not the purpose of the risk assessment itself to answer that question. In this case, the risk assessment examined the risk associated with the importation of Argentine citrus and estimated the likelihood of pest introduction. In any event, the systems approach for citrus black spot and sweet orange scab is not designed to suppress symptoms. It is designed to prevent infection. For that reason, part of the systems approach includes removal of debris to reduce inoculum and application of fungicides to prevent infection. As part of the entire systems approach, this prevention portion provides an appropriate level of protection against the introduction or establishment of either of these diseases. It is not ''clear'' that symptomless, infected fruit will be certified for export. In fact, using the systems approach makes it highly unlikely that symptomless, infected fruit will be certified for export.

Risk Assessment

Note: In this section, as well as in the subsequent section titled ''Risk Assessment—'Principles of Good Practice' some of the comments state that the proposed rule's supporting risk assessment failed to establish a connection between certain of its conclusions and the data or information that was used as the basis for those conclusions. We have responded to those comments by explaining the role that expert judgment played in reaching those conclusions or by pointing to our use of the sources cited in section III (''References'') of the risk assessment. However, in order to more thoroughly document the sources of the risk assessment's conclusions, we have prepared an addendum to the risk assessment that provides, node-by-node, specific references to the information or data used as the basis for those conclusions. The addendum may be obtained from the person listed at the beginning of this final rule under the heading **FOR FURTHER INFORMATION CONTACT**.

Comment: The consequences of introduction are addressed in the qualitative portion of the risk assessment via an estimation of the economic and/or environmental damage potential according to ratings applied to five risk elements. In these estimations, broad uncharacterized assumptions are used and the role of uncertainty is never discussed.

Response: The objective criteria we use to rate the five risk elements are stated on pages 22 through 25 of the risk assessment, and our findings regarding the five risk elements are provided on page 26. Our findings are not based on ''broad uncharacterized assumptions,'' but on specific information available in the scientific literature. The information used in rating each pest is provided in the pest data sheets provided for each of the rated pests (Appendix I–IV for four species of fruit flies and Appendix V–VII for the three citrus diseases), which are supported by the scientific literature cited and listed in each pest data sheet.

We did not discuss the role of uncertainty in the assignment of ratings for the five risk elements because uncertainty played an insignificant, if any, role in the assignment of those ratings. For each risk element, each pest received a qualitative ranking of high, medium, or low; the assignment of each ranking for each pest was dictated by the responses to specific and objective criteria. For example, the rankings assigned for Risk Element #2 (host range) were assigned as follows:

• High—Pest attacks multiple species within multiple plant families.

• Medium—Pest attacks multiple species within a single plant family.

• Low—Pest attacks a single species or multiple species within a single genus.

As can be seen in the pest data sheet included in the risk assessment for each of the pests examined, the host range of each pest has been established and documented, so there was no uncertainty involved in the assignment of a qualitative risk rating for each pest under this risk element. The same may be said for the other four risk elements as well, with the possible exception of Risk Element #5 (environmental impact), in which three of the five factors considered involve expected impacts on the environment or on threatened/endangered species. Because those factors involve likely future impacts as opposed to documented past impacts, some degree of uncertainty is inevitable; however, we do not believe that the level of uncertainty is sufficient to have had any substantive impact on the assigned risk ratings.

Comment: Climate-host interaction is estimated solely on the USDA s Plant Hardiness Zone Map. This map provides temperature zones for specified regions, and risk is calculated based on a pest's ability to exist in one to several temperature zones. Yet, rainfall and relative humidity play an equally critical role in the ability of a disease pathogen to survive and thrive in a new area. (For example, there is the added moisture that results from irrigation and fog, as in the coastal California growing areas, and the summer monsoon season that occurs in both Arizona and southern California.) The omission is never mentioned, so neither is the uncertainty this omission represents.

Response: The plant hardiness zone map is used in the discussion of Risk Element #1, ''Climate-Host Interaction,'' as an objective means of specifying the extent of the potential range of the pest. We agree that it may be appropriate, as suggested by the commenter, to introduce relative humidity and rainfall as factors for consideration at this stage. However, the addition of those factors at this stage would have the effect of further limiting the potential range of the pest under consideration to areas even smaller than temperature zones, as the pest would be restricted to areas with appropriate ranges of multiple factors (temperature, rainfall, and relative humidity), rather than just one factor (temperature). That being said, the role of moisture is in fact considered in the risk assessment, contrary to the commenter's assertion that it was not. Specifically, Risk Element #3, ''Dispersal Potential,'' considers ''whether natural factors (*e.g.*, wind, water, presence of vectors) facilitate dispersal'' as one of the three items examined when evaluating whether a pest has the potential to disperse (or, to use the commenter's terminology, ''survive and thrive'') after introduction into a new area.

Comment: Sweet orange scab is rated medium for its host range potential yet it is not known to infect genera of Rutaceae other than *Citrus* species. Citrus black spot is rated high for its dispersal potential (capable of movement over 10 km per year), yet the scientific data, and the data sheet provided, indicate that this fungus only spreads short distances under natural conditions. Long-distance dispersal is attributed to the artificial movement of citrus leaves and nursery stock, both of which are beyond the scope of the risk assessment. If this assessment is correct, the 150-meter buffer provision in the proposed program should be reexamined.

Response: Our understanding of this comment is that the commenter is pointing out that: (1) The rating we assigned for the host range potential of sweet orange scab was too high and (2) the rating we assigned for the dispersal potential of citrus black spot may have been too high, and if that is the case, the 150-meter buffer zone may be too large. We agree that *Elsinoe australis* (sweet orange scab) could have received a rating of ''low'' for host range potential and, as a result, sweet orange scab could have only been rated as ''medium''—not ''high''—for its consequences of introduction. Similarly, *Guignardia citricarpa* (citrus black spot) could have been rated as ''medium'' for dispersal potential, and as a result, citrus black spot could have been rated as ''medium''—not ''high''—for its consequences of introduction. Although our original rating of ''high'' for the dispersal potential of citrus black spot may have been somewhat conservative, we believe that the 150-meter buffer zone provision is still an appropriate measure to protect production groves from neighboring properties that are not participating in the export program.

Comment: Black spot is apparently on a wide range of other host plants. The risk of movement of *Guignardia citricarpa* on latently infected fruit and its ability to establish in a new area on various other hosts (*i.e.*, not citrus) is underrated.

Response: Guignardia citricarpa is morphologically identical to another *Guignardia* sp. that is latent in citrus and many other hosts. However, the identified host range of *Guignardia citricarpa* is limited to commercially grown *Citrus* spp. except for sour orange (*C. aurantium*) and its hybrids. Given the identified host range of *Guignardia citricarpa*, we believe that the risks presented by *Guignardia citricarpa* were appropriately rated in the risk assessment.

Comment: The likelihood of introduction is estimated using probabilistic scenario analysis. Here, uncertainty is addressed in the probability distributions, but these distributions were in turn based upon a number of assumptions that are not explained. Among other criteria, pest risk assessments must contain sufficient detail and identify all sources of uncertainty in data extrapolation in order to be open to evaluation and review. It is for this reason that the FAO Guidelines for Pest Risk Analysis require that the analysis or assessment clearly state the sources of information and the rationales used in reaching decisions regarding the phytosanitary measures proposed.

Response: Our risk assessment was conducted with strict adherence to the FAO guidelines. As explained in the risk assessment on p. 28, we estimated model inputs ''using the best available data and expert judgment as our basis.'' In those cases where data were available, we identified those data and the role they played in the development of our distributions. When data were not available, we used additional information provided by our experts to arrive at estimates that reflected what we considered to be appropriate levels of uncertainty, and the distributions were derived to reflect those estimates; in those cases, the role of expert judgment or expert information in arriving at the estimates was acknowledged. We believe, therefore, that our risk assessment clearly states the sources of information and the rationales used in reaching decisions regarding the phytosanitary measures proposed as required by FAO.

Comment: Although some background information was provided, it would have been extremely helpful to include some additional information within or accompanying the pest risk assessment. This would include a complete review of current pest status of citrus black spot and sweet orange scab in Argentina and in the four States; the trip reports for any and all site visits; all survey methods and results; and a complete discussion of Argentina s current and proposed control, harvesting, and packing procedures.

Response: All of the information cited by the commenter is either in the public domain or is part of the rulemaking record, which was made available to the commenter. We do not believe that it would be feasible or even necessary to reproduce the entire public record in the risk assessment.

Comment: APHIS has not adequately considered the risk of infestation and infection originating in residential areas.

Response: The risk of infestation/infection in residential areas was considered in the risk assessment as part of input probabilities P6 (fruit transported to suitable habitat), P7 (pest finds/pathogen reaches suitable host), and P8 (pest/pathogen able to complete life cycle). Those input probabilities considered both commercial production areas as well as residential areas.

Comment: The mitigation scenarios for the fruit flies and citrus canker are estimated against the systems approach proposed for citrus black spot and sweet orange scab; there is no analysis provided for the efficacy of the direct mitigation measures proposed for these pests. For the fruit flies, it would be more relevant to provide the supporting data evidencing the effectiveness of the post-harvest cold treatment. For citrus canker, it would be more appropriate to show how this program meets the requirements for designation of a pest free area.

Response: It is not the case that ''the mitigation scenarios for the fruit flies and citrus canker are estimated against the systems approach proposed for citrus black spot and sweet orange scab.'' The risk presented by each pest was analyzed individually with respect to pertinent mitigation measures. In fact, we state on page 32 of the risk assessment that the baseline treatments of washing, waxing, and dipping the fruit (for diseases) ''are expected to have only a minor effect on fruit flies.'' Our estimates do not include any reduced fruit fly risk from these treatments. As shown in Table 7 on p. 35 of the risk assessment, there are only two differences between the risk model inputs for the baseline (no specific mitigations) and the proposed risk mitigation program. That is, two of the nodes were affected by the proposed program. The first affected node is P5 (pest survives post-harvest treatment). As described on p. 32, all of the reduced likelihood of fruit fly survival with the proposed program comes directly from the cold treatment for fruit flies:

> USDA has an approved cold treatment schedule for both *Ceratitis capitata*, Treatment T107(a), and *Anastrepha* fruit flies other than *A. ludens*, Treatment T107(c) (PPQ, 1992). The treatment schedule allows different temperature/time combinations to be used. For example, T107(a) allows 32° F (or below) for 10 days as well as 36° F (or below) for 16 days. Treatment schedules were based on demonstrated efficacy of probit 9 (99.9968 percent) mortality. This corresponds to a survival rate of 0.00003 (0.003 percent). We represented survival as a lognormal distribution with a mean of 0.0001 and a standard deviation (sd) of 0.00011. A sd of 0.00011 was chosen because the resulting distribution has a mode (peak of the distribution) at 0.00003.

The other node that is different is P8 (pest able to complete life cycle). As explained on p. 33 of the risk assessment, we estimated that this value would be slightly lower as a result of the cold treatment for fruit flies. The reduced risk from fruit flies under the proposed program results from the cold treatment for fruit flies, and not from the treatments applied for the diseases of concern.

Regarding citrus canker, three main components are considered in the establishment and subsequent maintenance of a pest free area: Systems to establish freedom, phytosanitary measures to maintain freedom, and checks to verify freedom has been maintained. Argentina established its freedom from citrus canker, as stated on page 36 of the pest risk assessment, through 4 years of comprehensive specific surveys with negative results as well as general surveillance for canker in the field and in published literature. Argentina continues to maintain area freedom through phytosanitary measures outlined on pages 27 and 36 of the pest risk assessment document. These phytosanitary measures include restrictions on the movement and planting of citrus nursery stock in the free area and domestic quarantine controls at airports and roads servicing the area. Continuing canker surveys, field and packinghouse inspections, and the requirement for a phytosanitary certificate help verify that area freedom is maintained.

Comment: The probability estimate for ''harvested fruit is infected with citrus black spot and sweet orange scab'' is based on limited field survey data provided by Argentina. For example, treatment tests for grapefruit were performed on young trees in 1994 only, *i.e.*, trees known not to show symptoms with or without fungicidal treatment. The 1994–95 treatment data provided are for oranges only, and the age of the orchard trees is not provided. There were no data provided for lemons, the most susceptible citrus for citrus black spot infection. No treatment data were provided for sweet orange scab.

Response: We acknowledged in the risk assessment that the survey data provided by Argentina was limited. In the discussion of node P1, ''Harvested fruit is infected,'' we stated that ''our estimates * * * were based on limited field survey data provided by Argentina and expert information provided by scientists familiar with citrus production in Argentina and/or the pathogen.'' Because the field survey data were limited, we used additional information provided by our experts to arrive at estimates of these probabilities that reflected what we considered to be appropriate levels of uncertainty, and the distributions were derived to reflect those estimates.

Comment: The probability estimate for ''pathogen not detected at harvest'' is based solely on expert information that the fruit pickers would be able to find and cull diseased fruit. It does not provide any discussion regarding the latency period of citrus black spot symptom expression, nor that symptom expression does not occur at all in fruit from trees younger than 12 years. Yet, it does ironically assume in the mitigation scenario, based on a program that suppresses symptom expression, that this activity would result in fewer citrus black spot infected fruit escaping detection.

Response: In that latent infections would not be visible to pickers during harvest, we do not believe that it is necessary for the probability estimate for P2 (pathogen not detected at harvest) to provide a discussion regarding the latency period of citrus black spot symptom expression or the lack of symptom expression in all fruit from trees less than 12 years old. Rather, the issues of latency and lack of symptom expression are considered in, and factored into, the probability estimates provided in P3 (pathogen not detected at packing house inspection) and P4 (pathogens survive post-harvest treatment). With regard to the last sentence of the comment, the systems approach is not, as the commenter states, a ''program that suppresses symptom expression.'' Rather, as we have stated elsewhere in this document, the treatments and cultural practices required by this rule are designed to prevent fruit from becoming infected in the first place. Those requirements are the basis for the risk assessment's expectation that ''more rigorous export standards and reduced frequency of latent infection would result in fewer [citrus black spot] diseased fruit escaping detection.''

Comment: The probabilistic estimate for ''pathogens survive post-harvest treatment'' predicts that these minimal treatments would have a deleterious effect on the survival of both sweet orange scab and citrus black spot causal pathogens. What this estimate does not state is that this node only applies to pathogen spores that may be found contaminating the surface of the fruit and that the fruit at that point is resistant to infection.

Response: It is correct that mature fruit is not susceptible to new infection and that the post-harvest treatment is intended to render nonviable any spores contaminating the surface of the fruit. This is reflected in the risk assessment's discussion of node P4, ''Pathogen survives post-harvest treatment,'' where we stated that ''[w]e assumed that the additional treatments [*i.e.*, the chlorine dip] included in the proposed export program would further reduce the survival rate of the [sweet orange scab] pathogen'' and that ''[f]or our mitigated scenario we assumed that the chlorine dip would have an additional deleterious effect on the survival of the [citrus black spot] fungus.'' As noted elsewhere in this document, these post-harvest treatments are mainly to prevent post-harvest decay.

Comment: In section 8.f, ''Inputs, Sweet orange scab, citrus black spot and citrus canker,'' the probabilistic estimate for ''fruit shipped to a suitable habitat'' is based solely on the percentage of geographical area that supports cultivation of citrus. Yet, in fact, this node would be more accurate if estimates were based on population densities, as fruit is going to be shipped based upon a target market, not geography. Then, a comparison should be made relative to the population percentage found within the citrus growing areas. As it is estimated now, this node is particularly likely to be grossly underestimated. The probabilistic estimate for ''pathogen reach suitable host'' is based on an assumption that the initial inoculum source was introduced into an orchard setting. In fact, it is much more likely that the inoculum will initially be introduced into an urban setting. As a result, this node is another one that is particularly likely to be grossly underestimated. This probability node, along with the one above, should be recalculated more appropriately.

Response: We disagree with the commenter's statement that the probabilistic estimate for ''fruit shipped to a suitable habitat'' is likely to be grossly underestimated. With the large citrus markets throughout the United States, we have no reason to believe that our estimate of 5 percent (percentage of imported fruit that will be shipped to areas where citrus can survive) is too low or too high, nor have we received any specific information from any commenter that would allow us to change our estimate. (**Note:** Tables 8–10 on pp. 44–46 of the risk assessment correctly list our estimate as 5 percent, and this is the value used for the calculations. The text on p. 41 incorrectly states this value as 9 percent). While it is accurate to state that fruit will be shipped based on markets rather than geography, one cannot dispute the link between geography and suitable habitat. The ability of an area to support a pest population is a function of climate and the availability of host material, and not population density.

Similarly, the commenter's statement that ''the probabilistic estimate for 'pathogen reach suitable host' is based on an assumption that the initial inoculum source was introduced into an orchard setting'' is inaccurate. We can find no statement in the risk assessment that could lead the commenter to this conclusion. We stated in the risk assessment:

> All three pathogens analyzed are essentially restricted to citrus hosts (or closely related species). Suitable habitat for these organisms necessarily corresponds to the range of their citrus hosts. Consequently, we considered the citrus growing regions of the continental United States to be ''suitable habitat.'' We estimated the percentage of the area of the contiguous 48 States that supports the growth of citrus species.

This percentage of the area of the contiguous 48 States that supports the growth of citrus species includes all areas where citrus fruit can be produced, including ''backyard trees'' in urban, suburban, or rural settings, or any other areas where citrus plants can survive and produce fruit, as well as commercial citrus-production areas. However, citrus is a subtropical plant and can only survive and produce fruit in a small portion of the continental United States. Accordingly, we do not agree with the commenter's statement that both nodes are grossly underestimated and need to be recalculated.

Comment: The probabilistic estimate for ''pathogen able to complete disease cycle'' in particular should evaluate the effect of the systems approach, *i.e.,* it should provide a measurement of the level of infection and an estimation as to risk from latent or suppressed symptom expression. It should also include a discussion of the role of pycnidiospores in disease establishment and episode development. Although citrus black spot epidemics tend to be caused by the ascospores produced on dead leaves, the pycnidiospores from fruit are quite capable of being the source of introduction of the disease. The risk assessment should give more careful consideration to the pathogenicity of the pycnidiospores and should consider the possibility that citrus black spot could become established in the United States through pycnidiospores infecting residential citrus.

Response: Our understanding of the commenter's suggestion that ''[t]he probabilistic estimate for 'pathogen able to complete disease cycle' * * * should evaluate the effect of the systems approach, *i.e.,* it should provide a measurement of the level of infection and an estimation as to risk from latent or suppressed symptom expression'' is that the commenter believes that the intended effect of the systems approach is to suppress the symptoms of citrus black spot and, on the basis of that belief, that we should estimate the percentage of fruit that will be latently infected and provide an estimate of the risk presented by that latently infected fruit. As we have stated elsewhere in this document, we disagree with the commenter's assertion that the goal of the systems approach is simply to suppress symptoms; rather, the systems approach is intended to prevent infection in the first place, provide for the detection of infection if it should occur, and prevent the entry of infected fruit into the United States. That being said, this node of the risk assessment (P8: Pathogen able to complete disease cycle) is assumed to be an independent event and, as such, begins with the assumption that the pest, in some form, has reached a suitable habitat and a suitable host, including residential citrus. The node then describes ''our estimate of the likelihood that these pathogens would, having reached a host plant, be able to infect that plant and complete the disease cycle.'' Thus, we believe that the risk assessment does in fact provide the estimation of risk sought by the commenter in the first part of her comment.

In the second part of her comment, the commenter suggests that this node of the risk assessment ''should also include a discussion of the role of pycnidiospores in disease establishment and episode development.'' In our discussion of this node in the risk assessment, we stated that we ''took into account the type of infectious propagule produced by each of the three pathogens and the environmental and physiological requirements for host plant susceptibility and successful disease progression'' and later, specifically with regard to citrus black spot, that:

> The epidemiology of [citrus black spot] is influenced by the availability of inoculum, the environmental requirements for infection, the growth cycle of the host and the age of the fruit in relation to its susceptibility. Ascospores formed on dead leaves on the orchard floor form the main source of inoculum, however pycnidia on out of season or late hanging fruit can also serve as sources of rain splashed inoculum. Spores are released during rainfall and during irrigation. Except for lemons, leaf infections seldom occur. The critical period for infection starts at fruit set and lasts for 4 to 5 months. Symptom development is hastened by rising temperatures, high light intensity, drought and poor vigor.

Given the above discussion, we believe that we did give due consideration in the risk assessment to the pathogenicity of the pycnidiospores and the possibility that citrus black spot could become established in the United States through pycnidiospores infecting residential citrus. Our estimates of the risk presented by pycnidiospores are supported by the American Phytopathological Society's (APS) *Compendium of Citrus Diseases* (Whiteside, J.O., Garnsey, S.M. and Timmer, L.W., 1988, APS Press, American Phytopathological Society, St. Paul, MN. 80 pp.), which is cited repeatedly in the risk assessment. That publication states: ''Pycnidiospores formed on dead leaves on the ground can reach the susceptible fruit only by the splashing of raindrops, and they are not considered an important source of inoculum.'' The pycnidiospores play a role in short distance water-dispersal of this disease. They may be produced on symptomatic, late-hanging fruit or on dead, decaying leaves on the orchard floor. Pycnidiospores from fallen leaves are very unlikely to reach fruit because they are solely waterborne. Pycnidiospores from late-hanging, symptomatic fruit can infect fruit that is in physical contact with the infected fruit or that is hanging below the symptomatic fruit, if the fruit are susceptible and environmental conditions appropriate. This agrees with the findings of McOnie (McOnie, K.C., 1964, ''Speckled blotch of citrus induced by the citrus black spot pathogen *Guignardia citricarpa*,'' Phytopathology 54: 1488–1489), who concluded that ascospores are the major infective bodies and that spores of the asexual stage (*i.e.,* pycnidiospores) are unimportant in producing fruit infections.

Comment: The pest risk assessment concluded that the pest risk potential, minus the mitigation measures, is high for the fruit flies and sweet orange scab and medium for citrus black spot; citrus canker is not mentioned. No conclusions are expressed for the pest risk potential as mitigated by the proposed program. In any case, sufficient information necessary to assess the efficacy of the proposed systems approach for sweet orange scab and citrus black spot is not available within the proposed rule, the supporting pest risk assessment, or other documentation provided.

Response: The pest risk potential of an organism, which can be viewed as a constant, is not affected by mitigating measures, which is why the risk assessment expressed no conclusions for the pest risk potential as mitigated by the proposed program. Rather, it is the likelihood of introduction that will be affected by the mitigating measures, and we did provide our conclusions for the likelihood of introduction as mitigated by the proposed program. Citrus canker is not mentioned because fruit will be imported only from the citrus-canker-free area of Argentina. With regard to the efficacy of those mitigating measures, we believe that the data supplied by Argentina and the reports of APHIS personnel who conducted the site visits in Argentina, which are all part of the rulemaking record and were made available to the commenter, as well as the information contained in the scientific literature cited in the risk assessment, provided sufficient information to support the risk assessment and its conclusions relating to the risk reductions afforded by the mitigating measures required by this rule.

Comment: In the risk assessment, APHIS states that it evaluated only pests that can ''reasonably be expected to follow the pathway, *i.e.,* be included in commercial shipments of citrus.'' But the pathway contains more than just commercial shipment, and much of the protection estimated in the risk assessment for the diseases and pests evaluated comes from other components of the pathway. What should matter is not the probability of traversing the pathway as far as commercial shipment, but the probability of completing the whole pathway. The probability required for ''reasonably be expected'' appears to be extremely high compared with the required levels of protection. It is plausible that for other pests or diseases, other parts of the pathway are not of low probability. In that case, the risk assessment has not included sufficient pests.

Response: In stating that the pathway consists of ''more than just commercial shipment'' and that protection may be afforded by ''other components of the pathway,'' it appears that the commenter is confusing the pathway itself with the mitigation measures applied to fruit in the pathway. The only pathway ''opened'' by this rule, and thus the only pathway appropriately considered in a risk assessment supporting this rule, is the commercial shipment of citrus fruit from Argentina to the continental United States. Other pathways (*e.g.,* backyard fruit smuggled by airline passengers or placed in the mail) would exist with or without this rule, and thus did not fall within the scope of the risk assessment prepared for this rule. Commercial shipment is the whole pathway, and not merely a distinct stop along the pathway as the commenter suggests when he speaks of ''traversing the pathway as far as commercial shipment.'' In our risk assessment, the commercial shipment pathway for citrus fruit begins in the Argentine production area and ends in the continental United States in the ultimate consumer's trash can or compost pile, and this entire pathway was considered when assessing pest risk. The risk assessment lists all pests of citrus in Argentina, and all pests that can reasonably be associated with this pathway were analyzed in detail.

Comment: The desired result of a Monte Carlo analysis should be carefully defined, whereas the risk assessment has no stated, well-defined, goal. In our opinion, the goal that would provide the most useful information would be an estimate (and its uncertainty) of the average annual likelihood that the importation of Argentine citrus fruit will result in a pest outbreak in the United States. If this is the intended goal of the analysis, APHIS must reconsider its use of any distributions that reflect year-to-year variability. The distribution for the number of shipments of fruit that will be shipped to the United States was constructed ''to allow for variation in the frequency of shipments that might result from variation in production, frequency of shipments that are cleared for shipment, and variation in market demands in the United States.'' If the intended goal is to estimate an average likelihood of a pest outbreak, APHIS should ignore year-to-year variability in this value and instead construct a distribution that accounts only for uncertainty in the value for the average number of shipments that will be shipped to the United States. The same would apply for any other year-to-year variabilities included in the probability estimates, unless they were correlated. No explicit mention is made of such variabilities in the discussions of the other probability estimates, but the discussion of these estimates is inadequate. If there are correlations, such as that explicitly discussed in section 8.e P8 of the risk assessment, then such correlations have to be taken into account. One way to do so would be to incorporate the year-to-year variability together with the correlations in the modeling. Each iteration of the Monte Carlo assessment would then require a nested loop that averaged over multiple years in order to obtain the long-term average.

Response: We disagree with the commenter's statement that the risk assessment has no stated, well-defined goal. The overall purpose of our risk assessment is stated in the first sentence of that document, *i.e.* ''* * * to examine plant pest risks associated with the importation into the United States of fresh citrus fruit grown in certain areas of Argentina.'' Similarly, with regard to our use of Monte Carlo simulation methods to account for uncertainty in estimating probabilities, we stated the following in the first paragraph of section 8, Likelihood of Introduction (the only section of the risk assessment in which Monte Carlo simulation methods were used): ''For the pests listed in Table 6, we estimate the likelihood of introduction using a quantitative method referred to as 'probabilistic risk assessment' or 'probabilistic scenario analysis.' The purpose of a probabilistic risk assessment is to estimate the likelihood of an undesirable outcome (bad event). The bad event is represented by the endpoint of the risk model, *i.e.*, introduction of a quarantine pest. Our method has four basic components: Scenario analysis, development of a mathematical model, estimation of input values for the likelihood model, and Monte Carlo simulation * * *.'' Thus, the purpose of the Monte Carlo portion of the risk assessment is also stated clearly, *i.e.*, to estimate the likelihood that quarantine pests will be introduced.

The goal suggested by the commenter—to provide ''an estimate (and its uncertainty) of the average annual likelihood that the importation of Argentine citrus fruit will result in a pest outbreak in the United States''—is a reasonable approximation of our stated goal with a slightly different endpoint. As explained in the risk assessment, ''introduction'' of a pest means entry and establishment (*i.e.*, reproducing, self-sustaining population of the pest). Pest outbreak is one possibility for the next step if we were to continue our scenario. We have used pest outbreak as our endpoint in previous risk assessments. However, in this risk assessment, we chose pest introduction as our endpoint. Use of pest introduction as the endpoint is more conservative (more pest exclusionary) than using pest outbreak. Estimates of the likelihood of outbreak would be lower than estimates of introduction because additional events would have to occur before the introduction would lead to an outbreak.

The commenter also states that ''APHIS should ignore year-to-year variability in this value and instead construct a distribution that accounts only for uncertainty in the value for the average number of shipments that will be shipped to the United States.'' These remarks are premised on the belief held by some risk assessors that variability must be dealt with separately from uncertainty in all cases; however, the utility of this approach in all cases has not been demonstrated. In the case of our risk assessment, we believe that separating other forms of uncertainty from variability (*i.e.*, year-to-year) would obscure, rather than illuminate, the issue. Commercial shipments of citrus from Argentina have never entered the United States; there are no data that would allow us to characterize the expected year-to-year variability in quantity imported. Although the actual number of shipments would vary on a year-to-year basis, the data do not exist to characterize that variability. There is considerable uncertainty regarding the quantity of shipments. That is why we used a normal distribution that is not bounded above or below the mean.

Finally, with regard to the commenter's suggestion that we incorporate year-to-year variability together with correlations in the modeling, we did consider the implications of possible correlations among the nodes, but we determined that there were not any correlations that would affect the calculations in the Monte Carlo simulation.

Comment: APHIS uses a simple multiplicative mathematical model to estimate the frequency of pest outbreaks in the United States. The estimated number of shipments of citrus fruit is multiplied by eight probability distributions to arrive at the final distribution for the likelihood of a pest establishing itself in the United States. If each stage of the process were truly independent of all preceding stages, and if it were certain that all fruit would pass through each stage of the process, then this would be a simple, accurate model to describe the likelihood of an exotic pest establishing itself in the United States. However, we do not believe that each stage is independent of the all preceding stages, nor do we believe that it is certain that all fruit will pass through each stage of the process. The risk assessment's mathematical model should take into account the correlation of the stages and potential for the failure of fruit to pass through all those stages.

Response: We believe that the commenter has misinterpreted the risk model as a graphical representation of the risk mitigation process, which it is not. The steps in our model are consecutive—for example, fruit must be harvested before it can be taken to the packinghouse—which could give the impression of dependence, but the risks examined at each step are independent; the risks examined in one node do not have a direct impact on the risks examined in the next. Although certain of the risk mitigation steps are represented in the risk model, the model accounts for other steps (*e.g.*, biological) that are independent of human activities. For example, node P7 (figure 2 on page 30) is stated as ''pest locates suitable host.'' Clearly, this is not a risk mitigation step that can be skipped, it is a representation of the probability that a pest will find host material should it enter the United States. This probability is not correlated with the other nodes. The scenario should be viewed according to the description in the risk assessment:

First, we use the method of scenario analysis to conceptualize the events (referred to as nodes) that must occur before the endpoint or ''bad event'' (*e.g.*, introduction of *Anastrepha fraterculus* or *Elsinoe australis*) can occur. Scenario analysis provides a conceptual framework for assessing and managing risk. Before the quarantine pest can be introduced, all of the events shown in the model must occur.

Regarding the commenter's statement ''however, we do not believe that each stage is independent of the all preceding stages,'' we disagree and believe the nodes are independent; it is not possible to address this comment more specifically without further information from the commenter about which nodes he believes are correlated with others. We have discussed the basis for our belief in the independence of the nodes elsewhere in this document and address the issue in the addendum that is available from the person listed under **FOR FURTHER INFORMATION CONTACT.**

Regarding the commenter's statement ''nor do we believe that it is certain that all fruit will pass through each stage of the process,'' we would point out that the probabilities assigned to each node that represents a risk mitigation step relate directly to a ''failure'' of that particular step (*e.g.*, pest not detected, pest survives treatment), thus the possibility of failure in each of the stages was considered in the risk assessment. Further, this rule requires that only fruit that passes through each stage of the process may be approved for entry into the United States. SENASA inspectors will be present at each stage to supervise, confirm, and document the successful application of each of the required mitigations, and a phytosanitary certificate issued by SENASA confirming that the fruit has been produced in accordance with the requirements of this rule must accompany each shipment of fruit exported to the United States.

Finally, the commenter states that we used our model to estimate the frequency of pest outbreaks, but, as noted in our response to the previous comment, that is not the case. As shown in Figure 2 on page 30 of the risk assessment, the endpoint of our risk model for the likelihood of introduction was ''pest establishes.'' International guidelines for pest risk analysis (FAO 1996, as referenced in the risk assessment) define introduction as pest entry plus establishment.

Comment: APHIS selected an 18-kg box of fruit as the ''risk unit'' for the risk assessment and bases all estimates of probability on this unit. This is not appropriate for all steps, perhaps any step, in the analysis. For the first four stages of the pathway defined by the risk assessment (*i.e.*, until the fruit is boxed at the packinghouse), the fruit are acted on independently of the boxes in which they will be placed. Moreover, the processes of storage, sorting, and packing occur in such a way that the fruit become fairly well randomized. Thus if $p_1p_2p_3p_4$ are the ''per fruit'' probabilities designated as P1, P2, P3, and P4 on a ''per box'' basis in the risk assessment, then if $p_1p_2p_3p_4$ are independent (but see below), the probability for a box containing n fruit to be infection-free after the fourth stage is $1\text{-}(1\text{-}p_1p_2p_3p_4)^n$. But this cannot in general be written as the product P1P2P3P4 (as is done in the risk assessment) where P1 through P4 are independent, and it cannot even be so approximated if the product $p_1p_2p_3p_4$ is reasonably large, as certainly occurs in the unmitigated situation. The natural, indeed the only, unit for consideration is the individual fruit. Using individual fruit will also allow straightforward analysis of the experiments that have been or can be performed to test efficacy of various treatments or actions.

Response: As noted elsewhere in this document, we believe that a box of fruit is the most appropriate risk unit. No one unit is perfect for each node; prior to packing there is mixing of the fruit from an orchard. Once the fruit are packed, they are no longer independent of each other, and it is boxes, and not individual fruit, that will be shipped to—and, in all likelihood, remain in—specific destinations in the United States. Even though no one unit is perfect for each node, we decided that it would be most transparent, defensible, and correct to use a consistent risk unit throughout the model. The primary problem perceived with using individual fruit as the risk unit was the different size of the various fruit being considered (*i.e.*, lemons, oranges, and grapefruit). Separate modeling for each type of fruit would have complicated the assessment significantly and needlessly; the expert group did not believe that separate modeling would improve the accuracy of the risk estimates, especially given the inherent uncertainties in the input parameters.

As explained in the risk assessment (section 8.e.F1, p. 29), in each step of the scenario, the probabilities were estimated for one box of fruit. The commenter asserts:

> Thus if $p_1p_2p_3p_4$ are the ''per fruit'' probabilities designated as P1, P2, P3 and P4 on a ''per box'' basis in the risk assessment, then if $p_1p_2p_3p_4$ are independent (but see below) the probability for a box containing n fruit to be infection-free after the fourth stage is $1\text{-}(1\text{-}p_1p_2p_3p_4)^n$. But this cannot in general be written as the product P1P2P3P4 (as is done in the risk assessment) where P1 through P4 are independent, and it cannot even be so approximated if the product $p_1p_2p_3p_4$ is reasonably large, as certainly occurs in the unmitigated situation.

We believe that assertion is inappropriate because it mixes units, first assuming a per-fruit probability, then a per-box probability. We were consistent throughout the risk assessment and used per-box probabilities for each node.

Comment: To correctly model the mitigated situation, more information should be presented about exactly what happens when citrus black spot or sweet orange scab is detected on fruit destined for the United States. Is the entire shipment prohibited from entering the United States? What about other shipments en route from the same grove? These do not appear to have been accounted for in the probability distributions for the risk assessment. The proposed regulations require that the grove be removed from the export program for the duration of the growing season if citrus black spot or sweet orange scab is detected upon any required inspection, including inspection at the port of first arrival. Would the removal of such groves from the export program affect any of the distributions in the risk assessment? It certainly affects the structure of the overall probability model.

Response: As described in the proposed rule and noted by the commenter, should any of these diseases be detected on fruit destined for the United States, the entire shipment will be rejected and the grove will be eliminated from the program for the remainder of the shipping season. These events—the rejection of shipments and the elimination of groves—can be viewed as successful applications of the systems approach and, as such, contribute to the risk reductions estimated in our risk assessment. Because the probabilities assigned to each node that represents a risk mitigation step relate directly to a ''failure'' of that particular step (*e.g.*, pest not detected, pest survives treatment), our explicit focus was on failures rather than on successful applications of the systems approach. Those successes were, however, inherently reflected and accounted for in the appropriate probability distributions in the risk assessment.

Comment: APHIS makes no attempt to account for the number of fruit in a box that are affected or for the number of pests affecting each fruit. Certainly, if several pieces of fruit in a given box were infested with fruit flies, the probability of the pest establishing itself in the United States as a result of the contaminated box would be much higher than if only one fruit was infected, as is explicitly acknowledged in section 8.e P8 of the risk assessment.

Because the ranges for these variables are large (ranging from zero to the maximum number of fruit in a box and from zero to a large number of pests per box), accounting for variability in the number of infested or infected fruits per box and for the number of pests per fruit (or box) could have a large impact on the results of the risk assessment.

Response: As stated in the risk assessment (section 8.e P1, p.29), we considered the possibility that more than one fruit in a box might be infested with fruit flies (''Specifically, this node represents the probability of one or more individual fruit in a box being infested by any of the four species of fruit flies.'').

However, because the likelihood that any individual fruit will be infested is low (mode of distribution = 0.00009), and because the fruit are mixed thoroughly prior to packing, the likelihood that multiple fruit within a single box will be infested is considerably smaller than 0.00009. As indicated in the quote above, our estimates accounted for this possibility.

Regarding multiple larvae, the most likely way (virtually the only way) that one of these fruit fly species could become established as a result of the importation of infested fruit is if there are multiple larvae in a particular fruit. A reasonable consideration of this situation leads to the conclusion that unless multiple larvae are present, it would be nearly impossible for a breeding pair to form. Thus, multiple larvae infesting a given fruit was the primary factor in our estimate. In addition, it should also be remembered that this rule will require all susceptible fruit to be treated according to a treatment schedule with a documented efficacy of 99.9968 percent.

Comment: APHIS states, ''The nodes in our scenario (risk model) represent independent events that must all take place before an introduction can occur.'' However, it is not sensible to believe that the eight stages considered in the APHIS risk assessment are truly independent, or that the diagram (Figure 2 of the risk assessment) adequately represents the process of importation of citrus fruit. The model used in the assessment, which consists solely of independent stages, appears to have been selected to agree with APHIS's ''Detailed Description of the PPQ Pathway-Initiated Qualitative Commodity Pest Risk Assessment, Version 4.1'' for qualitative assessments. However, these guidelines are incorrect, even for a qualitative risk assessment. It may not be possible to construct such a linear sequence of steps to adequately represent the movement of a commodity—a more complex diagram may be necessary. Moreover, even if it is possible to construct such a sequence of such steps, it is incorrect to make estimates independently for each step. What is required are the conditional probabilities for subsequent steps, based on the prior steps in the sequence.

Response: We consider it completely reasonable, given the parameters of the model, that all eight nodes are independent. Indeed, the model was constructed with the express purpose of constructing a model with independent nodes (events), and an expert review of the model conducted by the Harvard Center for Risk Analysis reported in the journal *Risk Analysis* (Gray *et al.,* 1998) has validated our model and its assumption of independence. Without specific details from the commenter as to where and how dependencies might affect the model and its outcome, it is not possible to address this comment in detail except to repeat our statement that they are independent. Our model provides a framework for estimating risk, and we (and others, as noted above) believe the guidelines are valid. The model we selected has proven itself over the years, and for several commodity/pest combinations, to be an efficient means of estimating this type of risk. While we acknowledge that there are alternative ways of estimating this type of risk, we do not believe that using a different model would result in a substantively different outcome.

The risk model (scenario) was not, as stated by the commenter, offered to represent the process of importation of citrus fruit. The process was explained in the proposed rule, and details of the proposed risk mitigation program were listed in the risk assessment on pp. 26–28. Nor was our risk scenario offered to represent each mitigation measure in the proposed program; rather, it represents ''independent events that must all take place before an introduction can occur.'' The frequency of shipments/number of boxes (F1) and four of the eight nodes (P4, P6–P8) are not affected by risk mitigation measures. P1 is affected by standard and special pest control activities, P2 and P3 represent inspections for pests, and P5 represents a variety of treatments depending on host and pest.

The commenter asserts that the model appears to have been selected to agree with APHIS' guidance for performing qualitative risk assessments, when in fact our baseline scenario (risk model) for these risk assessments was developed before our qualitative process; the qualitative process is based on the probabilistic scenario. The commenter continues by stating: ''However, these guidelines are incorrect, even for a qualitative risk assessment. It may not be possible to construct such a linear sequence of steps to adequately represent the movement of a commodity—a more complex diagram may be necessary. Moreover, even if it is possible to construct such a sequence of such steps, it is incorrect to make estimates independently for each step.'' As stated above, the scenario was never intended to represent movement of a commodity. As we explained in the risk assessment, the nodes in our scenario represent independent events that must all take place before an introduction can occur. Regarding the commenter's statement that ''a more complex diagram may be necessary,'' we disagree. We believe that the events described in the risk model are necessary and sufficient for pest introduction. The commenter also states that ''What is required are the conditional probabilities for subsequent steps, based on the prior steps in the sequence.'' Conditional probabilities would be inappropriate because the nodes are independent.

Comment: APHIS' failure to account for human error and failure modes that could result in skipping one or more of the eight stages in its model is the most significant structural error in the assessment. It is inconceivable that 1.2 million boxes per year of fruit could all be treated forever according to the risk mitigation program without a single mistake. Some stages of the systems approach are likely to be omitted at times through negligence, accident, or design. Since some of the steps greatly reduce pest survival (assuming the pest traverses the step), even small probabilities for omission of such steps must be included in the analysis. APHIS should have used fault tree analysis in its assessment to evaluate the areas where failure can occur.

Response: All of the estimates for model inputs that are affected by human activities (P1 through P4) are based at least in part on a consideration of human error. For example, the most obvious reason that a pest would not be detected at harvest (P2) or during packing (P3) would be an insufficient inspection (*i.e.,* human error). The possibility of human error in fungicide applications is considered in P1 and the failure of post-harvest treatments is considered in P4. The other nodes are based either on marketing decisions (F1, P6) or pest biology (P5, P7–8). We do not believe that fault tree analyses are required in areas where failure can occur, as all of the nodes in our model that have a human component represent a ''failure'' of the system.

Comment: APHIS attempts to account for human error in some stages of the model, but ignores it in other stages. When constructing a distribution for sweet orange scab infection rates, APHIS claims to account for the nature of the sweet orange scab fungus and the possibility of human error in fungicide applications. However, it is impossible for us to review the appropriateness of the distribution constructed by APHIS' experts because APHIS does not describe in detail how it accounts for the possibility of human error.

Response: The direct data we had available when preparing this distribution were limited, and we explicitly acknowledged that in the risk assessment. As noted by the commenter, we recognized that human error (e.g., the improper or incomplete application of the fungicidal sprays) would limit the effectiveness of this aspect of the program. However, there are no objective criteria that one can use to move from recognizing that there is the possibility of human error in fungicide application to an estimate of how much human error there is likely to be. There is no database that can be used to predict the frequency or severity of human error in fungicide applications, and little or no direct experimental evidence exists from which one can derive estimates for the effects of human error. We recognized, therefore, that there would necessarily be a large element of uncertainty in our estimates of potential human error, which we considered along with the biology of sweet orange scab in estimating disease incidence; that uncertainty is evident in the fact that the experts agreed that the disease incidence might range from 0.1 to 30 percent. We believe that the distribution we constructed appropriately accounts for the uncertainty in our estimates of the effects of human error.

Comment: APHIS takes no account of the possibility of failure modes associated with the cold treatment for fruit flies. Treatment schedules for fruit flies are based on a demonstrated survival rate of 0.00003. This survival rate is the mode of the distribution selected to characterize the probability that fruit flies will survive cold treatment. If any boxes of fruit escape cold treatment (as will almost certainly happen for a small fraction of the 1.2 million boxes), the chance of fruit fly survival increases dramatically (by a factor of 33,000) for those boxes. Failure modes could easily be incorporated into the analysis by adding a Bernoulli function or a Dirac delta function to steps that could accidentally be skipped.

Response: The process of research and development for establishing commodity treatments is well documented in the scientific literature. Before any treatment is accepted, confirmatory tests must be completed to simulate treatments under actual treatment conditions. When fruit are treated, monitoring devices are placed to record the conditions of the treatment. Before fruit are allowed entry, the treatment record is verified to ensure that the fruit were treated according to the treatment schedule. If the fruit were not treated according to the schedule, they would be denied entry. This requirement directly addresses the possibility of failures in the application of the cold treatment.

Comment: The principal failure of the risk assessment with respect to the probability distributions is the failure to cite any credible data underlying their selection, and the failure to provide any documentation on their derivation. Where some studies are cited to provide a basis for the derivation, APHIS provides only vague references. Examination of the rulemaking record turns up summary data from various studies in Argentina that may correspond to those references, but there is no way a reviewer can be absolutely certain. No analyses of the studies are provided or referenced in the risk assessment or the rulemaking record, so the basis of the risk assessment estimates for mean values and variability or uncertainty cannot be evaluated. It is clear, however, that the entire risk assessment fails to distinguish variability and uncertainty.

Response: The probability density functions (PDF's) used by APHIS in the Argentine citrus and other assessments are what Hoffman and Kaplan refer to as ''subjective probability distributions'' in a recent article in *Risk Analysis, An International Journal* (''Beyond the Domain of Direct Observation: How to Specify a Probability Distribution that Represents the 'State of Knowledge' about Uncertain Inputs,'' Vol. 19, No. 1, 1999, pp.131–134). They are subjective precisely because no direct evidence existed to allow construction of a objective probability distribution. As emphasized by Hoffman and Kaplan, this is the norm in probabilistic risk assessment.

In no case were data available that could be used to directly specify a PDF, that is, data that represented results of studies that provided an estimate of the parameter with associated information regarding the range of values, variability or uncertainty in the data, and the shape of the distribution. ''Risk assessment does not legitimately focus on filling the information gaps, but rather on making a decision in the absence of information,'' (Orr, *et al.*, 1994). Although doing a risk assessment under these conditions may be considered unacceptable by non-practitioners, the only way to complete this type (and most types) of risk assessment is to make the best estimate possible based on whatever indirect information is available. In most cases, there were no indirect data either (results of experiments conducted to test a particular hypothesis). However, we relied on the best available scientific information and, in virtually every case, reliable data and information existed that related to the parameter for which an estimate was needed. For example, although there may be no data *per se* regarding the likelihood that *Xanthomonas axonopodis* would be ''. . . able to complete disease cycle'' (P8) following entry into the United States on fruit for consumption, there is a wealth of scientifically valid data and information, and conclusions in scientific papers, that demonstrate that the likelihood is extremely low. Although we did not, in all cases, explicitly link sources of information to the PDF's in which the information was used, our knowledge of each of the insect pests and diseases is summarized in the pest data sheets contained in the risk assessment's appendices and our sources of information are cited in each pest data sheet and in section III (References) of the risk assessment. Additional information regarding the construction of each of the distributions is contained in the addendum to the risk assessment that is available from the person listed under **FOR FURTHER INFORMATION CONTACT.**

Regarding the statement that ''it is clear, however, that the entire risk assessment fails to distinguish variability and uncertainty,'' we call the commenter's attention to section 8.c where we stated:

We were uncertain about the input values for the likelihood model. This is typical for risk assessments. Uncertainty in the estimated values may arise from (among other things):

- natural variation over time
- natural variation from place to place
- data gaps or unconfirmed data
- relationships among multiple components in a node.

This statement documents the fact that we considered both variability and uncertainty. While it is true that we did not model variability or uncertainty separately, doing so is not a common practice, and this approach is useful only in certain circumstances. While this approach may provide more detailed information, it is not a given that additional detail can necessarily be equated with greater accuracy. In the case of this particular risk assessment—and virtually any plant pest risk assessment—separating variability from other forms of uncertainty would constitute overinterpretation of available data.

Comment: The risk assessment states that all the distributions are based on the professional judgment of the team of entomologists who developed the risk assessment. That professional judgment appears to have been based on research or actual data in only a few instances. APHIS certainly must have access to data from inspections and from previous infestations of pests in the United States. The use of such data would result in much more credible distributions than those derived solely from professional judgment. It is possible, even likely, that distributions based solely on professional judgment (i.e., without reliance on data) are wildly inaccurate, placing the reliability of the analysis in serious question.

Response: We did indeed use those data whenever they were available, and they were cited in several locations (e.g., Alfieri *et al.*, 1994; Brown *et al.*, 1988; Gould, 1995; etc.). The distributions were not based solely on professional judgment, i.e., ''without reliance on data'' as suggested by the commenter. But for many of the nodes, no direct data existed to provide estimates for the input distributions, and professional judgment informed by the ''indirect'' sources of information available (e.g., scientific literature regarding a particular pest, interception records, etc.) was used according to international standards and accepted practice.

Comment: In no case does APHIS discuss the decision criteria used to select the type of probability distribution (normal, lognormal, beta), let alone why only these three particular distribution types were used. In most cases (such as in the construction of distributions for fruit fly and citrus canker incidence, the probability that a pest is detected at harvest, the probability that the pest is detected in the packinghouse, the probability that the pest survives shipment, etc.), no justification beyond ''expert judgment'' is given for the parameters selected to characterize the distributions. While we recognize that extensive data originally may not have been available to characterize, such deficiencies should have been recognized very early in the process and further studies carried out to fill in the gaps in data.

Response: In addition to the three distribution types identified by the commenter, we also estimated several nodes using another type of probability distribution, truncated lognormal. Distributions were chosen to reflect the current state of scientific knowledge. We explained the nature of each distribution chosen; in fact, we provide a separate section for each distribution. The explanations can be found in section 8.e., with titled subparts for each node (probability distribution) used for the fruit fly simulation, and section 8.f., with titled subparts for each probability distribution used for the three diseases. We provided justification for our choice of distribution in many, but not all, cases. For example, in the discussion of the choice of distribution to represent the likelihood that fruit fly larvae will survive post-harvest treatment (section 8.e P5) we state:

Treatment schedules were based on demonstrated efficacy of probit 9 (99.9968 percent) mortality. This corresponds to a survival rate of 0.00003 (0.003 percent). We represented survival as a lognormal distribution with a mean of 0.0001 and a standard deviation (sd) of 0.00011. A sd of 0.00011 was chosen because the resulting distribution has a mode (peak of the distribution) at 0.00003.

In this case, although we did not offer a discussion of why a lognormal distribution was used, since ''there is a significant body of work that shows a particular family of distributions to match the variability in the type of variable in question'' (D. Vose, in press), insect response to treatments such as this is distributed lognormally. The statistical procedure (probit analysis) that led to the probit 9 estimate (referred to above and in the risk assessment) is based on the assumption that response is distributed lognormally. This phenomenon and the lognormal distribution lies at the heart of this branch of science and is documented in the scientific references provided in the risk assessment. Additional information regarding the selection of distribution types, including those not discussed in detail in the risk assessment, is contained in the addendum to the risk assessment that is available from the person listed under **FOR FURTHER INFORMATION CONTACT.**

Comment: Some justification needs to be provided for the estimates in the risk assessment for situations in which some data are available. For example, APHIS acknowledges that field and laboratory research has been performed on fruit fly infestations in commercial citrus production, yet it does not specify how (or even if) this research was used to derive the fruit fly infestation distribution, beyond stating that the entomologists working on the risk assessment used their professional judgment. Neither risk assessment nor the rulemaking record contains any documentation of either the evidence used or the methodology used to codify that evidence as probability distributions.

Response: Our knowledge of each of the insect pests and diseases, which, given the lack of directly applicable data in many cases, played an important role in the formulation of our estimates, is summarized in the pest data sheets contained in the risk assessment's appendices, and our sources of information are cited in each pest data sheet and in section III (References) of the risk assessment. Where direct information was available, that information was identified; the same holds true for the use of expert judgment in arriving at our estimates. The addendum to the risk assessment that is available from the person listed under **FOR FURTHER INFORMATION CONTACT** identifies, for each node, the direct information and expert information that was available and provides a discussion of how the available information was used in the construction of the distribution.

With regard to the commenter's specific example, we had no direct evidence of what the past, present, or future fruit fly infestation levels may be in Argentina. But regardless of where citrus is produced, we are confident that our distribution, which was based on expert judgment informed by experience with fruit flies and by information gleaned from numerous cited sources, reflects the entire realm of possibilities. As stated in section 8.e P1 of the risk assessment:

The minimum infestation rate used in the calculations was 0.000535 (e.g., one infested lemon per 280,400 lemons). The maximum infestation rate sampled for calculations was 0.495 (e.g., half of all boxes or one infested grapefruit per every 100 grapefruit).

Thus, because of our uncertainty, we used a distribution providing values representing infestation levels from where the pest is nearly nonexistent (one lemon out of 280,400) to an infestation level that would stop production (half of all boxes infested).

Comment: The number of boxes of fruit that will be shipped to the United States from Argentina is estimated as 1.2 million 18-kg boxes of fruit per year. This information was provided by citrus industry representatives in Argentina. From this single piece of data, APHIS constructed a normal distribution with a mean of 1.2 million and a standard deviation of 200,000 to represent the frequency of citrus shipments each year. APHIS states that this distribution was constructed to allow for variation in the frequency of shipments that might result from variations in production, the frequency of shipments cleared for export, and market demands in the United States. Quite apart from the question as to whether a year-to-year variability is the correct statistic to evaluate in this context, APHIS does not specify how it arrived at a standard deviation of 200,000—APHIS presents no evidence whatsoever, nor provides any methodology. It is certainly possible to provide a plausible methodology for obtaining some value for variability; for example, basing it on distributions for the U.S. importation of citrus fruit from other countries, or on distributions for other exports from Argentina, or even citrus exports to countries other than the United States. Moreover, this annual variability may not be required, and should certainly not be used in the risk assessment as APHIS has used it.

Response: While it is true that this situation could have been analyzed in greater detail, conducting the suggested analysis would represent overinterpretation of available data. We believe that the suggested analysis would obscure the situation, provide a false sense of security, and probably lead to a less accurate estimate.

In constructing this distribution, the expert group started with the point estimate of 1,200,000 boxes per year supplied by Argentina; the group then considered whether it was reasonable to assume central tendency. The group agreed that the point estimate from Argentina was the best available estimate, but that values both above and below 1,200,000 were possible (*i.e.*, the distribution should demonstrate central tendency around 1,200,000). The group discussed a variety of factors that could affect the number of boxes imported, *e.g.*, variation in harvest, variation in U.S. demand, unanticipated costs of the export program leading to less interest by growers, unanticipated success from the exporters' point of view leading to greater interest by growers, etc. There were, however, no data available that would allow us to estimate the effects these factors would have on the number of boxes shipped. Thus, the standard deviation of 200,000 chosen by the expert group represents uncertainty and not, as the commenter suggests, variability per se, in the model. (As noted in a recent paper published in the journal *Risk Analysis* (Gray *et al.*, 1998), ''[k]nowledge of variability must be based on empirical estimates, otherwise it is another source of uncertainty.'')

With no information suggesting any particular distribution type, the group believed that a normal distribution was most reasonable (*i.e.*, symmetrical uncertainty around the mean/mode/median). They agreed that although the actual number of boxes imported would almost certainly be other than exactly 1,200,000 per year, they had no legitimate reason to believe it would be higher as opposed to lower or vice versa, or what the year-to-year variability would be. Using the software package Risk View ™ (Palisade Corp., Newfield, NY) and trial and error, the group specified the (standard deviation) value that provided what they considered to be appropriate positions for the 5th and 95th percentile values in the distribution.

Comment: In section 8.f. P1 of the risk assessment, APHIS identifies data for sweet orange scab and citrus black spot infection rates in Argentina. It claims that limited field surveys indicate that 39 percent of sampled trees in control plots (untreated) bear fruit with evidence of sweet orange scab. The distribution constructed by APHIS for sweet orange scab infection is a beta distribution with a mean probability of 0.5 that a box of produce is infected. How is APHIS's distribution related to the infection rates in field surveys? Why does APHIS select a beta distribution to characterize this probability? How does APHIS arrive at the two parameters necessary to characterize the beta distribution? There is no information in the risk assessment or the rulemaking record to support the constructed distributions. Similarly, APHIS cites the results of field surveys for citrus black spot as finding 14 percent and 82 percent of sampled fruit infected with citrus black spot in 1994 and 1995, and 56 percent of sampled trees infected in 1996. APHIS goes on to say, ''Our expert information predicted that the incidence of citrus black spot, on a per box basis, in untreated groves would range from a minimum of 10 percent to a maximum of 100 percent with a most likely value of 50 percent.'' APHIS then proceeds to construct a beta distribution with a mean of 60 percent and a mode (most likely value) of 67 percent. Again, there is no information in the rulemaking record or the risk assessment to indicate how this distribution incorporates either the results of the field surveys or the expert information.

Response: As stated in the risk assessment document, ''our estimates * * * were based on limited field survey data provided by Argentina and expert information provided by scientists familiar with citrus production in Argentina and/or the pathogen.'' Because the field survey data were limited, our expert estimates of these probabilities, which were informed by the body of scientific knowledge cited in the references and summarized in the pest data sheets, reflected what we considered appropriate levels of uncertainty, and the distributions were derived to reflect those estimates.

The experts relied on professional judgment to construct probability density functions that accurately represented their understanding of the available information. For both citrus black spot and sweet orange scab, the experts, after discussing available scientific and other information, identified the general shape of the distributions that were needed to account for all identified or assumed variation and uncertainty. In both cases, the experts agreed on a beta distribution, and discussions ensued to establish the parameters of the chosen distributions. The experts used an iterative process in conjunction with the software program Risk View ™ (Palisade Corp., Newfield, NY) to provide instant feedback on the shape and statistics associated with any particular set of parameters. This was largely trial and error, and the experts succeeded in producing beta distributions that represented the group's understanding of the available information. The experts used a consensus approach. The distributions captured the full range of variability and uncertainty considered essential by all experts, even though they may have represented more uncertainty than was felt necessary by any single expert.

Comment: The rulemaking record contains some information on the field surveys performed in Argentina, in the form of a very short summary of some results of those field surveys. However, the record omits crucial information required to interpret these summary results, including the protocols used for the field surveys; complete, written scientific documents describing the surveys and their results; and the contemporaneous field notes that should have been taken during the surveys. Despite this lack of information, we believe that APHIS' interpretation of the results is incorrect, as applied in its risk assessment. Adding up the results of the 1996 field results, in which 5 fruit per tree were sampled from each of 300 randomly selected trees, gives:

Number of infected fruit per tree	Number of trees (out of 300 in each case)	
	Sweet orange scab in oranges	Citrus black spot in lemons
0	181	133
1	95	78
2	22	46
3	2	25
4	0	15
5	0	3

(For this analysis, we do not distinguish *Elsinoe australis* from *Elsinoe fawcettii.*)

The incidence of infection (per fruit) was 9.67 percent for sweet orange scab in oranges and 21.3 percent for citrus black spot in lemons. APHIS apparently took the fraction of trees infected to be equal to the number of trees with observed infected fruit divided by the total number of trees (119/300=39.7 percent for sweet orange scab in oranges, 167/300=55.7 percent for citrus black spot in lemons). This is incorrect, however, since not all fruit on each tree were examined. It is clear that not all fruit are infected even on an infected tree, so sampling 5 fruit per tree will likely yield zero fruit infected from quite a few infected trees.

A simple approach to analyzing these experimental data is to assume some probability for a tree to be infected, and then to assume that all the fruit on an infected tree have an equal probability for infection (while those on uninfected trees have zero probability for infection). For sweet orange scab in oranges, this leads to a best estimate for the fraction of trees infected of 97.7 percent, and the observations are entirely consistent with (and statistically indistinguishable from) 100 percent infection. In that case, with 9.67 percent fruit infected, we would expect to see almost exactly the pattern of detections (per tree) actually observed (it is just a binomial distribution of infections). For citrus black spot in lemons, the best estimate for the fraction of trees infected is about 64 percent, with 33 percent of the fruit infected on an infected tree (note that $0.64 \times 0.33=0.21$, the observed fraction of fruit infected), using the same simple model.

The simple model used here leads to binomial statistics, although it is clear in the case of citrus black spot that there is actually more variability than the binomial distribution would predict. It is not difficult to postulate a more plausible model with the higher variability expected because of differences between geographic areas, groves, or field conditions. Accurate evaluation of the variability requires more field data, and is required for an adequate scientific evaluation of the Argentine situation.

Response: We acknowledged that the information we initially provided to this commenter did not reflect the entire body of data that was used to support the proposed rule. However, as we also noted, we did forward additional documentation to the commenter following the close of the comment period in response to the commenter's FOIA request. We understand that the commenter is reviewing that additional documentation, and we have stated our willingness to thoroughly consider, and address as appropriate, any new scientific information that comes to light as a result of that review that has a material and significant bearing on this rulemaking proceeding.

With regard to the commenter's argument that APHIS' interpretation of the results was incorrect, there are several ways to interpret and use the data presented by the commenter to support his argument. However, we believe that the analysis suggested by the commenter is based on invalid assumptions. Specifically, although it would be inadvisable to ''assume some probability for a tree to be infected,'' it would be a critical error ''to assume that all the fruit on an infected tree have an equal probability for infection''; this is known to be false. That is why the five fruit were sampled from the area of the trees where infected fruit were most likely. It would also be an error to assume that on trees where none of the five sampled fruit were infected, all fruit were not infected. With a sample of five fruit, it was known that not all infected trees were identified. That is one of the reasons why even though infected fruit were found on only 39.7 percent of the sampled trees, the mode and mean of our estimate (input distribution) was higher (50 percent). The commenter also does not account for the fact that our risk unit was a box of fruit, not an individual fruit or entire tree. This is discussed further in the response to the next comment.

Comment: From the description in section 8.f P1 of the risk assessment, APHIS appears to believe that the fraction of boxes infected is in some simple way related to the fraction of trees infected, since the only discussion of the former immediately follows the estimate of the latter in such a way as to suggest such a connection. There is no other discussion in either the risk assessment or the rulemaking record, and the values adopted by APHIS are very similar. This is incorrect however. The final shipping boxes are not filled from individual trees, but in the packinghouse after processes that will substantially mix fruit from multiple trees. To a good approximation, fruit will be randomized during harvesting, storage, and the packing process, so that a given box will be packed with fruit from a random selection of trees. For sweet orange scab in oranges, the probability for no fruit in a box to be infected would thus be about $(1-0.0967)^{100}$ for 100 fruit per box, or 3.8×10^{-5} if the structure of APHIS's model were correct. That is, the probability for an infected box of oranges (i.e., a box containing one or more infected fruit) in the base case for sweet orange scab is about 99.9962 percent. For citrus black spot in lemons, a similar calculation shows that the probability for a box of lemons (150 per box) to be infected in the base case is about $1–2.5 \times 10–16$, which is 100 percent for all practical purposes, under the same assumptions. In fact, the structure of APHIS's model is not correct, so these calculations are somewhat awry. One cannot follow a ''box'' of fruit through from harvest to packing, since the box is not constructed until after many processes that operate on individual fruit (independent of which box they finally end up in) and may affect the probability of infection. Thus estimating probabilities ''per box'' at this stage is itself a futile exercise. A better approach is to evaluate on a ''per fruit'' basis throughout the risk assessment.

Response: The commenter states that it is incorrect to believe that the fraction of boxes infected is in some simple way related to the fraction of trees infected. We agree that there is no way to go directly from a sample of trees (with a sample of fruit taken from each tree) to either a per-fruit or per-box estimate. However, we believe that the sample, which is indicative of the overall infection rate in the grove for the year in which the sample was taken, can be used as a starting point for an estimate of the per-box infection rate. That being said, our estimates were made with the knowledge that factors existed that argued for both (1) a lower per-box infection rate (i.e., not all fruit on a tree with infected fruit are infected) and (2) a higher grove infection rate (i.e., not all sampled trees with infected fruit tested positive). This is one of the reasons that even though sweet orange scab-infected fruit were found on 39.7 percent of the sampled trees, the mode and mean of our estimate was higher (50 percent).

As stated in the risk assessment, ''Our expert information predicted disease incidence, on a per box basis, to range from a minimum of 1 percent to a maximum of 90 percent with a most likely value of 50 percent.'' However, because of the uncertainty in the information, and because of the uncertainty of the experts regarding the per-box infection rate, we specified a distribution that allowed values for infection rates across the entire range of probabilities from 0 through 1 (100 percent). For sweet orange scab, we characterized our baseline estimate for the likelihood harvested fruit was infected (P1) with a beta (3.5, 3.5) distribution (see Table 8 of the risk assessment). With this distribution, although the most likely value was 50 percent, values up to and including 100 percent were possible. The maximum value actually used for calculations was 0.9773+, i.e., 97.7 percent. We made our estimates according to international guidelines for plant pest risk assessments, which have been endorsed by the United States, and are consistent with common practice in risk assessment as reported by Hoffman and Kaplan (1999, see reference above). We used available data and professional judgment to represent the data in the terms needed for the risk assessment.

With regard to our use of ''per-box'' probabilities, we have stated previously in this document that we believe that our selection of the box, rather than individual fruit, as the risk unit is appropriate. Once the fruit are packed, they are no longer independent of each other, and it is boxes, and not individual fruit, that will be shipped—to and, in all likelihood, remain in—specific destinations in the United States. Even though no one unit is perfect for each node, we decided that it would be most transparent, defensible, and correct to use a consistent risk unit throughout the model. The primary problem perceived with using individual fruit as the risk unit was the different size of the various fruit being considered (i.e., lemons, oranges, and grapefruit). Separate modeling for each type of fruit would have complicated the assessment significantly and needlessly; the expert group did not believe that separate modeling would improve the accuracy of the risk estimates, especially given the inherent uncertainties in the input parameters.

Comment: For citrus black spot, some additional data are available from the earlier small field experiments described in the rulemaking record. However, these were not field surveys as claimed by APHIS in the risk assessment (for example, the sampled trees were not selected at random), but rather the control side of experiments apparently designed to examine the effectiveness of fungicides; again no protocols, scientific documentation, field notes, or analyses are included in the rulemaking record. These small samples showed incidence per fruit of 0/432, 0/432 and 41/216 (19 percent) for grapefruit, and 36/252 (14 percent) and 207/252 (82 percent) for oranges. The first and last pairs of these samples were from the same plot in different years. The APHIS characterization of these surveys in the risk assessment omitted entirely the results in grapefruit. The results, although not field surveys, do illustrate the possibility of no observed infection even without fungicidal treatments, and the high variability from place to place and year to year.

Response: As noted by the commenter, the data we used were obtained through experiments using treated and untreated control plots. It is also the case that the risk assessment did not explicitly cite the grapefruit data reviewed by the commenter (which is available in the additional documentation that may be obtained from the person listed under **FOR FURTHER INFORMATION CONTACT**). That being said, it is clear from the available information that citrus black spot, as is the case with many diseases, is more prevalent in some years than in others. For this reason it is entirely possible that in some years no infection would be observed even if fungicides were not applied. The disease can be variable from place to place and year to year. This fact is not relevant to the efficacy of the systems approach, which is designed to mitigate the risk during years in which disease is likely.

Comment: In the risk assessment, APHIS makes estimates for the probability of infection when the mitigation measures are taken. There is some confusion over the precise meaning assigned to the various mitigation measures that may substantially affect infection probabilities. Although APHIS does not provide any indication of its approach (either citation or methodology) for estimating post-mitigation infection probabilities, simple analyses of the Argentine data on citrus black spot suppression by copper oxychloride treatment are possible, as shown in the following example.

In those experiments, assume that the probability for a control (untreated) fruit to be infected is p (different in each experiment and from season to season), and that treatment with one application of copper oxychloride multiplies that probability by a factor R (different for each treatment type, and hopefully less than unity, to have an effective treatment), with two applications reducing it by R_2 (one could, and should, test this latter assumption). Assume binomial responses (e.g., because all fruit are equally likely to be infected, and treatment is equally effective on all fruit), and use binomial likelihood methods. We can then estimate p and R from the available data, together with the uncertainty on R, if desired. For grapefruit, two of the three available experiments show no responses at all, so they are useless for estimation of R. For oranges, we could test whether two applications really reduced the incidence equally in each application; inspection of the data shows that this is certainly plausible.

Applying this simple model to the single useful experiment on grapefruit gives a maximum likelihood estimate (MLE) for R of 1.15 for the 1.8 percent treatment, and 0.31 for the 3.6 percent treatment. Thus two applications of 3.6 percent might reduce the rate 10-fold and three applications 33-fold. However, the uncertainty is large. This experiment shows no effect of the 1.8 percent treatment.

For oranges, the MLE for R is 0.22 for 1.8 percent and 0.20 for 3.6 percent, so that two applications of 3.6 percent might reduce the infection rate 24-fold, and three applications 118-fold. Notice that a 24-fold reduction from the control group rate of 36/252 is entirely consistent with the observed 0/252 in the 93–94 season when two applications were made.

Such analyses could be extended in various ways. For example, in this model the R values for 1.8 percent are significantly different for grapefruit and oranges, but for 3.6 percent they are not significantly different. The MLE for the combined value (for 3.6 percent) is 0.25, so that the model prediction for two applications is a 16-fold reduction in disease rate, and for three applications a 128-fold reduction. With so few experiments, and none available for analysis with three applications (versus one and two), one cannot test the model hypothesis that each application simply reduces the disease rate by a similar amount. Apparently, more experiments were in fact performed, but the rulemaking record reports only summary results that cannot be interpreted without much more information.

This analysis indicates the paucity of the data available in the rulemaking record. For grapefruit, the one available experiment on the effectiveness on citrus black spot of 1.8 percent copper oxychloride treatment shows it to be ineffective, although it is almost as effective as 3.6 percent on citrus black spot on oranges.

Response: The commenter offers an alternative way to consider the estimated efficacy of mitigation treatments. However, the approach is complex and highly speculative, and in our estimation represents an overinterpretation of available data, which, as the commenter notes and we acknowledged in the risk assessment, were limited. Copper oxychloride is a well established treatment for citrus black spot and sweet orange scab. Our estimates concerning the efficacy of these mitigation treatments are based on expert interpretation of results that have been obtained in a variety of studies on the control of these diseases (for example, as referenced in Whiteside *et al.,* 1988, as cited in the risk assessment).

Comment: Only one experiment reported in the rulemaking record addresses the effectiveness of copper oxychloride treatment on citrus black spot in lemons. While it apparently showed that the treatment was effective, there were no details on the protocols adopted (concentrations, number of applications, experimental procedures, and so forth), although a naive calculation indicates that the incidence was reduced more than 100-fold (approximately 95 percent confidence limit). In another document there are two figures labeled ''Chemical control (Santa Clara-Jujuy),'' apparently for treatments in the 1993–94 and 1994–95 seasons, that appear to correspond to suppression of citrus black spot in Eureka lemons, but there is no explanation of the origin of the data used in those two figures. APHIS should identify which treatments were applied in the tested groves and describe the level of disease in the region near the tested groves. Similarly, the effectiveness of copper oxychloride treatment for sweet orange scab is only demonstrated in one experiment (on oranges) in the rulemaking record, but the experimental protocols are not reported (number of treatments, concentrations, application rates, experimental procedures, and so forth). It is possible that some of this mitigating effect may be due to other simultaneous measures, such as cleaning of the orchard floors; however, in the absence of experimental protocols, this cannot be determined. Moreover, the available evidence is insufficient to adequately characterize that effect. For a defensible estimate of the effect of copper oxychloride treatments on citrus black spot and sweet orange scab, APHIS must have experimental data demonstrating its effectiveness under varying conditions, in different areas, and for different fruit. Furthermore, APHIS must provide details of its analyses demonstrating effectiveness, and must show the connection between the experimental data and the distribution used in the risk assessment.

Response: As we have recognized in numerous instances in this document, there is not always a one-to-one correlation between the experimental data, which is limited in some cases, and the distributions used in the risk assessment. In this case, our estimates on the effectiveness of the copper oxychloride treatment, which is the treatment that was applied in the tested groves, are derived not solely from evidence supplied by Argentina but also from reports in the scientific literature (e.g., as reported by Whiteside *et al.,* 1988, cited in the risk assessment). These reports represent results that demonstrate the effectiveness of copper oxychloride in reducing disease incidence under varying conditions, in different areas, and for different fruit, even in areas where the level of disease is high.

Comment: The risk assessment (8.f. P4) states that it is assumed in the baseline that the fruit ''treatments may include, but are not limited to, washing fruit in a detergent bath, waxing and fungicide dips.'' It is not clear how much more extensive the proposed treatment program is, since the proposed treatment program could be described in exactly the same fashion as the baseline (although washing in detergent is not prescribed). The risk assessment (8.f. P4) also states that ''the only post-harvest treatment for pathogens that is specifically prescribed in the proposed export program is a fruit dip in 200 ppm sodium hypochlorite (bleach) for 2 minutes.'' Actually, the preamble and proposed rule prescribe other specific treatments (immersion in orthophenilphenate of sodium, spray with imidazole, and application of 2–4 thiazalil benzimidazole and wax) that are specifically for treatment for pathogens (although this may depend on one's definition of ''pathogen'' in this context).

Response: The fact that the proposed treatment program examined in the risk assessment did not take into account the other specific treatments (immersion in orthophenilphenate of sodium, spray with imidazole, and application of 2–4 thiazalil benzimidazole and wax) that were described in the proposed rule and required by this rule can be attributed to the fact that the risk assessment was completed before the proposed rule was fully developed. However, it is clear that considering those treatments in the mitigated scenario in section 8.f. P4 of the risk assessment would have resulted in a higher risk reduction rating for the post-harvest mitigations, thus lowering the overall risk, which we already considered to be very low.

Comment: APHIS's assumptions that sweet orange scab-infected fruit is removed with 89 percent probability at harvest (mean value for both baseline and mitigation program), while citrus black spot-infected fruit is removed at harvest with mean 50 percent probability (baseline) and 89 percent probability (mitigation program), cannot be supported by any available evidence. We see three problems with this assumption:

- The incidence data used to support this are largely, if not totally, post-harvest incidences for latent disease, not field-apparent incidence of disease in unharvested fruit. Any probability for detection during harvesting is apparently already incorporated in such values.
- APHIS has assumed that pickers in Argentina make an attempt to cull blemished/diseased fruit, but our information indicates that pickers in Argentina do not cull fruit; rather all picked fruit is sent to the packinghouse for sorting there.

The entire object of chemical and other treatment is suppression of disease. The disease infections in the export groves should be latent at the time of picking, as evidenced by the data provided by the Argentines, so that there is no visible evidence of disease in harvested fruit. It should therefore be physically impossible for the pickers to detect latent disease.

With a reduced incidence at harvest, in the case of citrus black spot probably of entirely latent infections, there is no evidence that infected fruit is more likely to be removed by harvesters. At minimum, APHIS needs to document harvesting practices and obtain experimental evidence for removal probabilities at harvest. Such experiments would be very straightforward, since they simply involve random sampling of unharvested trees followed by sampling of fruit harvested in the normal course of events (and preferably also of the fruit, if any, that is culled by the harvesters). These should have been incorporated in experimental protocols at an early stage of experiment planning.

Response: The commenter states that we used incidence data to support our estimates regarding the removal of diseased fruit in P2, ''Pathogen not detected at harvest.'' This statement is incorrect. While data on disease incidence did affect our estimates for the likelihood that fruit are diseased in P1, ''Harvested fruit is infected,'' we indicated in the risk assessment (section 8.f P2, p.36–38) that our estimates for P2 were based on a variety of factors, including ''the nature of the disease symptoms, the skill of the picker in recognizing diseased fruit and the quality standards employed by a given grove in culling diseased fruit.'' Because sweet orange scab symptoms are easily seen during harvest, our estimates were based on a higher (compared to citrus black spot) degree of confidence that sweet orange scab-infected fruit will be identified and removed at harvest. The commenter also states that the ''entire object of chemical and other treatment is suppression of disease.'' This statement, which we understand to be referring to citrus black spot, is also incorrect. As we have stated elsewhere, the object of the field treatments is the prevention of the disease, and not merely the suppression of symptoms. Latent infections of citrus black spot would not be observed, which is why our baseline estimate that this disease will be missed is higher. However, the systems approach will reduce the likelihood of latent infections, thus decreasing the likelihood that diseased fruit will be missed.

Comment: APHIS provides estimates for the probability of detection of sweet orange scab and citrus black spot at packinghouse inspection. Again, no evidence is provided to support its estimates of 82 percent (mean: baseline) and 95 percent (mean: mitigation program) probability of detection of sweet orange scab, or with 74 percent (mean: baseline) and 95 percent (mean: mitigation program) probability of detection of citrus black spot. Factored into these estimates, according to APHIS, was the 20-day preharvest sampling and incubation of a small fraction of fruit.

The very existence of the 20-day preharvest sampling and incubation program ensures that the detection probability at this stage is correlated with the incidence of citrus black spot or sweet orange scab, since the detection probability is higher for higher incidences. Thus, the structure of the risk assessment model is incorrect. It is important also to note that the detection probability is correlated with the actual incidence, not with the probability of citrus black spot or sweet orange scab. The structure of the model has to be adjusted to account for this. In a Monte Carlo analysis, for example, the simplest way is to ensure that the detection probability at this stage depends correctly on the incidence in the particular Monte Carlo sample.

APHIS provides no documented evidence for the effectiveness of packinghouse inspections in either the risk assessment or the rulemaking record. The Argentines provided experimental data on the effectiveness of ''post-harvest treatments'' or ''post-harvest assays'' that presumably assessed all events occurring at the packinghouse, but again, because of the failure to provide protocols, experimental details, scientific reports, and field notes in the risk assessment or elsewhere, we cannot decipher what ''post-harvest treatments'' or ''post-harvest assays'' means. We believe that all the ''post-harvest treatments'' or ''post-harvest assays,'' perhaps including any inspections, have essentially no effect on the incidence of latent infections of citrus black spot. Should it be necessary to evaluate the effect of packinghouse inspection, as distinct from further packinghouse treatment, the experimental procedure would be straightforward, since all that is required is sampling of fruit prior to and after such inspection (and preferably, also, sampling of rejected fruit).

Response: The commenter's statement that ''The very existence of the 20-day preharvest sampling and incubation program ensures that the detection probability at this stage is correlated with the incidence of citrus black spot or sweet orange scab, since the detection probability is higher for higher incidences'' is incorrect. The packinghouse inspection and our estimates regarding the likelihood of detecting pests during this inspection are independent of both the 20-day preharvest sampling protocol and the results of that sampling. If any disease is detected as a result of the 20-day preharvest sampling, none of the fruit from that grove can be shipped to the United States. The only fruit that will be inspected and subsequently shipped to the United States are fruit from groves where the 20-day preharvest sampling resulted in a finding of no disease. The 20-day preharvest sampling that would be conducted to detect the presence of citrus black spot in the grove was accounted for in the risk model in P1, the likelihood that harvested fruit is infected. This sample must be taken from all groves that would ship fruit to the United States.

The commenter's statement that ''[i]t is important also to note that the detection probability is correlated with the actual incidence, not with the probability of citrus black spot or sweet orange scab'' is likewise incorrect. The likelihood that diseased fruit will be detected during packing is not related to disease incidence. Although the number of times that diseased fruit are detected is related to disease incidence (i.e., more disease, more detections), the likelihood that diseased fruit will be detected is not correlated with disease incidence.

In stating ''APHIS provides no documented evidence for the effectiveness of packinghouse inspections in either the risk assessment or the rulemaking record,'' the commenter is correct. These packinghouse inspections have not yet been conducted. Our estimates are based on examinations of citrus packinghouses in Argentina, experience with inspections and culling in citrus packing operations, direct knowledge of the etiology of these diseases, and familiarity with the symptoms of these diseases.

Comment: APHIS estimates the effect of post-harvest treatments on citrus black spot survival (on a per-box basis, which itself may not be appropriate) as giving a mean survival of 0.64 in the baseline situation, and a mean of 0.50 under the mitigation program. APHIS appears to have ignored the results of experiments apparently designed to test the effects of post-harvest treatments. Since APHIS does not document how it arrived at its estimates, it is impossible to tell whether it examined these data. There are no APHIS analyses of the data in the risk assessment or the rulemaking record, but the assumptions in the risk assessment for probability distributions appear to be contradicted by these data.

Response: The ''results of experiments'' referred to by the commenter are found in Argentine document Nota S.P. No. 338, which contains a summary of experiments to test the efficacy of post-harvest treatments on citrus black spot. Our analysis of that document indicates that the treatment effects were variable; compared to untreated controls, the proportion of treated fruit that developed black spot disease ranged from 30 to 100 percent. The primary difference between the treatments Argentina will use as part of its regular program (what we refer to as the baseline risk) and the treatments it will use as part of the program for exporting fruit to the United States (the proposed treatment program) is the sodium hypochlorite treatment. We did not ignore the results of the Argentine experiments, as the commenter asserts; rather, we believed that it would not be appropriate to assume that the difference in efficacy shown in the experiments, which compared treated to untreated fruit, would be the same as the difference in efficacy between the baseline scenario and the mitigation scenario examined in the risk assessment. This is because most of the treatments applied in the experiments cited by the commenter were, appropriately, considered in the risk assessment's examination of the baseline risk, as those treatments are routinely applied by citrus producers in Argentina as part of their regular program. Therefore, as documented in the risk assessment (8.f P4), our estimates for the mitigated scenario focused on the degree of additional risk reduction offered by the sodium hypochlorite treatment, which we assumed would have an additional deleterious effect on the survival of the citrus black spot fungus. The increased level of efficacy of the mitigation program is modest, a probability of 0.50 that the fungus will survive treatment as opposed to a probability of 0.64 in the baseline scenario. The primary purpose of these treatments is to reduce post-harvest spoiling, not kill fungus diseases, and the main effect of the chlorine dip is to kill spores on the surface of the fruit.

Comment: Since there is no information in the rulemaking record on the protocols for the experiments on the effectiveness of post-harvest treatments, nor any scientific documentation, we have to make some plausible assumptions in order to perform the simplest analysis. Assume that each experiment measures the disease rate in control and treated fruit, with the disease rate possibly differing in all the replicates of all the experiments. Assume that the post-harvest treatment alters the disease rate in the corresponding control by a fixed factor Q (by inspection, there is little difference within any set of replicate experiments; while one could and should formally test for equality, our simple analysis will forgo that testing for the sake of brevity). Assume that the same factor Q applies to all the experiments on a given fruit (again, this could and should be formally tested). Assume binomial distributions for infection, as would occur if the fruit were randomly chosen. Then the maximum likelihood estimates for Q are: 0.71 (grapefruit), 1.16 (orange), and 0.92 (lemon).

It should be noted that for this analysis, we have assumed that the detailed tables included in the rulemaking record and largely corresponding to the summaries provided by Argentina in Note S.P. 338, Annex III, are correct, and we have treated discarded fruit as though they were diseased. There are significant differences between those tables and the summaries presented by Argentina in Annex III in the descriptions of the number of fruit examined, and one table (Orange, Third Replicate) has the control and T2 groups transposed for all observations Rl, R2, R3, and R4. Once again, we are hindered by the absence of protocols, scientific documentation, and field notes from the rulemaking record. For example, whether discarded fruit should be analyzed as though infected depends on experimental details that are not presented within the rulemaking record, and even the summary tables in the record are inconsistent in their treatment of such discards. There are no comments by APHIS in either the risk assessment or the rulemaking record on these significant discrepancies.

These experimental results indicate that the post-harvest treatments have little, if any, effect on latent infections of citrus black spot. It would be possible to find confidence limits and test for equality of effect, but the effort would be wasted given the tiny number of experimental conditions, and the likelihood for variation (beyond the assumed binomial randomness) with field conditions, fruit, and possibly experimental conditions. The results do, however, throw considerable doubt on the values used for Q in the risk assessment for citrus black spot (0.64, range 0.4 to 0.85).

Response: In this comment, the commenter states in several places that there is no information in the rulemaking record on the protocols for the experiments on the effectiveness of post-harvest treatments for citrus black spot. In fact, the Argentine document to which the commenter refers, Note S.P. 338, states that ''[t]he results that appear in Annex III are the results of the assays that were carried out applying the methodology informed [sic] to APHIS in the 'Protocol of Assays to Evaluate the Effectiveness of the Post-Harvest Treatments for the Control of Guignardia citricarpa in Citrus Produced in the North-West of Argentina (NOA)' * * *.'' That document, which is actually titled ''Assays to Test Effectiveness of the Postharvest Treatment for the Control of *Guignardia citricarpa* in Citrus Fresh Fruit Produced in Argentine Northwest Region (NOA),'' was provided to the commenter following the close of the comment period and is included in the material provided in the addendum to the risk assessment that may be obtained from the person listed under **FOR FURTHER INFORMATION CONTACT**.

In discussing discrepancies that he believes exist among varies documents in the record, the commenter first states that the ''detailed tables,'' which are not identified in the comment, ''largely'' correspond to the summaries in Annex III of Note S.P. 338, and then states in the next sentence that there are ''significant differences'' between those tables and the summaries in Annex III. Without specific information as to where the differences occur, we are unable to provide the commenter with any clarification regarding possible discrepancies.

The commenter concludes, as a result of the simple analysis set forth in his comment, ''that the post-harvest treatments have little, if any, effect on latent infections of citrus black spot.'' We acknowledged this in the risk assessment and recognized that the primary purpose of these treatments is to reduce post-harvest spoiling, not kill fungus diseases, and the main effect of the chlorine dip is to kill spores on the surface of the fruit. The expert information used in the risk assessment reflected the variability of the treatment data and the experts' uncertainty around those data. While assuming that the fungicidal and chlorine dips would have a deleterious effect on the viability of *Guignardia citricarpa* propagules, the experts recognized the latent nature of black spot infections. The germinating fungal spore forms an appressorium from which an infection peg penetrates the cuticle, and mycelium grows in between the cuticle and the epidermis where it may remain quiescent (Whiteside, 1988) and effectively protected from fungicidal treatments. However, the form in which the fungus remains after treatment (i.e., mycelium) can hardly be considered infective (McOnie, 1967). The experts predicted that between 10 and 90 percent of infected boxes would survive post-harvest treatment with a most likely value of 50 percent.

In our response to the previous comment, we discussed the data provided by Argentina on this subject and our analysis and interpretation of those data. As we noted in that response, we assumed that the addition of the sodium hypochlorite dip to the baseline post-harvest treatments would have an additional deleterious effect on the survival of the citrus black spot fungus, but that the increased level of efficacy would be modest, reducing our estimate of the probability that the fungus will survive treatment from 0.64 (baseline) to 0.50 (mitigated).

Comment: For sweet orange scab, APHIS admits to having no efficacy data for the post-harvest treatments and provides no documentation of its method of reaching the values used in the risk assessment. Comparison with the citrus black spot case, where some data are available, leaves considerable doubt as to the adequacy of APHIS's methodology. In any case, it would be relatively straightforward to perform efficacy studies using methodology similar to that used on citrus black spot, and there is no indication of why such studies have not been performed for sweet orange scab.

Response: As noted by the commenter and in the risk assessment, no specific sweet orange scab efficacy data were available for the fungicidal activity of any of the individual post-harvest treatments that might be employed in the proposed export program. The incidence of sweet orange scab in a test sample of fruit subjected to the entire preharvest, harvest, and post-harvest export program was described in Argentine document 450/96 (September 30, 1996). In this survey, 300 boxes of fruit were randomly chosen from a larger lot that had been subjected to the conditions of the export program. Ten fruit were collected from each of the 300 boxes and visually inspected for symptoms of sweet orange scab. None of the 3,000 total fruit examined expressed disease symptoms. However, the survey did not include controls and its design did not allow for the separation of the effects of field treatments, inspections, or post-harvest treatments. The data provided by this survey were nonetheless useful in illustrating the effectiveness of the measures required by the export program and, when combined with the considerations discussed in the next paragraph, led us to conclude that additional studies such as those suggested by the commenter would not be necessary for the purposes of our risk assessment.

As we have noted elsewhere in this document and in the risk assessment, the only additional post-harvest treatment specifically required by the proposed export program (compared to the baseline) is the sodium hypochlorite dip. We assumed that the sodium hypochlorite dip—a treatment with widely recognized antifungal efficacy—would further reduce the survival rate of the sweet orange scab pathogen. An important consideration taken into account by our experts is the fact that, unlike citrus black spot, sweet orange scab lesions are erumpent and exposed on the surface of the rind. Thus, our experts believed that the sodium hypochlorite dip, along with the fungicidal treatments found in both the baseline program and the proposed export program, would be effective in killing any viable conidia on the surface of a pustule or contaminating the rind of fruit and may have some minor effect on sweet orange scab stomatic tissue.

Comment: For citrus canker, APHIS cites literature efficacy studies on the effect of chlorine dips. However, the method by which probability distributions were assigned from this literature is undocumented.

Response: The chlorine dip was only one factor considered when estimating the appropriate value for model inputs for this node (P4). The efficacy data on chlorine dips were considered along with other data and information, as cited on p.39 of the risk assessment:

> These treatments may include, but are not limited to, washing fruit in a detergent bath, waxing and fungicide dips. The only post-harvest treatment for pathogens that is specifically prescribed in the proposed export program is a fruit dip in 200 ppm sodium hypochlorite (bleach) for 2 minutes.

The probability distribution resulted from the expert judgment of a group of three plant pathologists familiar with treatment of commercial fruit for export, after consideration of all pertinent, available information. References for that information were provided in the risk assessment.

Comment: The proposed rule calls for testing 320 fruit/200 ha, according to SENASA's randomized sampling protocol, a protocol that is not described in the proposed rule or the risk assessment. We believe that the presence of such a testing procedure alters the structure of the model that must be used for the risk assessment. It also appears that such a testing procedure is designed to fail—we believe that fruit with a startlingly high infection rate could pass through such a screen.

From the information provided in the rulemaking record, total citrus production in northwestern Argentina appears to have been about 20 tons/ha in 1989, indicating yields similar to those in California and Florida (20–40 tons/ha). The tree planting densities also appear similar (200 to 250 trees/ha). Thus, for lemons, at 150 fruit per 18-kg box (as assumed in the risk assessment), the lemon yield will be about 170,000 to 340,000 per ha, and the total area required to produce the 1,200,000 boxes examined in the risk assessment will be about 600 to 1,000 ha.

For the sake of argument, assume that Argentina sets up 20 groves each of 100 ha as potential U.S. export groves, and follows all the procedures of the proposed rule (and note that this is, at first sight, about twice the required area). A 100 ha grove might have a buffer zone of 69 ha, so that the total area of the grove plus buffer would be 169 ha, calling for a sample of 270 fruit per grove+buffer (assuming that the buffer has to be sampled, but that is ambiguous in the proposed rule).

Now suppose that all the fruit from all the proposed U.S. export groves are infected at a rate of 1 in 400 fruit (0.25 percent), which is fairly high, just 100 to 400 times lower than the unmitigated rate. The probability for no infected fruit in a random sample of 270 fruit is $(1-0.0025)^{270} = 0.5$. Thus one could expect about 10 of the 20 groves to pass this test, providing the necessary area of 1,000 ha, while the other 10 groves would be removed from the export program for this season. The next season, the same thing might happen, but with a different (random) set of 10 or so groves excluded, and 10 or so included. Examination of this scenario and its extensions shows that with suitable subdivision of the potential U.S. export acreage into groves, and acceptance that some groves each year will be randomly removed from the program, almost any infection rate in the fruit is possible under the sampling scheme suggested. That is, the sampling scheme is not effective at controlling the allowable infection rate.

There is no need to postulate a deliberate effort to outwit the sampling scheme. It might prove economically advantageous for the citrus-producing region of northwestern Argentina to adopt all the procedures of the proposed rule for the entire citrus producing region, since such procedures may produce superior yields for many markets, not just the United States. Only a very small fraction of groves would have to meet the testing requirements to generate the suggested export volumes; and with the proposed sampling approach, these are likely to occur randomly even if the infection rates are higher than the 1-in-400 fruit of the preceding example. It would be straightforward to design statistically adequate sampling and testing regimes to ensure that the overall infection rate of fruit from any grove is below any required value, and such schemes can be extended to account for nonuniform infection rates between groves, and even infection rates that vary within each grove, but there is no evidence in the record of any such attempt.

Response: We disagree with the commenter's statement that a testing procedure that calls for a certain number of fruit to be collected from a defined area ''alters the structure of the model that must be used for the risk assessment.'' If the model we used in the risk assessment was a scenario tree model with branches that were based in some way on the outcome of the sampling, then the sampling protocol might have an impact on the structure of that model. In simple terms, the outcome of the sampling determines whether the fruit produced in an export grove will be considered in the export program, since the detection of disease in a grove or buffer area as a result of the sampling will result in the elimination of the grove and the fruit it produces from the export program. Thus, the nature of the sampling protocol used for the export program does not affect the structure of the model because the sampling is outside the scope of the model; the risk model deals only with fruit from groves that have been cleared for participation in the program.

In response to the comments regarding this sampling protocol, we are modifying the protocol for the 20-day preharvest sample and clarifying the basis and details of the sampling. The sampling protocol will be based on a statistically valid hypergeometric distribution. The ''lot size,'' or population size, is equal to the number of trees in the grove and buffer area. We will set our desired level of detection as follows: We will sample enough trees to have a confidence level of at least 95 percent of detecting an infection rate of 1 percent or more of the trees. In preparing this protocol, we have assumed that there will be 250 trees per hectare, and we have assumed a maximum grove/buffer area size of 800 hectares based on our available information. Given those two assumptions, we will require that 298 trees be sampled from each grove and buffer area (if an area to be sampled exceeds 800 hectares, this rule provides that SENASA will contact APHIS, and APHIS will determine the number of trees to be sampled). The 298 trees must be selected at random. In order to increase the likelihood of detecting disease, the fruit must be sampled from portions of the trees that are mostly likely to have infected, symptomatic fruit (i.e. near the outer, upper part of the canopy on the sides of the tree that receive the most sunlight). We have set the number of fruit to be sampled from each tree (number of replicates) at four fruit per tree.

Sampling 4 fruit from each of 298 trees will yield a sample size of 1,192 fruit, which is somewhat less than what would result from sampling 800 hectares at the rate called for in the proposed rule (320 fruit from each 200 hectares, i.e., 1,280 fruit). However, given that this new sampling protocol is based on a statistically valid hypergeometric distribution, we believe that it provides the ''statistically adequate'' sampling regime called for by the commenter and, given its random selection of trees and focus on collecting fruit from those parts of the tree most likely to contain infected fruit, will, as suggested by the commenter, ''account for nonuniform infection rates between groves, and even infection rates that vary within each grove.''

This sampling protocol will provide information regarding the disease status of farms wishing to be included in the program to export citrus fruit to the United States. Our risk model focuses on the risk to the United States of imported citrus fruit from farms in Argentina that are part of the official export program, i.e., farms that have already been certified for export to the United States. There are numerous risk mitigation measures in place, both as part of the regular risk mitigation program and the various special requirements of the U.S. export program. We believe that the testing and inspections required by this rule will ensure that fruit with a startlingly high infection rate does not enter the United States.

Comment: The sampling of 320 fruit per 200 hectares shortly before harvest is an utterly insufficient sample size to be assured of detecting the presence of citrus black spot or sweet orange scab:

- At an 8 m × 5 m planting density, there would be 50,000 trees/200 hectares; if 320 fruit are sampled, then 0.64 percent of all the trees would be sampled. If one assumes only 250 fruit are harvested per tree, then 0.00256 percent of the harvested fruit is sampled.
- At a 10 m × 5 m planting density, there would be 40,000 trees/200 hectares; if 320 fruit are sampled, then 0.8 percent of all the trees would be sampled. If one assumes only 250 fruit are harvested per tree, then 0.0032 percent of the harvested fruit is sampled.

This sampling size is especially inadequate when one considers that disease incidence will be low due to the fungicide treatments. Further, the ability of a sampling program to detect, for example, citrus black spot, may depend upon the location of the trees sampled within the grove, the location of the samples on those trees, the age of the trees, etc. Sample size should be based on biometric principles that consider the characteristics of the disease, the incidence, and the level of precision desired to detect any present infections. APHIS should explain why the 320 fruit/200 hectares sample size was chosen and why it is appropriate for the desired purpose.

Response: As explained in the response to the previous comment, the sampling protocol has been modified in this final rule to provide a statistically valid hypergeometric distribution that will provide for the sampling of enough trees to have a 95 percent confidence level of detecting an infection rate of 1 percent or more of the trees, and we have provided for four replicates per tree. The sampling system described in the proposed rule was the protocol offered by Argentina and was designed to be consistent with Argentina's existing monitoring system for citrus canker, which was based on a transect design.

Comment: The probabilistic estimation for ''pathogen not detected at packinghouse inspection'' relies here on the results of the 20-day preharvest sampling results. But, this sampling consists of random collection of fruit at a rate of 320 fruit from each 200 hectares surveyed. No information on the statistical or biometrical validity of this sampling protocol is provided in the pest risk assessment or the proposed rule. Without this information, it is impossible to evaluate its impact as a safeguarding element, particularly as it relates to the mitigation scenario estimation.

Response: As discussed in the responses to the previous comments, we have modified the sampling protocol that will be used to collect the fruit that will be subjected to laboratory analysis. Also, the commenter inaccurately states that ''the probabilistic estimation for 'pathogen not detected at packinghouse inspection' relies here on the results of the 20-day preharvest sampling results.'' We understand, however, how the reader could reach that conclusion based on our statements on p. 38 in section 8.f P3 of the risk assessment, which may have given a false impression. To clarify, the packinghouse inspection, and our estimates regarding the likelihood of detecting pests during this inspection, are independent of both the 20-day preharvest sampling protocol and the results of that sampling. If any disease is detected as a result of the 20-day preharvest sampling, none of the fruit from that grove can be shipped to the United States. The only fruit that will be inspected and subsequently shipped to the United States are fruit from groves where the 20-day preharvest sampling resulted in a finding of no disease. The 20-day preharvest sampling, which would be conducted to detect the presence of citrus black spot in the grove and buffer area, was accounted for in the risk model in P1, the likelihood that harvested fruit is infected. Upon reconsideration, our estimates for this node should probably be considerably lower, given the rigor of the 20-day preharvest sample. This sample must be taken from all groves that ship fruit to the United States.

Comment: Because we recognize that it is not practical to hold all harvested fruit for up to 3 weeks to detect latent symptoms, we suggest that the number of fruit examined in the 20-day preharvest sample be increased by at least tenfold to reduce the risk of disease introduction.

Response: Because the sampling protocol required by this rule will provide for the sampling of enough trees to have a 95 percent confidence level of detecting an infection rate of 1 percent or more of the trees, and because the sampling protocol requires four fruit to be selected from each tree, with those fruit being chosen from the portion of the tree most likely to have infected fruit, there is almost no chance that infection could exist in a grove without infected fruit being included in the sample subjected to laboratory examination. Further, during the 20 days that the sampled fruit is in the laboratory, the fruit will be held under conditions that are ideal for the expression of symptoms in any infected fruit. Given those considerations, and given that the detection of symptoms in a single fruit will result in a grove being removed from the export program, we do not believe that a tenfold increase in the sample size is necessary.

Comment: It is possible to design testing requirements that will reduce the failure rate below any given value under normal circumstances, but the risk assessment ought also to evaluate the effect of abnormal or unusual events. For example, the following need to be explicitly evaluated:

- Failure to apply field control (copper oxychloride) treatment (e.g. through inadvertent failure to add the solution, etc.);
- Failure of the field control treatment, even if applied;
- Failure to include the chlorine dip in the treatment schedule;
- Failure of the chlorine dip itself (e.g. inadvertent neutralization or failure to refresh or test);
- Temporary or permanent failure of inspection machinery (e.g. through operator inattention);
- Reintroduction of culled fruit (from harvest culling, if any, and/or packing plant inspection) into the product;
- Infection through the use of the same packinghouse at different times for U.S. export and non-U.S. export fruit (e.g. by accidental inclusion of non-export fruit still in the packinghouse; or by infection carried on machinery); and
- Infection through failure to disinfect tools, clothing etc. used in U.S. export groves after being used elsewhere.

Response: Our entire model is a fault model; thus, it takes into account the kinds of events suggested by the commenter, e.g.:

- Failures in the application or efficacy of field treatments are considered in the probabilities constructed for node P1, ''Harvested fruit is infected'';
- Failures in the application or efficacy of the chlorine dips are considered in the probabilities constructed for node P4, ''Fungus survives post-harvest treatment'';
- Inspection failures are considered in the probabilities constructed for P2, ''Pathogen not detected during harvest,'' and node P3, ''Pathogen not detected at packing house inspection.''

As discussed in our responses to earlier comments, measures will be in place to prevent non-export fruit from being present in the packinghouses when any export fruit is present and we believe that it is unlikely that fruit could become infected as a result of coming in contact with packinghouse machinery or tools, clothing, etc. Finally, the risk mitigation program has a series of checks to confirm that the required steps have been taken.

Comment: From the time the fruit leaves the packinghouse to the time it arrives at the U.S. port of entry, the only control system applied is the labeling on the boxes. APHIS has not evaluated the possibility for deliberate introduction of export-labeled boxes of untreated fruit in transit, for which there is presumably considerable economic incentive, nor for the possibility of misdirected, non-export-labeled boxes containing infected fruit that are missed by U.S. port-of-entry inspection.

Response: The commenter states that there is ''presumably considerable economic incentive'' for the deliberate placement of nonprogram fruit in export-labeled boxes. We disagree, and would argue that there are actually economic disincentives for such actions. As stated in the proposed rule and in this final rule, the detection of citrus black spot or sweet orange scab during the course of any inspection or testing required by this rule will result in the grove in which the fruit was grown or is being grown being removed from the SENASA citrus export program for the remainder of that year's growing and harvest season, and the fruit harvested from that grove may not be imported into the United States from the time of detection through the remainder of that shipping season. Because citrus fruit from nonparticipating groves is more likely to be infected with citrus black spot or sweet orange scab than fruit grown in registered groves, we believe that it is unlikely that the growers and packers participating in the SENASA citrus export program (and incurring additional costs of production by doing so) would allow their entire export operation to be jeopardized by allowing potentially infected fruit from nonparticipating groves to be commingled with their export-quality fruit, especially given that Argentina already has strong domestic demand for its citrus and numerous well-developed export markets to which nonprogram fruit may be exported. In addition to that purely economic disincentive, SENASA inspectors will also be present in the groves and packinghouses during the growing, harvest, and shipping seasons to ensure that all requirements of the regulations are being observed.

Regarding the possibility of misdirected, non-export-labeled boxes containing infected fruit being missed by U.S. port-of-entry inspection, we believe that it is unlikely that such misdirection would occur, given that this rule prohibits non-export fruit from being in the packinghouse when export fruit is present. That being said, the possibility of boxes containing infected fruit arriving in the United States is considered throughout the model. The model is a fault model and estimates the probability of pests entering the United States and becoming established. Each of these nodes are assumed to be independent events and, as such, begin with the assumption that pests, in some form, have infested or infected the fruit (P1), avoided detection (P2, P3), survived treatment (P4), survived shipment (P5), been shipped to a suitable habitat (P6), found a suitable host (P7), and will be able to complete the disease cycle (P8). As such, each of these nodes represents a ''fault'' in the system. One such fault that could lead to infected or infested fruit being inserted into the system includes boxes of fruit that are not part of the system being inserted into the system.

Comment: Because the proposed rule does not include any safeguarding requirements on the fruit as it is moved from the grove to the packinghouse and from the packinghouse to the point of export, the risk assessment needs to include an evaluation of the probabilities for infection with citrus diseases or contamination with infected material (*e.g.* blown leaves, ascospores attaching to fruit or fruit boxes) during transport within Argentina. Examination of the transport system must include staging areas on the road and in port, and must take account of simultaneous movement of other fruit that has not been subject to the same sanitary requirements as the U.S. export fruit.

Response: Mature fruit is not susceptible to infection by citrus black spot or sweet orange scab, so the possibility of infection during transport is not relevant and, therefore, did not need to be considered in the pest risk assessment.

Comment: APHIS estimates the fraction of the United States that is suitable habitat for fruit flies to be 10 to 15 percent, and the fraction of the United States that is suitable for sweet orange scab, citrus black spot, and citrus canker to be approximately 9 percent. From the text of the risk assessment, it appears that these values are simply a fraction of the area of the United States. A more appropriate value would be the probability that fruit will actually be shipped to an area with a suitable habitat. Such a distribution should take account of the population of the United States that lives in suitable habitats or current (or potential) shipping patterns for fresh citrus. The distribution should take account of the seasonal probability of shipping fruit to a citrus-growing region, and the correlation of this probability with the probability for pest survival.

Response: We have no reason to believe that the analysis suggested by the commenter would result in a different distribution than the ones we used. As we noted in response to an earlier comment, with the large citrus markets throughout the United States, we have no reason to believe that our estimate of 5 percent (percentage of imported fruit that will be shipped to areas where citrus can survive) is too low or too high. Nor have we received any specific information from any commenter that would allow us to change our estimate. Further, we do not believe that human population density or shipping patterns for citrus fruit are relevant when one is considering whether or not an area provides a suitable habitat for an organism, as that suitability is more a function of climate and the availability of host material. The ability of an area to support a pest population exists regardless of the factors raised by the commenter.

Comment: The U.S. segment of the pathway is identical in the risk assessment for the baseline and the mitigation program. The probability distributions appear to be pure guesswork by APHIS (so far as can be evaluated from the documentation in the risk assessment and proposed rule). There is no indication of the potential infection routes that were considered, nor of the use of any data either on prior infections elsewhere in the world or (except to a minor extent for fruit flies) on the population biology of the pests themselves.

Response: There is no evidence, nor any reason to believe, that these diseases have ever been introduced by this pathway—*i.e.*, commercial shipment of citrus fruit—or a similar pathway anywhere in the world. Every scientific reference—and the known biology of these diseases—indicates that other pathways are responsible for introductions that have occurred. Because our risk assessment focused on the commercial shipment pathway, it did not consider other pathways such as the smuggling of plant material and nursery stock, which is by far considered the most likely pathway for introduction in all known introductions with uncertain cause. Our estimates resulted from our consideration of a variety of potential infection routes, such as consumers discarding rinds or whole fruit in compost heaps in the vicinity of citrus trees on their property, and rinds or fruit discarded in orchards. The scope of our risk assessment and consideration of potential infection routes are discussed in greater detail in our response to the next comment.

Comment: There are multiple potential pathways for pests to get into U.S. citrus areas or other areas of concern. Without documentation, it is impossible to evaluate whether APHIS has considered all of them in the risk assessment, and it is impossible to evaluate their relative importance. For example, citrus groves or backyard trees could be exposed to pests by a fruit or peel discarded by workers, trespassers, or passers-by; by peels placed in compost piles; by truck accidents scattering fruit; and by air dispersion of spores or contaminated material from ventilated trucks. Indeed, the probability of discarded fruit will be higher for sweet orange scab or citrus black spot infected fruit, since a consumer is more likely to discard fruit in which infection has become apparent. All these examples could readily be examined using event-tree modeling, using available data on consumption of raw fruit, human activity patterns, accident statistics, shipping statistics, and so forth. It should also be noted that most of the pathways by which infections might take hold in the United States are based on single fruit, not on boxes. Thus any quantitative risk assessment for these pathways would most readily (and possibly can only) be conducted on a ''per fruit'' basis, not on a ''per box'' basis.

Response: The purpose of the risk assessment, as stated in the first sentence of the risk assessment on p. 1, is ''* * * to examine plant pest risks associated with the importation into the United States of fresh citrus fruit grown in certain areas of Argentina.'' The document is a commodity-based risk assessment conducted to inform the decision of whether commercial citrus from Argentina should be enterable under a specific set of mitigation measures. It was not the purpose of the risk assessment to consider all the various pathways by which citrus pests could enter the United States. A plant pest risk assessment that considers all the different pathways by which a pest can enter an area, which is referred to as a pest-initiated risk assessment, would be the appropriate vehicle for conducting the types of analyses suggested by the commenter.

That being said, the possibility that citrus groves or backyard trees could be exposed to the pathogen via discarded fruit or peel was considered in our risk assessment (P7, Pathogen reaches suitable host). We concluded that it is highly unlikely that infected fruit producing viable pycnidiospores will ever reach the United States. If this did occur and the fruit or peel was thrown in a compost heap, even under a backyard citrus tree, it would be highly unlikely that fruit in the tree could become infected. The pycnidiospores are only waterborne and, therefore, can only infect fruit when the inoculum source is in direct contact with or physically close to fruit on the tree, or if there was fruit positioned beneath the inoculum source so that the spores could drip onto that lower-hanging fruit. This also would assume that the environmental conditions were favorable for infection and that fruit were susceptible. Realistically, it would be difficult to infect U.S. fruit, even if infected fruit was purposely placed in the tree canopy. In greenhouse inoculation studies conducted by an APHIS scientist, it was necessary to place fungal cultures of citrus black spot directly on susceptible fruit and to keep the inoculum and fruit moist for nearly 7 days. Even under these highly favorable conditions, not all inoculated fruit became infected. Thus, the likelihood of infection in the field, even by symptomatic fruit, is very low. Finally, we believe that our use of the box as the risk unit, as opposed to the individual fruit as the commenter suggests, is an appropriate choice. Retail boxes stay intact from the packinghouse until their point of final sale (*e.g.*, a supermarket), and it is reasonable to assume that most or all of the fruit in a box would be used, and the remains discarded, in the same general vicinity (*e.g.*, town, neighborhood) as the point of final sale.

Comment: For the U.S. segment of the pathway considered (including shipping), APHIS estimates the probability for citrus black spot outbreak to be about 10^{-9} per infected 18-kg box (0.83 0.05 $\times$ 0.005 $\times$ 0.000005), using the mean values for the distributions given in Table 9 of the risk assessment. The total U.S. consumption of fresh citrus fruit is about 25 lbs/person/yr, or 2.8×10^9 kg/yr, or 1.6×10^8 boxes/yr at 18 kg/box. Thus, APHIS is effectively suggesting that if the entire U.S. fresh citrus fruit supply were imported, and it was all infected at source (100 percent), the probability for a citrus black spot outbreak in the United States would be on the order of 0.16 per year. This is an unreasonable prediction, given the experiences elsewhere with citrus black spot infection. Note that the APHIS approach (on a ''per box'' basis) cannot apparently distinguish between 1 infected fruit per box, and 100 percent infected fruit in a box, whereas these clearly pose different risks.

Response: First, as explained in the response to the previous comment and elsewhere in this document, we believe that a box of fruit is an appropriate risk unit. Second, given the preponderance of evidence and expert opinion that long distance spread of *Guignardia citricarpa* via infected fruit is unlikely, and the dearth of documented cases of such spread, we believe that the probability calculated by the commenter is not unreasonable and our distributions, therefore, are appropriate. We offer the following citations from the scientific literature to support our conclusions:

- ''Ascocarps of the pathogen have never been found on fruit and the pycnidiospores are not airborne. Therefore, disease spread is unlikely through the movement of infected fruit.'' (Whiteside, J.O.; Garnsey, S.M.; Timmer, L.W. 1988. St. Paul, MN: American Phytopathological Society. 80 p.).
- ''The fungus can readily be carried on imported citrus fruits, but the risk of spread from these is relatively low.'' (Smith, I.M.; McNamara, D.G.; Scott, P.R.; Holderness, M.; Burger, B. 1997. *Quarantine Pests for Europe.* New York: CAB International. 1,425 p.).
- ''Fruit cannot rate high as an effective source of inoculum (pathway) in international trade. Ascospores have never been found on fruit, but pycnidiospores are produced that are not airborne.'' (Santacroce, N.G. 1982. ''Guignardia citricarpa Kiely.'' Hyattsville, MD: USDA, APHIS, BASS. 7 p.)

Comment: To provide a reliable risk assessment, APHIS must provide documentation according to the procedure of Kaplan (1992), which APHIS claims to have followed in preparing the risk assessment. First, this documentation must explicitly lay out the evidence upon which the probability distributions are based, including any disagreements between the experts. Second, it must show the reasoning leading from the evidence to the distributions. Third, APHIS should state the names of the experts involved, and the risk assessors involved. In several places throughout the risk assessment, there is confusion between the experts and the authors—or are they the same, and does this violate the spirit of Kaplan's approach? We suggest that if the experts and the risk assessors are the same people, then the spirit of Kaplan's approach requires a substantially larger effort to separately document the evidence and the line of reasoning taken in obtaining distributions from such evidence.

Response: The reliability of a risk assessment depends on the extent to which it accurately represents the actual risk. We agree, however, that it is important to document the basis of a risk assessment so that readers can make judgments about the validity of the information in the risk assessment. That is why we provided extensive information and references concerning the scientific information that formed the basis of our risk assessment. The information, scientific data, and evidence used to estimate the appropriate input values (distributions) was cited in the 162 scientific references, 13 regulatory references, and supporting documents cited in the risk assessment. Specifics about how this information was interpreted and used is provided in the discussions for each of the nodes in our model (sections 8.e. and 8.f.) and in the pest data sheets prepared for, and presented in, the risk assessment (Appendices I through VII). The three authors of the document are listed on the cover sheet. Tables 7 through 10 list the 72 node estimates used to conduct the Monte Carlo portion of the risk assessment. Each estimate consists of a distribution type and estimates for the distribution parameters. The exact list of experts used to estimate each of the 72 distributions varied from node to node. However, section IV of the risk assessment (''Preparation, Consultation and Review,'' pp. 58–59) lists the 21 experts (including the three authors) within and outside USDA who were consulted during production of the risk assessment. While the three authors did, in some cases, double as both risk assessors and experts, we believe that the review provided by the remaining 18 listed experts who were consulted, as well as the State regulatory personnel and others who reviewed the risk assessment in its draft form, preclude the lending of any undue weight to the opinions of the authors when it was necessary for them to act in both capacities.

Comment: The FAO ''Guidelines for Pest Risk Analysis'' provide that risk assessments must be well documented: ''A risk assessment [pest risk analysis] should be sufficiently documented so that when a review or a dispute arises, the risk assessment will clearly state the sources of information and the rationales used in reaching a management decision regarding phytosanitary measures taken or to be taken'' (FAO, International Standards for Phytosanitary Measures, adopted November 1995 by the 28th Session of the FAO Conference, p. 20). In contrast to the FAO requirements, however, the 1997 risk assessment does not disclose the sources of much of the data relied upon, the basis for a number of assumptions relied upon, nor the names of particular experts who were looked to for estimates that are used in the risk assessment.

Response: The commenter states that we did not disclose the sources of much of the data relied upon, but we believe that we thoroughly documented our sources of information in section III of the risk assessment (References) and in the references listed at the end of each of the pest data sheets provided as appendices.

The commenter states that we did not disclose the basis for a number of assumptions relied upon, but we did provide a narrative discussion of how we arrived at probabilities used in each of the nodes for each of the pests of concern (fruit flies and diseases). While the information we provided for each node may not have contained the level of detail that the commenter appears to believe would have been appropriate, we did attempt to describe how we arrived at each of our estimates in those discussions rather than simply reporting our estimates in table form. Additional information regarding the construction of our distributions is provided in the addendum to the risk assessment that may be obtained from the person listed under **FOR FURTHER INFORMATION CONTACT.**

The commenter states that we did not disclose the names of particular experts who were looked to for estimates that are used in the risk assessment, but section IV of the risk assessment (Preparation, Consultation, and Review) lists the names of each of the entomologists, botanists, plant pathologists, agriculturalists, plant virologists, and information specialists who participated in the preparation of the assessment, as well as the names of the APHIS and State personnel who were consulted during the preparation of the assessment and who reviewed drafts of the assessment. As can be seen by the Argentine citrus risk assessment and our previous risk assessments, it has not been our normal practice to explicitly tie individual experts to the estimates provided for specific nodes; we will, however, consider doing so in future risk assessments.

Comment: Variability represents known heterogeneity of a quantity. Uncertainty represents lack of knowledge about that quantity that could be better characterized with further research and/or measurement. Variability and uncertainty should be considered separately in a Monte Carlo risk assessment, so that one can identify the sources of the spread in the resulting distribution. A final risk distribution might be interpreted very differently if the source of most of the spread were uncertainty than if the source were true variability in the input parameters. The APHIS risk assessment focuses primarily on uncertainty, with a smaller emphasis on variability, but APHIS makes no distinction between the two in its risk assessment calculations. Moreover, APHIS seems to confuse the two when it states, ''Uncertainty in the estimated values may arise from natural variation over time, natural variation from place to place, data gaps or unconfirmed data, [and] relationships among multiple components in a node.'' Many of the distributions presented in the risk assessment are claimed to be uncertainty distributions for probabilities, but since the methods used to elicit these distributions are not specified, we cannot evaluate whether the distinctions between variability and uncertainty were maintained during the elicitation. The object of the risk assessment is not adequately specified with respect to variability and uncertainty, but the most logical interpretation would exclude year-to-year variability as being of great interest. However, such year-to-year variability is explicitly included in at least one distribution incorporated in the assessment.

Response: As noted in a recent paper published in the journal *Risk Analysis* (Gray *et al.,* 1998) and cited in response to a previous comment, [k]nowledge of variability must be based on empirical estimates, otherwise it is another source of uncertainty. With the exception of one or two nodes, data providing an estimate of ''variability (as it) represents known heterogeneity of a quantity'' do not exist for these parameters. Accounting separately for variability and other forms of uncertainty in this risk assessment would constitute overinterpretation of available data. Overinterpretation of available data would most likely lead to risk estimates that are less, rather than more, accurate.

Comment: APHIS states that the risk analysis computer software package @Risk for Excel (Palisade Corp., Newfield, NY) is used to run the Monte Carlo Analysis. However, APHIS does not state which version of this software was used, in what spreadsheet package, nor where to find technical details of the software that are necessary to critically evaluate the adequacy of this software for the assessment. The spreadsheet itself is not included in the risk assessment or in the rulemaking record. To ensure reproducibility of the analysis, APHIS should at least document which version of @Risk was used, and should provide a copy of the spreadsheet used for the analysis. We have reservations that even this is sufficient, since required technical details of @Risk are not publicly available. These include such important details as the algorithm used to generate (pseudo) random numbers. Other software packages with similar capabilities make technical details available.

Response: We used @Risk for Excel, version 3.5c, to run the analysis. We did not supply the ''required technical details of @Risk'' because we believed that sufficient information—*i.e.,* all the technical information the software company has chosen to make publicly available was provided in the @Risk documentation. We concluded that including the spreadsheets would provide no new information; the risk model (*i.e.,* the calculations used) is completely described and adequately represented in Figure 2 (p. 30) and section 8.b. (p. 28) of the risk assessment, and all input values used in all spreadsheets are completely specified in Tables 7 through 10. The spreadsheets themselves may be obtained from the person listed under **FOR FURTHER INFORMATION CONTACT.**

Comment: Although the primary focus of the risk assessment is, as it should be, on pests that affect or are present on Argentine citrus crops, the citrus fruit itself is not the only item that will be imported. The fruit will be packed in crates or boxes and shipped on pallets. The North American Plant Protection Organization (NAPPO) has recognized that a large percentage of wood dunnage or packing materials moving in international trade is composed of low quality, inexpensive wood products that may contain quarantine pests. The structure of the model used by APHIS does not allow problems such as this to be addressed in the risk assessment.

Response: APHIS recognizes the plant pest risk presented by solid wood packing materials and has separate regulations in 7 CFR 319.40–3(b) that address these risks. Further, on January 20, 1999, we published in the **Federal Register** (64 FR 3049–3052, Docket No. 98–057–1) an advance notice of proposed rulemaking soliciting public comment on how to amend our regulations on the importation of logs, lumber, and other unmanufactured wood articles to decrease the risk of solid wood packing material (*e.g.,* crates, dunnage, wooden spools, pallets, packing blocks) introducing exotic plant pests into the United States. We are currently reviewing the information received in response to that notice and are preparing a risk assessment and other documentation regarding the issue.

Comment: The eighth step in the risk assessment (pest able to complete its life cycle) is likely to be the most uncertain of all, certainly for the diseases, since so little is known of the population biology of these diseases. For fruit flies, APHIS clearly recognizes that a problem exists, but its attempt to take account of it (section 8.e. P8) is unfortunately incorrect and inadequate. It seems likely that a better incorporation of concepts from population biology would almost certainly change the model used in the risk assessment, at least for the final step(s).

Response: Much is known about the population biology of the diseases and fruit flies, and we believe that we took into account all the pertinent aspects of the known biology of these plant pests in our estimates for P8 for both the diseases and fruit flies. For the diseases, we considered the type of infective propagules produced by the pathogens and the environmental and physiological requirements for host plant susceptibility and successful disease progression. For fruit flies, we estimated the probability of an outbreak, per infested lot of fruit fly host material, for infested lots delivered to suitable habitats using data on the known number of *Anastrepha* outbreaks from 1990 through 1996 and estimates of the number of infested lots entering favorable habitats in the United States.

The paper that forms the basis of those estimates (Miller *et al.* 1996, cited in the risk assessment) was subjected to international review by scientists conducting research on the population biology of fruit flies. Thus, we believe that we did incorporate concepts from population biology in our estimates for P8 for each of the diseases and fruit flies, and do not believe that there are any pertinent aspects of the known biology of these plant pests that were not considered in the risk assessment.

Comment: The most difficult and least certain parts of the pathway (the U.S. segment) are common to the mitigated and unmitigated scenarios. It seems unlikely that incorporation of details of population biology would make as large a difference for diseases as it might for fruit flies, since it is unlikely that interactions between fungal spores or colonies are as substantial as between individual fruit flies. In such circumstances, it may be useful to perform a differential analysis of the risks for diseases that will isolate just the effects of the mitigation measures. In this case, a differential analysis would stop at the calculation of the probability for infected fruit to enter the United States, and so emphasize the relative effect of the mitigation measures. This procedure has the effect of removing the substantial uncertainties in the rest of the pathway from consideration, since such uncertainties would be common to both mitigated and unmitigated scenarios (unless, for some reason, there were correlations connecting the Argentine and U.S. segments of the pathways).

Response: Separate analyses were performed for the fruit flies and the diseases. International guidelines, and APHIS interests, dictate that the likelihood estimate of primary interest is the likelihood of introduction, not the likelihood of entry. Nonetheless, it is possible to calculate our estimates for the likelihood of entry using the information provided in the risk assessment. Estimates for the likelihood of entry could be obtained by using P5 as the endpoint of the simulation and the values provided in Tables 7 through 10. Regarding the issue of a differential analysis, it is not clear how conducting a differential analysis to emphasize the relative effect of the mitigation measures would aid APHIS' decisionmaking process. We must consider the risk posed by the entire pathway. The decision of whether to proceed with the rulemaking process is based on the risk presented by the entire pathway.

Comment: In the current assessment, the known total mitigation effect for citrus black spot (ratio of infection rates for fruit at the U.S. in the unmitigated versus mitigated scenarios) is controlled solely by the effect of the copper oxychloride treatment, and might amount to a factor of 50 to 200-fold under the conditions of the experiments available in the record. No evidence has been presented in the record for any mitigating effect of the other proposed steps, and there is evidence indicating a lack of effect for the post-harvest treatments. The full system tests are entirely consistent with such minimal effects, given the detection limits of those tests. Moreover, there is no evidence that good results could be achieved consistently over time, with fruit from different areas, with grapefruit, or with different varieties of lemons and oranges. This minimal and relatively unproved mitigation effect might be compared with the much higher and well-proved 30,000-fold (probit 9) mitigation effect afforded against fruit flies by cold treatment, although the absolute probability for subsequent infection in the United States must also be taken into account.

Response: It is not true, as stated by the commenter that ''the known total mitigation effect for citrus black spot (ratio of infection rates for fruit at the U.S. in the unmitigated versus mitigated scenarios) is controlled solely by the effect of the copper oxychloride treatment.'' Although the copper oxychloride treatment is the primary risk mitigation measure against citrus black spot, other measures that will have a mitigating effect on citrus black spot were identified and discussed in the risk assessment; these measures are required by this rule and thus will be applied consistently over time. Specifically, the removal of debris prior to bloom is also an effective mitigation measure in that it reduces inoculum present in the grove. Additionally, the harvest and packinghouse culling reduces the likelihood that diseased, symptomatic fruit will be shipped. It is correct that the post-harvest treatments have little effect on citrus black spot. With the inclusion of the 20-day preharvest incubation to detect latent infection, whereby observation of a single infected fruit will remove the entire grove from the export program for the entire year, the overall systems approach results in a substantial risk reduction. Our estimates of the risk reduction afforded by all these measures, and our use of supporting data and expert judgment in arriving at those estimates, are set forth in the risk assessment.

The commenter concludes by contrasting the 30,000-fold mitigating effect of cold treatment for fruit flies with the smaller (50- to 200-fold) effect of the mitigating measures for citrus black spot. Taken on its face, this comparison would seem to indicate that the mitigating measures for citrus black spot leave something to be desired in terms of their ability to reduce the risk presented by that disease. However, as is clearly presented in table 11 of the risk assessment, the baseline (unmitigated) risk presented by citrus black spot is far lower than that presented by fruit flies (in the mean, 1 chance in 28,653 for citrus black spot versus 1 chance in 7.4 for fruit flies). Thus, even with the comparatively more modest mitigating effect of the citrus black spot measures, the risk estimated for citrus black spot in the mitigated scenario is still lower than that estimated for fruit flies (in the mean, 1 chance in 3.2 million for citrus black spot versus 1 chance in 350,000 for fruit flies).

Comment: APHIS does not have guidelines for performing quantitative pest risk assessments. While such guidelines can, in many cases, be restrictive and prevent development of better approaches, they can also serve a useful purpose by preventing common errors. In view of the myriad problems with the risk assessment, APHIS should consider developing quantitative guidelines, in consultation with experts in probabilistic risk assessment, to prevent similar problems in future quantitative assessments.

Response: APHIS has published very specific guidelines for qualitative plant pest risk assessments (USDA 1995, ''Pathway-Initiated Pest Risk Assessment: Guidelines for Qualitative Assessments, version 4.0,'' USDA–APHIS–PPQ, Riverdale, MD). The only difference between the methods described in that document and our probabilistic assessments is section 8, where we estimate the likelihood of introduction. APHIS has not published a separate document describing the methods it uses to estimate the likelihood of introduction when using probabilistic methods. Although our methods have evolved slightly with each probabilistic assessment as we obtain comments, our methods have remained fairly consistent and clearly illustrated. Additionally, the methods we used in the present risk assessment are clear. Our process was created in consultation with world leaders in the field of probabilistic risk assessment, and our process has indeed been subjected to extensive peer review by experts in probabilistic risk assessment. Subsequent reviews by experts have been very favorable and have led to several improvements in our process.

Although improvements will be made following the present risk assessment, we have not been made aware of any significant errors that require significant changes in our methods.

Risk Assessment—''Principles of Good Practice''

The following comments were generated by a commenter who evaluated the risk assessment against 14 principles of good practice for Monte Carlo risk assessment outlined by Burmaster and Anderson (1944). APHIS is familiar with this publication, has referred to it often, and has used it along with other similar works as a guide when conducting probabilistic risk assessments. However, this particular work represents only one set of suggestions and does not represent an ''industry standard.'' Despite that, as indicated in the individual responses below, our methods are consistent with many of the suggestions listed by the commenter. Below, we have presented each principle and the accompanying critique provided by the commenter, and each is followed by APHIS' response. Further, as discussed in the introductory note to the previous section of this document (''Risk Analysis''), additional documentation regarding the information or data used as the basis for the risk assessment's conclusions is contained in an addendum to the risk assessment that may be obtained from the person listed under **FOR FURTHER INFORMATION CONTACT**.

Show all formulas used in the risk assessment. We do not agree with the structure of the model used in the risk assessment. However, the only formula used in the APHIS risk assessment is the simple multiplicative formula used to calculate the likelihood of pest establishment. This formula is simple and, while not presented algebraically, is presented in Figure 2 and adequately described in the text. However, Figure 2 is illegible, even in the electronic version of the report available on the Internet, due to the extremely low resolution of the image file. No better copy is available anywhere in the risk assessment or in the rulemaking record.

Response: As indicated by the commenter, our risk assessment is quite transparent. We explained in extensive detail how we conducted our risk assessment, and we and our peer reviewers have found the structure of our model to be appropriate and correct. We apologize if the commenter had difficulty downloading material from our web site and we would be happy to provide additional copies of our model. APHIS regularly supplies paper copies of the risk assessment to anyone requesting a copy.

Calculate and present point estimates of risk. APHIS does not calculate a point estimate of the risk of infestation; however, this principle is not necessarily applicable to a plant pest risk assessment. In a human health risk assessment, such a point estimate provides a point of comparison for the results of the Monte Carlo analysis with standard analyses that are familiar. In a plant pest risk assessment, a point estimate would be somewhat less useful since quantitative point estimates are as unfamiliar as probabilistic estimates, and so may not be necessary.

Response: We agree with the commenter's sense that point estimates are not a necessary element of a plant pest risk assessment, which is why we did not calculate a point estimate of the risk of infestation.

Present the results from sensitivity analyses to identify inputs suitable for probabilistic treatment. APHIS does not perform sensitivity analyses or analyze inputs to determine how given variables affect the predicted risk. As mentioned previously, many of the distributions used in the risk assessment are not based on measured data. A sensitivity analysis could be used to help focus data collection on the most important variables. Additionally, such an analysis could identify variables that drive the risk assessment in two senses: (1) Variables that account for the magnitude of the predicted risks and (2) variables that account for the range of the predicted risks. Understanding which variables drive the resulting risk distribution in these two senses is key to interpreting the results of the risk assessment and focusing future research.

Response: We did perform sensitivity analyses as part of the final step of the probabilistic analysis of the proposed mitigation program; as the earlier steps in the risk assessment were not probabilistic, sensitivity analyses were not performed on those earlier steps. Further, because sensitivity analyses are not particularly useful with a simple, linear, multiplicative model of the type used in the risk assessment, they were not discussed in the risk assessment. If the commenter is interested, our sensitivity analyses are part of the documentation contained in the supplemental information that is available from the person listed under **FOR FURTHER INFORMATION CONTACT**.

The commenter suggests that sensitivity analysis could be used to help focus data collection on the most important variables, but that was not the purpose of the risk assessment. Rather, the purpose of the risk assessment was to estimate the risk associated with a particular proposed program, and not to aid in the design of a new program.

The commenter also suggests that: ''Additionally, such an analysis could identify variables that drive the risk assessment in two senses: (1) Variables that account for the magnitude of the predicted risks and (2) variables that account for the range of the predicted risks. Understanding which variables drive the resulting risk distribution in these two senses is key to interpreting the results of the risk assessment and focusing future research.'' Regarding item (1), the risk assessment discusses mitigations that reduce risk, and it provides estimates of the likelihood of pest introduction with and without the system of risk mitigations. The various input parameters do not represent sources of risk per se, they represent events that must occur before a pest can be introduced; some of them represent specific risk mitigations (*e.g.,* P5, cold treatment for fruit flies), not sources of risk, while others reflect the biology of the organism and are not sources of risk (*e.g.,* P7, pest locates suitable host). The sources of risk are identified in the hazard identification section of the assessment (Sections 4–6).

Regarding item (2), the sensitivity analyses we conducted do in a sense identify ''variables that account for the range of the predicted risks,'' but the commenter's wording does not reflect the purpose, outcome, or use of the risk assessment. The risk assessment does not deal with a ''range of predicted risks.'' The probabilistic portion of the risk assessment estimates, for four separate pests, the likelihood of introduction given importations with no specific risk mitigations (the baseline scenario) and with a specific set of mitigations (the proposed program). However, our sensitivity analyses do indeed identify those variables that account for the largest amount of uncertainty in the output (the estimated likelihood of pest introduction). As noted earlier, with the type of model used in the risk assessment (*i.e.,* simple, linear, and multiplicative), that information can be obtained by examination of the input parameters (Tables 7–10).

Restrict the use of probabilistic techniques to issues of regulatory importance. The APHIS risk assessment is restricted to the issue of regulatory importance, *i.e.,* the likelihood that exotic pests imported with Argentine produce will establish themselves in the United States. There are few enough parameters in the model that probabilistic techniques can be used on all. A more realistic model (*e.g.* including failure modes and correlations) might, however, be too complex for such an approach (particularly using the chosen software).

Response: We agree that our model is appropriate to the task at hand. We disagree that a more complex model would necessarily be more realistic; thus, we see no reason to needlessly complicate our model.

Provide detailed information on the input distributions selected. APHIS presents the parameters necessary to characterize the distributions used in the risk assessment. It also, and unnecessarily, presents the mean, mode, standard deviation, 5th percentile, and 95th percentile of most distributions, at great length and repetitively in the text. This allows an informed reader to reproduce the calculations. APHIS, however, provides very little additional information about the distributions it selected. It presents no graphs of the distributions used in the assessment. Very little justification is provided for the choice of distributions in the report beyond ''expert judgment,'' so that even knowledgeable persons cannot reproduce the full analysis. For some distributions, APHIS identifies data that can be used to support the distribution (such as for sweet orange scab incidence), but offers no justification for the type of distribution selected and no description of how the data are used to construct the distribution.

Response: We agree that the information we provided was sufficient to allow an informed reader to reproduce our calculations. We did not present graphs for a variety of reasons, not the least of which is that graphs would be redundant. However, an informed reader could produce graphs of our distributions using the information provided in the risk assessment. We believe we included sufficient information about the generation of our input distributions in the narrative descriptions that are provided in the risk assessment for each of the input values (F1, P1 through P8) used in our likelihood model. If the commenter is interested, expanded explanations regarding our selection of input distributions are part of the documentation contained in the supplemental information that is available from the person listed under **FOR FURTHER INFORMATION CONTACT.**

Show how the input distributions capture and represent both the variability and the uncertainty in input variables. APHIS makes no effort to distinguish between variability and uncertainty, and offers no discussion of their separate contributions to the results of the analysis. The roles played by uncertainty and variability in the risk assessment depend on the goal of the analysis. If the goal of the analysis is to estimate a distribution for the average annual likelihood that an infestation will occur in the United States, uncertainty will play a larger role in the analysis than variability. Year-to-year variability may be intentionally ignored in the analysis because the analysis would not be focusing on variations in the likelihood of an infestation from year to year. If, instead, the goal of the analysis is to generate a distribution of the likelihood that each box of fruit will cause an infestation, year-to-year variability may play a much larger role. The goal of the analysis should be more clearly defined, and APHIS should include a discussion of the roles of uncertainty and variability in the analysis.

Response: The approach suggested here is relatively new and is appropriate only in certain situations. In other situations, such as the present risk assessment, it is not clear that better results would be obtained. In fact, using this approach would require a significant overinterpretation of available data and would most likely lead to risk estimates that are less, rather than more, accurate. When making a decision about whether to allow importation of a particular commodity, whether uncertainty in the estimate results from variability or other forms of uncertainty may not matter. The primary consideration is the value of the risk, not the shape of the output distribution.

The purpose of our analysis is closer to the first of the possible goals suggested by the commenter (''to estimate a distribution for the average annual likelihood that an infestation in the United States'') than it is to the second (''to generate a distribution of the likelihood that each box of fruit will cause an infestation''). Specifically, in section 8 of the risk assessment, we state: ''The purpose of a probabilistic risk assessment is to estimate the likelihood of an undesirable outcome (bad event). The bad event is represented by the endpoint of the risk model, *i.e.,* introduction of a quarantine pest.''

Use measured data to inform the choice of input distributions whenever possible. As noted above, most of APHIS's distributions are based on expert judgment. The risk assessment includes little discussion of the reasoning behind the selection of distribution type and the parameters used to characterize the distributions. In some cases, APHIS identifies available data, but it is not clear how these data are used in the construction of the distribution.

Response: We did, in fact, use measured data whenever possible to inform our choice of input distributions when preparing the risk assessment. Ideally, existing data would provide the basis for direct estimation of model inputs; however, when conducting probabilistic assessments to inform decisions regarding importation of agricultural commodities, scientific experiments have not, except in rare cases, been conducted that provide data that represent ''direct evidence'' for risk assessments. In fact, results are seldom provided that can even be used as indirect model inputs. As we made clear in the risk assessment, all available data were reviewed and professional judgment then used to represent the available information. Because most of our commodity risk assessments are conducted to support decisions that must be made within relatively narrow time frames, research programs can seldom be designed and conducted to provide data specifically for the assessments (although in the present case, the United States required Argentina to design and conduct additional experiments that were completed before completion of the risk assessment). Beyond directly applicable measured data, USDA bases the estimates needed for its probabilistic commodity risk assessments on pest interception records, the known biology of the organism being assessed (or the known biology of related taxa) as represented in the scientific literature, expert judgment based on laboratory experience with the pest or related organisms, expert judgment based on field experience with the pest or related organisms, expert judgment based on experience conducting commodity inspections at ports of entry or in the exporting country, and experience working with export programs and export-quality commodities.

Discuss the methods and report the goodness-of-fit statistics for any parametric distributions that were fit quantitatively to measured data. It is not clear from the text of the report whether APHIS actually fits distributions to any real data. No goodness-of-fit statistics are reported in the assessment. There is no discussion of any relation between the cited experts' estimates of minimum, maximum, and mode, and the parameters of the distributions, nor is such a relation self-evident. If the data fitting algorithms in @Risk were used to fit distributions to data, the procedure should be clearly described in the text.

Response: The only situation where goodness-of-fit statistics are appropriate was for the distribution used to characterize fruit fly survival with the cold treatment. We did not conduct goodness-of-fit tests because they were completed as part of the scientific research conducted during establishment of the treatment protocol.

Discuss the presence or absence of moderate to strong correlations between input variables. The APHIS report assumes that each of the eight steps in the model is independent from all other steps. It is unlikely that the eight steps are truly independent. Whether or not strong correlations exist, APHIS should discuss the possibility that correlations exist and estimate the effects of such correlations on the results of the analysis.

Response: We did consider the possibility of correlations among the various nodes. As we reported in the risk assessment, we are confident that the nodes are independent, given the model and values used. Our analyses detected no correlations. Our conclusion that the nodes are independent resulted from both prior and ad hoc considerations, as well as model outputs.

Provide detailed information and a graph for each output distribution. APHIS presents the mode, median, mean, and 95th percentile of the output distributions for each pest under the baseline import program and assuming the presence of a pest mitigation program. APHIS does not provide a graph for any of the output distributions.

Response: We have frequently considered whether we should include graphical representations of our output distributions. We have repeatedly reached the conclusion that it is neither necessary nor important to do so. In fact, we believe it could serve to obscure our findings.

Perform probabilistic sensitivity analyses for all key inputs to distinguish the effects of variability from the effects of uncertainty in the inputs. APHIS does not perform any sensitivity analyses to identify the inputs with the greatest contributions to the output distribution. As discussed previously, APHIS makes no attempt to distinguish the effects of variability from those of uncertainty.

Response: We always conduct sensitivity analyses as part of our probabilistic risk modeling, and did so for the Argentine citrus risk assessment; contrary to the commenter's assertion, those analyses did indeed indicate those inputs that contributed the greatest amount of uncertainty to the output. (Those analyses are part of the documentation contained in the supplemental information that is available from the person listed under **FOR FURTHER INFORMATION CONTACT.**) A sensitivity analysis addresses the relationship between variation in the input parameters and variation in the output. Specifically, the analysis quantifies the degree of correlation between variation in individual input parameters and the output parameter. The value of these coefficients does not, however, indicate the amount of uncertainty in an input parameter. Because of the type of model we used (*i.e.,* simple, linear, and multiplicative), the values represent the magnitude of the uncertainty (as represented by the standard deviation of the input distribution) relative to the mean of the input distribution.

The commenter suggest that sensitivity analysis can be used to distinguish the effects of variability from the effects of uncertainty in the inputs, but we do not believe that is possible. When data are available to allow analysts to distinguish variability from other sources of uncertainty, variability and other forms of uncertainty can be accounted for, and modeled, separately. This is accomplished by having separate inputs for variability and other forms of uncertainty in the input parameters. However, in this particular case (as in the majority of probabilistic risk assessments), the available information did not allow us to model variability separately from other sources of uncertainty. A sensitivity analysis cannot change this fact and cannot provide us with the ability to distinguish the effects of variability from the effects of other sources of uncertainty.

In a simple, linear, multiplicative model of the type used in the Argentine citrus assessment, the sensitivity analysis reflects little more than the ''coefficient of variation'' of the input parameters. The coefficient of variation is obtained by dividing the standard deviation of the distribution by the mean. Parameters with relatively large amounts of variation relative to their mean will have a relatively high ''sensitivity coefficient'' and will have a ''larger impact'' on the output. Another way of stating this is that the output is most sensitive to those input parameters about which the experts were most uncertain. Thus, with this type of model, the sensitivity analysis reflects uncertainty in the input parameters. Tables 7 through 10 reveal those parameters about which the experts were most uncertain (P1, P5, P6, P7, P8, depending on pest and scenario); thus these are the parameters that had the ''biggest impact'' on the output. The values for both the standard deviation and the mean were provided in the tables of input values (Tables 7 through 10), so the information necessary to obtain the coefficient of variation was available in the risk assessment. As the sensitivity analysis provides information that is already available in Tables 7 through 10, we believed that little if any additional information would have been provided by reporting the sensitivity analysis in the risk assessment.

Regarding distinguishing the effects of variability and uncertainty, as stated above, we have not encountered many situations where we had sufficient, directly applicable data to provide separate estimates for variability and other forms of uncertainty. Thus, to conduct such an analysis would constitute overinterpretation of available data.

Investigate the numerical stability of the output distribution. APHIS does not investigate the numerical stability of either the central moments of the output distribution (such as the mean and standard deviation) or the tails of the output distribution. Additionally, APHIS provides no discussion of the sensitivity of the upper tails of the output distribution to the tails of the input distributions. One option for investigating the numerical stability of the output distribution is to calculate the uncertainty for the mean and the 5th and 95th percentiles of the distribution. A second option would be to perform a larger run (*e.g.*, 50,000 iterations instead of 10,000) and to compare the distributions.

Response: The @Risk software we used automatically monitors convergence ''to help monitor the stability of the output distributions created during a simulation'' (@Risk software documentation: *@Risk Advanced Risk Analysis for Spreadsheets,* 1997, Palisade Corporation, Newfield, NY). That documentation states that the statistics monitored on each output distribution are the average percent change in percentile values (0 to 100 percent, in 5 percent steps), the mean, and the standard deviation. Thus, we monitored the stability during all simulations. Although @Risk simulations can be run with an ''automatic shutoff'' option that is triggered when the output distribution has reached stability, and despite the fact that the distributions reached stability before completing all 10,000 iterations, we completed 10,000 iterations on each simulation. Prior to conducting the Argentine citrus assessment, APHIS conducted informal investigations of the number of simulations needed to reach stability with our simple, linear, multiplicative models. We found that in some cases that running 1,000 iterations was not sufficient to reach stability, so we increased the number of iterations in our simulations to 10,000. In the Argentine citrus risk assessment, 10,000 iterations was found to be sufficient to reach stability.

While considering out response to this comment, we re-ran our simulations with 10,000 iterations (as done in the assessment) and then with 50,000 iterations as suggested by the commenter. We used the same random number generator seed. Results were the same with 10,000 iterations and not significantly different with 50,000 iterations. For example, with the fruit fly program (as opposed to baseline) simulation, the 95th percentile value with 10,000 iterations was 1.07×10^{-5} (0.0000107) and with 50,000 iterations the 95th percentile value was 1.08×10^{-5} (0.0000108). Another example with the same simulation is for the 90th percentile value, the value with 10,000 iterations was 5.80×10^{-6} (0.00000580) and with 50,000 iterations was 5.61×10^{-6} (0.00000561); thus, the 90th percentile value (part of the upper tail) was lower (less risk) with more iterations. Because the 90th and 95th percentile values can be considered representative of the upper tail (upper estimate for the likelihood of pest introduction), we offer this as an indication of the stability of the upper tail. The purpose of conducting a probabilistic assessment is to try a range of values to see how the output changes. When the experts constructed the input distributions, all necessary uncertainty regarding the inputs was captured and the simulations included calculations based on the upper tails of all nine distributions.

Present the name and statistical quality of the random number generator used. APHIS does not present any information about the random number generator used for the risk assessment. We assume that the random number generator provided with @Risk was used in the assessment, but as mentioned previously, the version of @Risk that was used in the assessment is not specified. Even if this was the random number generator used, more information should be provided, such that a reader of the risk assessment could determine the quality of the random number generator without purchasing @Risk.

Response: In section 8.d of the risk assessment, we stated that ''a computer program randomly selects a value from each of the input probability distributions. * * * We use the risk analysis computer software package @Risk for Excel (Palisade Corp., Newfield, NY, USA) to run our simulations.'' As noted previously, we used version 3.5c of that program. We did not supply additional information regarding @Risk's random number generator because we concluded that sufficient information was provided in the @Risk documentation.

Discuss the limitations of the methods and the interpretation of the results. APHIS offers neither a discussion of the limitations of the methods used in the risk assessment nor an interpretation of the results. APHIS does not acknowledge any sources of bias in the risk assessment and does not discuss how additional research or measurements might be able to improve the analysis.

Response: The purpose of our risk assessment was to inform a decision regarding the enterability of commercial citrus from Argentina under a specific risk mitigation program. We improve our risk assessment process as needed, and it was not our purpose to discuss the evolution of our risk assessment process as part of this or any other plant pest risk assessment. An interpretation of our results and specific recommendations are provided on p. 48 in the section titled ''Conclusion: Pest Risk Potential and Phytosanitary Measures.'' In that section we stated that without mitigations, there is a high likelihood that one or more of the analyzed pests will be introduced. Regarding the proposed risk mitigation measures, we state that ''an appropriate level of protection from introduction of plant pests with shipments of commercial citrus from Argentina requires strict adherence to risk mitigation measures such as those analyzed in this assessment,'' *i.e.*, the proposed risk mitigation measures provide an appropriate level of protection. With regard to the commenter's statement regarding a discussion of the ability of additional research or measurement to improve the risk assessment, it is the very nature of risk assessment to deal with incomplete information—otherwise, the risk assessment would be rendered unnecessary. We believe that the available information is sufficient to support the efficacy of the measures required by this rule and our analysis of the risks associated with Argentine citrus.

Economic and Other Analyses

Comment: The proposed rule's economic analysis states that Argentine citrus would enter the U.S. market at a time when few lemons are produced by U.S. growers. This is not true. The California lemon industry has invested heavily in developing specialized lemon trees that are harvested year round. Moreover, although the peak of the California harvest comes from March to June, the fruit is capable of being stored for 90 to 120 days without loss of color, flavor, or quality. Hence, the great majority of California lemons are sold into the summer marketplace at the very time Argentina intends to export fruit.

Response: The proposed rule's economic analysis was not focused on lemon production alone, as the commenter suggests. Rather, our consideration of the domestic citrus market was more general. Specifically, we stated in the proposed rule that ''* * * domestic shipments of citrus fruit are at their lowest during the months of July, August, and September, dropping to approximately 3.5 to 5 percent of average annual shipments * * *. Since the peak production period for citrus in Argentina is from May to October, the entry of Argentine fresh citrus fruits would likely peak during these months, which represent the most likely window of opportunity for Argentine imports to enter the U.S. market * * *. Importers and brokers would likely benefit from the entry of Argentine citrus fruit into the U.S. market because they would be able to provide quality fruits during the months when domestic production is lowest.'' That discussion in the proposed rule was intended to illustrate the complementary nature of production in the northern and southern hemispheres, and not to discount the potential presence of domestically produced fruit in the marketplace.

Comment: The economic analysis prepared for the proposed rule provides an inaccurate representation of the potential economic effects of imported Argentine citrus by: (1) Assuming that oranges, grapefruit and lemons are in the same product market, *i.e.,* that they are perfect substitutes in both production and consumption and that a pound of imported oranges has the same impact on lemon prices as does a pound of imported lemons; (2) asserting that there is very little U.S. citrus production during the summer months when most Argentine exports occur and that few U.S. citrus producers would, therefore, be affected; (3) assuming that the composition of citrus imports (oranges, grapefruit, or lemons) does not alter the impact of imports; (4) ignoring the multiplier effects of fresh citrus sales; and (5) assuming that marketing margins are constant and that price changes at the producer and wholesale levels are transmitted immediately to the retail level.

Response: The commenter's statements numbered 1, 3, 4, and 5 are addressed in our final economic analysis set forth in this final rule under the heading ''Executive Order 12866 and Regulatory Flexibility Act.'' With regard to point number 2, we noted in the response to the previous comment that our economic analysis did not discount the presence of domestically grown fruit in the marketplace during the summer months. Rather, we stated that because Argentina exports most of its fresh fruit during the summer months, those imports would not compete with the peak production season in the United States (late fall, winter, and early spring), which would limit—not eliminate—the impact on U.S. producers, exporters, and importers of citrus. In several places, including both the introduction and conclusion of our analysis, we explicitly recognized that the magnitude of the economic effect of Argentine citrus would depend on the additional Argentine supply, the U.S. supply and demand for citrus, and price conditions in the rest of the world, and concluded that the larger the share of Argentine imports, relative to U.S. domestic supply, the larger the U.S. producer losses and the larger the U.S. consumer gains. We did not, as the commenter suggests, assert that only a few U.S. producers would be affected by Argentine citrus imports.

Comment: The economic analysis prepared for the proposed rule fails to recognize that the growth in Argentine citrus exports has been and will continue to be concentrated in fresh lemons and that there are significant amounts of lemons now being processed that could be diverted to the fresh export market, since the price paid for lemons for processing is usually much lower than for fresh use. There is, therefore, the potential that fresh lemon imports from Argentina during the summer months could likely range from 40 to 100 million pounds, and not the 10 to 50 million pounds examined in the analysis.

Response: The economic analysis did recognize the growth in Argentine citrus production and, since that growth is predominantly in the lemon sector, implicitly recognized the concentration on fresh lemons noted by the commenter. Indeed, it was the growth in Argentine citrus production levels that served as the basis for our estimates of potential imports of Argentine citrus into the United States, as we expect that Argentina will maintain its well-established export markets in Europe, given the substantial investment that they have made to cultivate those markets and the inadvisability of developing a heavy dependence on a single market such as the United States. With regard to the diversion of lemons from the processing market to the fresh market, we acknowledge that fresh lemons bring higher prices than lemons for processing, but one must also consider that the costs of production will be higher for those groves producing fresh lemons for the U.S. export market in light of this rule's requirements for additional phytosanitary measures during the growing and packing process and the costs of transporting fresh lemons versus the costs of transporting concentrated lemon juice and essential oils. With these considerations in mind, we do not believe that a significant diversion of lemons from the processing market to the fresh market is likely.

Comment: Section 603 of the Regulatory Flexibility Act requires agencies to prepare and make available for comment an initial regulatory flexibility analysis in connection with any proposed rule. The purpose of the analysis is to assess the impact of the proposed rule on small entities. While APHIS correctly recognizes that 96 percent of U.S. citrus fruit farms are small entities, it nonetheless states that ''this action would not have a significant economic impact on a substantial number of small entities.'' We do not understand how APHIS could conclude that the approval of citrus imports, some of which will be in direct competition with domestic growers, would not have a significant economic impact on a significant number of those small growers. Thus, APHIS must prepare the analysis required by 5 U.S.C. 603, including the preparation of an analysis of significant alternatives. Even if APHIS concludes that no significant alternative exists which can accomplish the stated objectives and minimize the impact on small growers, this discussion must still be set forth in the proposed rule.

Response: In the economic analysis provided in the proposed rule, we identified 17,898 farms producing citrus in the United States and stated that 96 percent (17,182) of those farms were small entities with gross sales of less than $500,000. The remaining 4 percent (716) of those farms had gross sales of more than $500,000 and thus were not considered small entities under the applicable Small Business Administration criteria. In the scenario we examined in which 50 million pounds of Argentine citrus entered the United States (the largest import volume of the five scenarios considered), we stated that the expected loss to producers would be $36.674 million. When spread evenly across the 17,898 producers identified, that would amount to a loss of $2,049 per farm. However, we also noted in our analysis that the 4 percent of producers who are not small entities owned 66 percent of the total citrus-growing acreage. If the expected losses are weighted to the relative shares of citrus-producing acreage, the 17,182 small entities could expect to bear a collective loss of $12,469,160 (*i.e.,* $36.674 million multiplied by 0.34), which amounts to $726 per small farm. Under section 605(b) of the Regulatory Flexibility Act, the requirements of section 603 do not apply to any proposed or final rule if the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. Thus, our statement in the proposed rule that ''this action would not have a significant economic impact on a substantial number of small entities'' was the Administrator's certification of this minimal effect, as required by section 605(b).

Comment: There is no evidence in the proposed rule that APHIS prepared an environmental impact assessment of the rule, which should have been prepared in order for APHIS to comply with the requirements of the National Environmental Policy Act (NEPA). APHIS' NEPA implementing regulations in 7 CFR 372.5(b)(1) require the preparation of such a report. If either the Medfly, various species of *Anastrepha*, or possibly other pests were to enter the United States via Argentine fruit and become established, a significant, and perhaps widespread spraying program would be required. We submit that APHIS is obligated to consider this possibility, and prepare, at a minimum, an environmental impact assessment if such an event were to occur.

Response: For the proposed rule, those issues were considered in the risk assessment in section 7 (Consequences of Introduction: Economic/Environmental Importance) of chapter II (Risk Assessment). An environmental assessment was not prepared for the proposed rule because APHIS previously decided, in accordance with our NEPA implementing regulations in 7 CFR 372.5(c), to classify future amendments to 7 CFR part 319 as categorically excluded actions not requiring the preparation of an environmental assessment. However, in December 1998, following the publication of the proposed rule, our review and consideration of the comments that had been received by that time led us to prepare an environmental assessment that addresses the concerns raised by the commenter. That environmental assessment, as well as a finding of no significant impact based on the information presented in the environmental assessment, may be obtained by contacting the person listed under **FOR FURTHER INFORMATION CONTACT.**

Comment: APHIS has failed to prepare a civil rights impact analysis to analyze the impact of the proposed rule, if adopted, on various minority groups. The potential for the rule to lead to a significant loss of jobs for one or more ethnic groups must be considered.

Response: We did in fact prepare a civil rights impact assessment for the proposed rule. It may be obtained by contacting the person listed under **FOR FURTHER INFORMATION CONTACT.**

Miscellaneous

In addition to the changes discussed previously in this document, we are also amending two other sections of the fruits and vegetables regulations to correct outdated and erroneous references to several sections of the regulations, including § 319.56–2f, which will be the location of this rule's provisions regarding the importation of grapefruit, lemons, and oranges from Argentina.

Specifically, paragraph (e) of § 319.56a, ''Administrative instructions and interpretation relating to entry into Guam of fruits and vegetables under § 319.56,'' refers to ''the provisions of §§ 319.56–2d and 319.56–2f to 319.56–2m, inclusive,'' but all of those sections, with the exception of § 319.56–2d, have been removed or redesignated since the time the regulations in § 319.56a became effective in 1959. Therefore, we are amending § 319.56a(e) so that it accurately reflects the locations of those remaining sections of the regulations to which it originally referred.

Similarly, we are amending § 319.56–2i to remove a reference to § 319.56–2f that dates back to when that section contained provisions regarding the importation of Manila mangoes from Mexico. In 1995, § 319.56–2f was removed and reserved and its provisions regarding the importation of oranges, grapefruit, and mangoes from Mexico were integrated into the table contained in § 319.56–2x. Section 319.56–2i should have been amended at that time to reflect the removal of § 319.56–2f, but was not. Further, the inclusion of mangoes from Mexico on the list of commodities in § 319.56–2x that may be imported subject to treatment in accordance with the PPQ Treatment Manual means that it is no longer necessary to include provisions regarding Mexican mangoes in § 319.56–2i. Therefore, we are amending § 319.56–2i by removing the reference to Mexico from the title of the section, eliminating paragraph (a)(2), and removing the reference to § 319.56–2f from paragraph (b).

Therefore, for the reasons set forth in the proposed rule and in this document, we are adopting the provisions of the proposal as a final rule with the changes discussed in this document.

Effective Date

This is a substantive rule that relieves restrictions and, pursuant to the provisions of 5 U.S.C. 553, may be made effective less than 30 days after publication in the **Federal Register**.

Argentina has demonstrated in accordance with international standards that the citrus-growing areas of the States of Catamarca, Jujuy, Salta, and Tucuman are free from citrus canker. Further, we believe that the phytosanitary requirements contained in this rule to prevent the introduction of other plant pests will reduce the risks posed by the importation of grapefruit, lemons, and oranges to a negligible level. Given these considerations, we believe that it is no longer necessary to prohibit the importation of grapefruit, lemons, and oranges from Argentina.

Immediate implementation of this rule is necessary to provide relief to those persons who are adversely affected by restrictions we no longer find warranted. This rule requires that certain measures be taken in order for grapefruit, lemons, and oranges to be imported into the continental United States, including measures that must be applied early in the growing season. Making this rule effective immediately will allow plant health authorities and interested producers in Argentina to initiate the required measures as the growing season begins in order for their fruit to be eligible for export to the continental United States during the 2000 shipping season. Therefore, the Administrator of the Animal and Plant Health Inspection Service has determined that this rule should be effective less than 30 days after publication.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

This rule amends the citrus fruit regulations by recognizing a citrus-growing area within Argentina as being free from citrus canker. This rule also amends the fruits and vegetables regulations to allow the importation of grapefruit, lemons, and oranges from the citrus canker-free area of Argentina under conditions designed to prevent the introduction into the United States of two other diseases of citrus, sweet orange scab and citrus black spot, and other plant pests. These changes will allow grapefruit, lemons, and oranges to be imported into the continental United States from Argentina subject to certain conditions.

The entry of Argentine fresh citrus fruits into the continental United States can be expected to place additional competitive pressure on domestic producers and on exporters from other countries who currently market fresh citrus fruits in the United States. The net benefits of this rule are likely to be positive, where consumers would benefit from lower prices while producers would likely bear the primary losses.

Analysis

This analysis, which also serves as our cost-benefit analysis, considers the potential economic effects on domestic producers and consumers of citrus of allowing the importation of fresh citrus fruits from Argentina into the continental United States. Since entry of Argentine citrus to the continental United States will take place in three stages, the study focuses on citrus production, price and potential economic effects of this rule on consumers and producers during each stage. The major effects considered are losses to domestic producers and gains to consumers due to decreased prices resulting from increased volume. The magnitude of the impact will depend on the size of additional Argentine supply, the U.S. supply and demand for citrus, and price conditions in the rest of the world. Because Argentina already has well-established international markets, particularly in Europe, potential additional Argentine supply to the United States would likely be limited. After brief overviews of U.S. and Argentine production and import/export status and a discussion of prices, we evaluate the impact of increased imports from Argentina on the U.S. lemon, orange, and grapefruit markets.

The data sources used for the analysis include: USDA, National Agricultural

Statistics Service (NASS) production statistics; the 1997 Census of Agriculture; USDA, Economic Research Service, ''Foreign Agricultural Trade of the United States''; USDA, Agricultural Marketing Service, marketing information; USDA, Foreign Agricultural Service, ''Annual Citrus Report''; and United Nations, Food and Agricultural Organization, production and trade statistics. A complete bibliography of the sources used in this analysis is available from the person listed under **FOR FURTHER INFORMATION CONTACT**.

U.S. Citrus Industry

Citrus production

The United States produced 30,270 million pounds of grapefruit, lemons, and oranges (citrus henceforth) in 1996, with a value of $2.4 billion. Four States—Arizona, California, Florida and Texas—accounted for about 98 percent of the grapefruit, lemon, and orange farms and more than 99 percent of the acreage in 1997 (the latest census year).

As shown in Table 1, in 1997 there were 4,410 farms in the four main citrus-producing States that produced grapefruit, 1,978 that produced lemons, and 13,133 that produced oranges. Approximately 97 percent of these fruit farms (Standard Industrial Classification 0272) had gross sales of less than $500,000 and thus are considered to be small entities according to the Small Business Administration size standards (13 CFR 121.601). These small citrus farms accounted for less than 34 percent of the total citrus growing acreage, while the remaining 3 percent of citrus farms (*i.e.,* those with annual gross sales of $500,000 or more) accounted for about 66 percent of the acreage.

TABLE 1.—FARMS BY STATE AND TYPE OF CITRUS, 1997

State	Grapefruit		Lemons		Oranges	
	Number of farms	Small entities (%)	Number of farms	Small entities (%)	Number of farms	Small entities (%)
Arizona	159	100	154	95	266	98
California	1,279	97	1,824	93	5,640	98.5
Florida	2,549	97	....	....	6,893	96.2
Texas	423	97	....	....	334	99
Total farms	4,410	....	1,978	....	13,133	....

Source: USDA/NASS, *Census of Agriculture 1997.* Note the United States Summary includes farms that may be producing more than one type of citrus and thus reports fewer farms than when farms are added up by States.

Oranges, grapefruit, and lemons account for about 95 percent of the total U.S. citrus production. The 1996 value of U.S.-produced oranges was $1.82 billion; grapefruit, $289 million; and lemons, $261 million. Table 2 below shows the end use of grapefruit, lemons, and oranges for the United States (1993/94 to 1997/98 average). As the table shows, the share of processed fruit is greater than that diverted to the fresh export market or fresh domestic market.

TABLE 2.—END USE OF CITRUS IN THE UNITED STATES: AVERAGE OF 1993/94 TO 1997/98

Fruit	Percentage to:		
	Export	Fresh fruit market	Processing
Grapefruit	18.6	28.7	52.7
Lemons	14.4	36.8	48.8
Oranges	5.4	14.7	79.9

Source: USDA/ERS, Fruit and Tree Nuts: Situation Outlook Yearbook, FTS–287, October 1999.

Production for the fresh orange, grapefruit, and lemon markets accounted for about 25.2 percent of total citrus production or approximately 8,662 million pounds in 1997/98. The share of citrus fruits destined for the fresh market varied by State and by fruit. Table 3 below shows fresh utilized production, fresh fruit share, and distribution by State.

TABLE 3.—FRESH PRODUCTION AND SHARE BY STATE AND TYPE OF CITRUS, 1993/94 TO 1997/98

State	Grapefruit		Lemons		Oranges	
	Fresh utilized production*	Fresh fruit share (%)	Fresh utilized produc-tion*	Fresh fruit share (%)	Fresh utilized produc-tion*	Fresh fruit share (%)
Arizona	56	68	168	59	84	87
California	400	68	807	50	3,700	78
Florida	1,904	42	....	....	940	5
Texas	250	70	....	....	69	77

*Fresh utilized production is in millions of pounds.

Source: USDA/ERS, *Fruit and Tree Nuts: Situation Outlook Yearbook,* FTS–287, October 1999.

As can be seen from Table 3, the fresh market accounted for about 87 percent of the oranges, 68 percent of the grapefruit, and 59 percent of the lemons produced in Arizona; about 78 percent of the oranges, 68 percent of the grapefruit, and 50 percent of the lemons produced in California; about 5 percent of the oranges and 42 percent of the grapefruit produced in Florida; and 77 percent of the oranges and 70 percent of the grapefruit produced in Texas.

The annual average consumption of oranges, grapefruit, and lemons in the United States has stayed at around 21.7 pounds per person (12.6 pounds of oranges, 6.5 pounds of grapefruit, and 2.4 pounds of lemons), 1977 to 1997, with a variability of about 10 percent. Fresh citrus fruits are marketed throughout the year, most heavily between October and May. Table 4 shows the marketing seasons for the fruits, by State.

TABLE 4.—MARKETING SEASONS BY FRUIT AND STATE, 1999

Fruit	State	Marketing season
Grapefruit	Arizona	November 1 to July 31.
	California	November 15 to October 30.
	Florida	September 10 to July 31.
	Texas	October 1 to May 30.
Lemons	Arizona	August 15 to March 1.
	California	August 1 to July 31.
Oranges	Arizona	November 1 to August 31.
	California (Navels)	November 1 to June 15.
	California (Valencias)	March 15 to December 20.
	Florida (Early and midseason)	October 1 to April 15.
	Florida (Valencia)	February 1 to July 31.
	Texas	September 25 to May 15.

Source: USDA, NASS, Citrus Fruits 1999 Summary, September 1999.

Domestic shipments of citrus fruit are at their lowest during the months of July, August, and September (the distribution of oranges drops to approximately 6.4 percent of average annual shipments, grapefruit to 0.7 percent, and lemons to 16.3 percent). U.S. citrus exports are also at their lowest during these months. Citrus imports are also widely distributed throughout the year, but with above-average imports during July, August, and September (about 29 percent). Wholesale prices follow the same seasonal supply patterns, as they are lower during peak production months—October to May—and higher during summer months from June to September. Since the peak production period for citrus in Argentina is from May to October, the entry of Argentine fresh citrus fruits will likely peak during these months, which represent the most likely window of opportunity for Argentine imports to enter the U.S. market. The annual average terminal market wholesale price in 1996 in major U.S. cities was approximately 40 cents per pound for oranges, 29 cents per pound for grapefruit, and 43 cents per pound for lemons. (The average monthly wholesale prices were estimated from Terminal Market Prices by cities for January to December 1996; USDA/AMS, Fruit and Vegetable Market News.)

Importers and brokers will likely benefit from the entry of Argentine citrus fruit into the U.S. market because they will be able to provide quality fruits during the months when domestic production is lowest. Consumers will be able to obtain a wide choice of fresh citrus throughout the year and will not need to wait for the peak domestic production season or switch to non-citrus fruits.

Citrus Trade

Foreign markets play an increasingly important role for U.S. producers, accounting for approximately 29 percent of the 1996 annual fresh citrus fruit sales. The total value of the U.S. fresh grapefruit, lemon, and orange exports was approximately $659 million in 1996. In terms of value, oranges accounted for 43.9 percent of citrus exports, grapefruit for 38.1 percent; and lemons for 18 percent. The United States is a net exporter of citrus fruits. Imports of fresh grapefruit, lemons, and oranges were valued at about $26.7 million in 1996; by value, about 5.4 percent of imports were grapefruit, 10.1 percent were lemons, and 84.5 percent were oranges.

A few countries accounted for the bulk of the U.S. fresh citrus export market. In Asia, Japan (46 percent), Hong Kong (10.4 percent), the Republic of Korea (3 percent), and Taiwan (3 percent) together accounted for approximately 62.4 percent of total U.S. exports. Next, exports to Canada were about 25 percent. In Europe, France (3.3 percent), The Netherlands (2.9 percent), and the United Kingdom (1 percent) are the major importers. The United States, as noted above, is not a major importer of fresh citrus fruits. Major suppliers are Australia (67 percent), Mexico (13 percent), and Chile (6.2 percent); these countries together supplied about 86 percent of U.S. fresh citrus imports in 1996.

U.S. fresh orange exports increased at an average growth rate of 4.2 percent between 1985 and 1996; fresh grapefruit exports increased by 3.7 percent during that same period. In contrast, exports of lemons declined by an average rate of 1.1 percent between 1985 and 1996.

Citrus imports to the United States increased at an average annual growth rate of 10 percent between 1985 and 1996. Imports are heaviest during the months when U.S. production and shipments are lowest. There is also a reciprocal window of opportunity for U.S. producers to step in during the months when production is low in countries of southern hemisphere. At present, the United States is exporting approximately $100,000 worth of citrus fruit to Argentina and importing none.

Argentine Citrus Industry

Production

Argentina produced an annual average of 3,104 million pounds of grapefruit, lemons, and oranges between 1985 and 1996. Of this, about 1,632 million pounds is from three States: Jujuy, Salta, and Tucuman. (The fourth State affected by this rule—Catamarca—has little to no commercial citrus production.) Table 5 shows the end use of the three fruits in Argentina.

TABLE 5.—END USE OF CITRUS IN ARGENTINA, 1996–1998 AVERAGE

Fruit	Percentage to:		
	Export	Fresh fruit market	Processing
Grapefruit	13	69	18
Lemons	18	15	67
Oranges	11	71	18

Source: USDA/FAS, Argentina Citrus Annual Report 1999, No. AR9034.

A greater proportion of grapefruit and oranges is consumed domestically as fresh fruit, while a larger proportion of lemon is industrially processed.

The annual rate of increase in Argentine citrus production between 1985 and 1996 is attributable mostly to a 4.7 percent increase in lemon production. For the other citrus varieties, the growth rate was much less (0.7 percent for oranges and 0.4 percent for grapefruit). Export growth rates during this period were 15.4 percent for lemons, 4.1 percent for oranges, and 0.7 percent for grapefruit.

Citrus Trade

Argentina is one of South America's major exporters of grapefruit, lemons, and oranges. It exported 638 million pounds of those varieties in 1996 and an average of 470 million pounds per year between 1992 and 1996 (433, 334, 445, 500, and 638 million pounds per year, respectively). Most of that fruit went to Europe, which accounted for nearly 87 percent of exports. Major destinations included The Netherlands (52 percent), France (14 percent), Spain (8 percent), the United Kingdom (10 percent), and Russia (8 percent). Smaller importers of Argentine citrus include Portugal, Belgium, Germany, Hong Kong, and Saudi Arabia. Since the majority of the U.S. fresh citrus exports went to the Far East, the United States and Argentina appear to be serving distinct markets. Imports of fresh citrus accounted for only about 0.06 percent of the utilized total Argentine citrus supply.

Argentina can be expected to maintain its well-established export markets, which, as noted in the previous paragraph, are mainly in Europe. Exports to the United States would provide another potential outlet for the Argentine citrus industry.

Wholesale Terminal Market Prices

Fresh citrus fruit wholesale prices are lower in Argentina than in the United States. Average wholesale prices in Argentina for fresh grapefruit, oranges, and lemons were 17, 18, and 17 cents per pound, respectively, in 1996. These are lower than the average U.S. wholesale price of 29, 40, and 43 cents per pound of the respective fresh fruits for the same period. However, the Argentine wholesale prices do not reflect the additional costs that exporting these fruits to the United States would entail; *i.e.,* overland transport cost from northwestern Argentina to the south-central coast, the sea freight rate, cold treatment, and the tariff rates, which add about 15 to 20 cents per pound to the average Argentine wholesale price. In addition, even before their fruit is exported to the United States, participating groves will incur added production costs in meeting the requirements of this rule. These requirements include grove cleaning, grove treatment, visual survey of groves 20 days prior to harvest, sampling and laboratory examination of fruit from the grove and buffer area, registered technicians at each packinghouse to verify the origin of fruit coming in, and sodium hypochlorite dipping prior to packing. These additional requirements are expected to add about 3 to 5 cents per pound to costs. Thus, by the time the fresh citrus from Argentina arrives at U.S. ports, the gap in prices will be narrower.

Effects on Producers and Consumers

This section of the analysis examines the potential economic effects on U.S. producers and consumers of allowing fresh lemons, oranges, and grapefruit from Argentina to enter the U.S. market. Because of our conclusion that the importation of Argentine citrus poses a negligible pest risk, we do not believe that it is necessary to evaluate the costs of pest introduction in this analysis.

This analysis is based on expected additional exports of these fruits by Argentina.[1] As noted previously, the entry of Argentine citrus fruit into the continental United States will be phased in over three stages. In the first stage (the 2000 and 2001 shipping seasons), the fruit will be authorized entry into 34 non-citrus-producing, non-buffer States; in the second stage (the 2002 and 2003 shipping seasons), the fruit may enter the original 34 States plus an additional 10 buffer States; and in the final stage (beginning with the 2004 shipping season), the fruit may enter all areas of the continental United States.

A partial equilibrium economic surplus framework is used in this analysis to consider the benefits and the costs of this rule. Potential producer losses and gains to consumers are quantified for each citrus product in terms of changes in producer and consumer surplus resulting from increased imports from Argentina. This analysis measures the direct effects of this rule on domestic producers of oranges, grapefruit, and lemons. Indirect and induced effects on income, output, and employment are not considered.

To simplify the analysis, supply and demand curves are assumed to be linear and the supply shift is assumed to be parallel. We use point estimates for the elasticities of supply and demand, average annual prices, and estimates of annual U.S. production and annual Argentine exports in the analysis. We assume U.S. and Argentine citrus are substitutes for one another. Seasonality in their production, consumption, and distribution are ignored.

To estimate the total exports of oranges, lemons, and grapefruit that could be expected to result from this rule, we use State- and fruit-specific 1995 production data from three of the four eligible Argentine States—Jujuy, Salta, and Tucuman. Because export levels for Argentine citrus fruit have been subject to marked fluctuations over

[1] Producers and exporters in Argentina would not have the flexibility to make adjustments from domestic sales to exports or from processing to fresh, at least not within a single season. The rule essentially requires growers to commit their groves to the U.S. export market before a tree ever blooms, given that they must register with SENASA prior to the start of the growing season and begin applying specific phytosanitary measure (e.g., grove cleaning, field treatments) very early in the season. A non-registered grove that normally produces fruit for the Argentine domestic fresh or processing market could not, in response to high U.S. prices, simply decide to begin shipping fruit to the United States. It is possible that a profitable shipping season in the U.S. market for Argentine export could lead additional Argentine growers to enter into the export program for the following year. Historical export growth is a good indicator of what could happen. The recent growth in lemon exports is used to estimate Argintina's fresh lemon exports to the United States.

time, a simple semi-log model is used to estimate the growth rate of exports of each of the three fresh fruits. Exports to the United States are then calculated by assuming that Argentina would maintain its current exports to the rest of the world and divert its incremental export to the United States.

Exports from Argentina will depend to a large extent on whether Argentine citrus will be price competitive with U.S. citrus. Table 6 shows the average annual prices in Argentina, plus shipping and additional costs imposed by the rule, and U.S. prices. While seasonal prices can vary substantially from the average, we believe that the averages provide some sense of the incentives for Argentine citrus exports to the United States. Price differentials for the three citrus commodities indicate that Argentine lemons will be able to compete effectively with U.S. lemons. It is less likely that oranges and grapefruit from Argentina will have the same competitive advantage and, therefore, it is less likely that they will be exported to the United States.

TABLE 6.—ESTIMATES OF PRICE DIFFERENTIALS FOR CITRUS

Fruit	Per-pound price (dollars)				
	Argentina wholesale price	Transport cost	Additional costs due to rule	Price of Argentine fruit in U.S.	Price of U.S. fruit
Grapefruit	.17	.15–.20	.03–.05	.35–.42	.29
Oranges	.18	.15–.20	.03–.05	.36–.43	.40
Lemons	.17	.15–.20	.03–.05	.35–.42	.43

Lemons

Using a 5-year average (1992/93 through 1996/97) of U.S. consumption, production plus imports minus exports, we estimated U.S. domestic consumption of lemons to be 728 million pounds. The average price is $0.43 per pound. There are very few published elasticity estimates available. Published estimates from quantity-dependent models for lemon demand elasticity are not available, but Ferguson and Carman find an elasticity of demand for lemon of −0.44 in an unpublished study. Another study yielded an elasticity of supply for lemons greater than zero (Kinney *et al.*, 1987, p.9, equation 6). Estimation by various data points, using acreage and per-acre revenue data in Tables 9 and 6, respectively, of Kinney *et al.* yields elasticities of supply for lemons between 0.04 and 0.17. In our analysis we use the −0.44 estimate for the elasticity of demand and assume an elasticity of supply equal to 0.09.

Because export levels for Argentine lemons have been subject to marked fluctuations over time (*e.g.,* increases of 73 percent in 1994, 17 percent in 1995, 49 percent in 1996, and almost 10 percent in 1997 and decreases of 55 percent in 1986, 15 percent in 1989, and 25 percent in 1993), the quantities of fruit considered in this analysis are based on growth rates in Argentina's fresh lemon exports to the rest of the world. As discussed above, a simple semi-log model was used to estimate the growth rate of lemon exports between 1985 and 1998. The results show that lemon exports increased at the rate of 15 percent during that period. Using 1994–1998 average exports from the eligible Argentine States, 293.6 million pounds, as a baseline number, the total expected increase in exports would be 44.04 (293.6×0.15) or, rounding, 44 million pounds.

We assume that the elasticities, the quantity of the domestic lemons produced and consumed, and the quantity of Argentine lemons imported would not change over the 3-stage phase-in period.

Estimated results of introducing imported fresh lemons from the Argentine States of Jujuy, Salta, and Tucuman into the U.S. market are as shown in Tables 7, 8, and 9. Because the price differential between Argentine lemons and U.S.-produced lemons shown in Table 6 appears to be sufficient to make export of lemons profitable to Argentine exporters, we estimate the impacts on consumers and producers considering three scenarios for each phase of the rule's implementation. The three scenarios examine the impact of 60 percent, 80 percent, and 100 percent of the 44-million-pound increase in lemon exports being shipped to U.S. markets.

We assume that the elasticities and the quantity of Argentine lemons imported would not change over the 3-stage phase-in. Our point of comparison in each stage is the absence of lemon imports from Argentina. In other words, the analysis at each stage assumes the same level of domestic production and consumption and the same price prior to importation of Argentine lemons. We have made no attempt to assess the incremental effects of the rule over the 3-stage phase-in period and, furthermore, it is not appropriate to compare the impacts of the various stages or to sum across the stages to obtain a total effect.

Table 7 provides an analysis of expected impacts during Stage 1, including percent change in price, percent change in quantity, resultant producer losses, consumer benefits, and net benefits, for each diversion scenario. Stage 1 allows for importation of citrus into 34 States. These States account for approximately 60 percent of fresh lemon consumption in the United States, about 437 million pounds.

TABLE 7.—THE IMPORTATION OF FRESH LEMONS FROM ARGENTINA TO APPROVED STATES (STAGE 1)

	Percentage of average Argentine lemon export growth diverted to the U.S. market:		
	60	80	100
Imports (millions of pounds)	26.4	35.2	44
Percent change in price	−11.4	−15.2	−19
Percent change in quantity	−1.03	−1.37	−1.71

TABLE 7.—THE IMPORTATION OF FRESH LEMONS FROM ARGENTINA TO APPROVED STATES (STAGE 1)—Continued

	Percentage of average Argentine lemon export growth diverted to the U.S. market:		
	60	80	100
Decrease in producer surplus (millions of dollars)	−22.251	−29.616	−36.957
Increase in consumer surplus (millions of dollars)	22.926	30.817	38.833
Net benefit (millions of dollars)	0.675	1.201	1.876

As Table 7 shows, during the first stage producer losses could potentially range between $22.251 million and about $36.957 million, while consumer gains could range between $22.926 million and $38.33 million. The net benefits, therefore, would be between $675,000 and about $1.876 million.

In Stage 2, Argentine imports will be shipped to 44 States, which account for 72.4 percent of lemon consumption, approximately 527 million pounds. Table 8 shows that the expansion in Stage 2 will yield about the same results as Stage 1.

TABLE 8.—THE IMPORTATION OF FRESH LEMONS FROM ARGENTINA TO APPROVED STATES (STAGE 2)

	Percentage of average Argentine lemon export growth diverted to the U.S. market:		
	60	80	100
Imports (millions of pounds)	26.4	35.2	44
Percent change in price	−9.452	−12.602	−15.753
Percent change in quantity	−0.851	−1.134	−1.418
Decrease in producer surplus (millions of dollars)	−22.270	−29.651	−37.011
Increase in consumer surplus (millions of dollars)	22.830	30.647	38.567
Net benefit (millions of dollars)	0.560	0.996	1.556

Table 9 presents the results for the third stage, when fresh lemons imported from Argentina are allowed in all areas of the continental United States.

TABLE 9.—THE IMPORTATION OF FRESH LEMONS FROM ARGENTINA (STAGE 3)

	Percentage of average Argentine lemon export growth diverted to the U.S. market:		
	60	80	100
Imports (millions of pounds)	26.4	35.2	44
Percent change in price	−6.84	−9.12	−11.4
Percent change in quantity	−0.62	−0.82	−1.03
Decrease in producer surplus (millions of dollars)	−21.35	−28.44	−35.52
Increase in consumer surplus (millions of dollars)	21.74	29.13	36.59
Net benefit (millions of dollars)	0.39	0.69	1.07

As shown in Table 9, both producer losses and consumer gains during this final period would be slightly less than during the previous two stages, as Argentine imports would compete with the entire domestic fresh supply. Producer losses in this scenario range between $21.35 million and $35.52 million, while consumer gains are between $21.74 million and $36.59 million. The net benefits would thus be between $390,000 and $1.07 million.

One of the commenters who responded to our proposed rule stated that in Argentina, 30 percent of lemon acreage is due to begin bearing during the next 5 years, thus annual production of lemons will increase significantly. This commenter reported that estimated lemon production increased 240 million pounds from 1996 to 1997 and concluded that within 5 years, Argentine citrus exporters, with an established distribution network, could very easily export 100 to 200 million pounds or more of fresh lemons to the United States during the summer months, a much larger export level than was considered in the proposed rule's economic analysis.

With regard to current increases and potential suitable land for future expansion of lemon groves in Argentina, both planted acres and harvested acres have increased from their 1996 levels. Planted acreage increased from 76,763 acres to 102,698 acres in 1998, while harvested acreage increased from 69,854 acres to 95,095 acres. As can be seen, harvested acres accounted for about 92.6 percent of the planted acreage in 1998. For 1999, acres planted are forecasted to increase to 106,210 acres, while harvested acres are forecasted to decline to 93,860 acres as older groves are replaced by younger, non-fruit-bearing trees. Over 90 percent of the planted acreage is being harvested, and about 5 percent of new plantings are replacement plantings. If these expansions continue and if weather conditions are favorable, Argentina will have a much larger potential to export more fresh lemons to all countries, including the United States. (USDA/FAS, Argentina Citrus Annual Reports for 1997 [AR7043], 1998 [AR8032], and 1999 [AR9034], U.S. Embassy, Buenos Aires, Argentina; Randall J. Hager, Agricultural Attache, Office of Agricultural Affairs, U.S. Embassy, Buenos Aires, August 1999, personal communication; and Mariano Ripari, Agricultural Attache, Embassy of Argentina, Washington DC, August 1999, personal communication).

Whether this expansion will continue, and how it will affect the United States, depends not only on the availability of suitable land in Argentina and the capital to convert that land to lemon groves, but also on many other factors such as production costs, relative world prices for fresh lemons, U.S. prices, the exchange rates for major currencies, changes in consumer taste for fresh lemons, growth in the demand for fresh lemons in other countries that are already importing from Argentina, the opening of other potential markets (*e.g.*, new markets for Argentine lemons are opening in the Far East), and the profitability of alternative land use. Since inclement weather can affect both the quantity and quality of fresh lemons, there is added uncertainty in predicting Argentina's fresh lemon export capacity. For example, although production increased from about 1,905 million pounds in 1997 to 2,260 million pounds in 1998, this did not translate to large export levels for fresh lemons. Instead, exports declined from 388 million pounds to 344 million pounds, as fresh lemons were diverted for processing due to rainy weather that caused poor quality.

Table 10 shows an import of 100 million pounds of fresh lemon to the United States would result in price decline of about 26 percent and producer loss of about $80 million. However, consumer benefit would be about $86 million dollars, yielding a net benefit of about $5.57 million. We do not expect this level of lemon imports from Argentina to be realized.

TABLE 10.—IMPACT IN THE UNITED STATES OF LARGER ARGENTINE LEMON EXPORTS TO THE UNITED STATES

[Price elasticity of demand is −0.44 and price elasticity of supply is 0.09]

Potential exports to the United States (millions of pounds)	*100
Percent change in price	−25.92
Percent change in quantity**	−2.33
Decrease in producer surplus (millions of dollars)	−80.19
Increase in consumer surplus (millions of dollars)	85.76
Total surplus (millions of dollars)	5.57

*Less than perfectly inelastic supply.
**This decrease in quantity may be due to diversion of fresh lemons to the processing sector as the price of fresh lemons declines.

Increased ability to export will translate to sales only if there is a comparable market demand for fresh lemons. Over the last several years, per capita consumption (between 2.54 and 2.90 pounds per person) has remained stable, with very small variability (a mean of 2.7 pounds per person and a standard deviation of 0.12 pounds per person). U.S. consumption of fresh lemons over the last 3 years has declined from 766.3 million pounds (peak amount in 1995/96) to 747.9 million and 675.8 million pounds in 1996/97 and 1997/98, respectively (USDA/ERS, ''Fruit and Tree Nuts: Situation and Outlook Report,'' October 1999, p.74). Most available estimates for the price elasticity of demand for fresh lemon are below -0.5, implying that the demand for fresh lemons is price inelastic. This means that for every 1 percent decrease in their price, the demand for fresh lemons would increase by less than 0.5 percent. Given an estimated price elasticity of -0.44, a 100-million-pound increase in supply of fresh lemons would require a price decrease of about 26 percent. In other words, for a large quantity of fresh lemons to be absorbed, the price of fresh lemons has to decrease substantially. If 100 million or more pounds of fresh lemons were to be imported from Argentina, the negative effect on domestic producers would be much larger than predicted under the importation scenario of 44 million pounds. Consumer benefits would still outweigh producer losses. Since such a large influx of fresh lemons would require a large price decline to be absorbed, it would not be profitable for Argentina to export fresh lemons in such large quantities to the United States.

Oranges

Using a 5-year average (1992/93 through 1996/97) of U.S. consumption, production plus imports minus exports, we estimated U.S. domestic consumption of oranges to be 3,479 million pounds. The average price is $0.40 per pound. As with lemons, there are very few published elasticity estimates available. The two studies most often referred to are by Huang (1993) and Thompson *et al.* (1990) and relate to oranges and grapefruit. Huang provides estimates both for Marshallian and Hicksian demand systems. The results of the Marshallian demand system are reported and used here—a demand elasticity of -0.849 for oranges. Thompson, *et al.* estimate -0.719 for the demand elasticity for oranges. A recent study showed that the elasticity of supply for California oranges was 0.149 (Villezca-Becerra and Shumway 1992). In our analysis, we use the -.849 estimate made by Huang for the elasticity of demand and assume an elasticity of supply equal to 0.149.

Similar to lemons, our estimate for Argentine orange exports to the United States are based on growth rates in Argentina's fresh orange exports to the rest of the world. As above, a simple semi-log model was used to estimate the growth rate of orange exports between 1985 and 1996. The results show that orange exports increased at the rate of 4.1 percent during that period. Using 1992–1996 average exports from the Argentina, 171 million pounds, as a baseline number and assuming the share of exports from the eligible Argentine States would continue to be 26.59 percent, the total expected increase in exports would be 1.86 million pounds ($171 \times 0.2659 \times .041$) or, rounding, 2 million pounds.

Table 11 reports the potential effects of orange imports from Argentina during the first, second, and third stages of the import program. We believe the price differential between U.S. and Argentine oranges illustrated in Table 6 suggests that a lower proportion of Argentine orange exports will be diverted to the United States. Therefore, we assume a 20 percent diversion of the 2 million pounds of the expected increase in Argentine exports, or 400,000 pounds. Table 11 shows that price decreases as the volume of imported oranges increases, given domestic supply in the approved States during every stage.

TABLE 11.—THE IMPORTATION OF FRESH ORANGES FROM ARGENTINA TO APPROVED STATES FOR STAGES 1 THROUGH 3, ASSUMING 20 PERCENT OF AVERAGE ARGENTINE ORANGE EXPORT DIVERTED TO THE U.S. MARKET

	Stage		
	1	2	3
Imports (millions of pounds)	0.4	0.4	0.4
Percent change in price	−0.04	−0.03	−0.012
Percent change in quantity	−0.003	−0.003	−0.002
Decrease in producer surplus (millions of dollars)	−0.3019	−0.3019	−0.16032
Increase in consumer surplus (millions of dollars)	0.3019	0.3019	0.16033
Net benefit (millions of dollars)	0.0000	0.0000	0.00001

Note: The utilized supply for Stage 1 is 2,089 million pounds for approved States; for Stage 2 it is 2,518 million pounds.

Consumer gains in every stage are approximately equal to producer losses.

Grapefruit

Using a 5-year average (1992/93 through 1996/97) of U.S. consumption, production plus imports minus exports, we estimated U.S. domestic consumption of grapefruit to be 1,602 million pounds. The average price is $0.29 per pound. As with lemons, there are very few published elasticity estimates available. The two studies most often referred to are by Huang (1993) and Thompson *et al.* (1990) and relate to oranges and grapefruit. Huang provides estimates both for Marshallian and Hicksian demand systems. The results of the Marshallian demand system are reported and used here—a demand elasticity of -0.455 for grapefruit.

Thompson, *et al.* estimate -0.523 for the demand elasticity for grapefruit. A recent study showed that the elasticity of supply for California grapefruit was 0.409 (Villezca-Becerra and Shumway 1992). In our analysis we use the -0.455 estimate made by Huang for the elasticity of demand and assume an elasticity of supply equal to 0.409.

Similar to lemons and oranges, our estimate for Argentine grapefruit exports to the United States are based on growth rates in Argentina's fresh grapefruit exports to the rest of the world. As above, a simple semi-log model was used to estimate the growth rate of grapefruit exports between 1985 and 1996. The results show that grapefruit exports increased at the rate of 1 percent during that period. Using 1992–1996 average exports from the Argentina, 79.72 million pounds, as a baseline number and assuming the share of exports from the eligible Argentine States would continue to be 51.22 percent, the total expected increase in exports would be 0.41 million pounds ($79.72 \times 0.5122 \times 0.01$).

Given the price advantage possessed by U.S. producers of grapefruit (see Table 6), we believe that it is highly unlikely that Argentine grapefruit will be marketed in the United States.

However, if we perform an analysis of the impact of grapefruit imports similar to the analysis done for oranges and lemons, we find that there is not a significant effect on either U.S. producers or consumers. On the basis of the growth rate of grapefruit production in Argentina, which was less than 1 percent, the maximum that could be diverted would be about 410,000 pounds. This amount, when compared to about 1,603 million pounds of domestic supply of fresh grapefruit in the United States, is very small. As a result, price would decrease by only about 0.03 percent with 100-percent diversion in Stage 3. Producers losses and consumer gains both would be around $137,600, yielding a net benefit of zero.

Conclusion

Overall, the estimated net economic effects of this rule are positive. There is a direct relationship between producer losses and consumer gains on the one hand and the quantity of imports on the other hand. Therefore, the larger the share of imports from Argentina, relative to U.S. domestic supply, the larger the U.S. producer losses and the larger the U.S. consumer gains. In all cases, consumer gains are equal to or slightly outweigh grower losses.

As seen in Tables 7 through 11, the entry of fresh citrus fruits from Argentina into U.S. markets would induce producer losses and consumer gains. The greatest effect would be due to importation of lemons because the price differential between domestic fresh lemons and Argentine lemons may be largest. The expected lemon imports from Argentina would represent a larger proportion of the U.S. domestically available fresh lemon volume compared to that for fresh oranges and grapefruit.

Overall, considering all three stages of the import program, fresh lemon prices could potentially decrease between 6.84 percent and 19 percent. Producers would possibly lose between $21.35 million and $36.96 million, while consumers would potentially gain between $21.74 million and $38.83 million annually as the result of importing fresh lemons from Argentina, yielding a net benefit of between $390,000 and $1.876 million. In all cases, consumer gains slightly outweigh grower losses.

The extent of any actual decrease in prices would depend to a great degree upon the size of the price elasticity of demand, the magnitude of the change in supply, and the size of the baseline price. For lower price elasticities, both losses and gains would be higher. Since fresh fruit exports from Argentina, especially of oranges and grapefruit, are not expected to be large, they are not expected to change citrus fruit production and consumption patterns in the United States.

Because Argentina's peak season of production complements the U.S. low season of production (particularly for oranges and grapefruit) and vice versa, this rule should have a positive effect for consumers. U.S. prices during the months of June through September are higher than the annual average. The effect would vary by commodity, with the largest effect on lemon prices. As a result of the highest expected additional fresh lemon supply, the average lemon price in the United States would decrease by as much as 19 percent (in Stage 1), from 43 cents per pound to about 34.83 cents per pound. Orange prices would decline by as much as 0.04 percent (in Stage 1), from 40 cents per pound to 39.98 cents per pound. The effect on grapefruit prices is even more insignificant.

In addition, it is important to note that the analysis implicitly assumes the worst-case scenario because the partial equilibrium analysis does not allow for substitution among producers. If the price of fresh citrus fruits decreases significantly, then the producers may choose to channel their products to overseas markets or to processing markets. Under those scenarios, the decrease in prices expected to result from this rule would be less than that estimated in this analysis, resulting in less of a decrease in producer surplus.

This rule would have a net positive effect on the overall economy, since consumer benefits would be slightly higher than producer losses. The increased potential for trade and facilitation of flow of goods will benefit the welfare of both countries. These trading relationships benefit numerous sectors in the U.S. national economy. Increased trade in these sectors have dual benefits. Those employed are also consumers of fresh citrus fruit. Since fresh citrus fruits are normal goods, with positive income elasticities, increased jobs, outputs, and income in those sectors can also mean increased consumption of citrus products.

The only significant alternative to this rule would be to make no changes in the regulations; *i.e.*, to continue to prohibit the importation of grapefruit, lemons, and oranges from Argentina. We have rejected that alternative because we believe that Argentina has demonstrated that the citrus-growing areas of the States of Catamarca, Jujuy, Salta, and Tucuman are free from citrus canker and because we believe that the systems approach offered by Argentina to prevent the introduction of other plant pests reduces the risks posed by the importation of grapefruit, lemons, and oranges to a negligible level.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12988

This final rule allows the importation of grapefruit, lemons, and oranges from Argentina under certain conditions. State and local laws and regulations regarding grapefruit, lemons, and oranges imported under this rule are preempted while the fruit is in foreign commerce. Grapefruit, lemons, and oranges are generally imported for immediate distribution and sale to the consuming public and will remain in foreign commerce until sold to the ultimate consumer. The question of when foreign commerce ceases in other cases must be addressed on a case-by-case basis. No retroactive effect will be given to this rule, and this rule does not require administrative proceedings before parties may file suit in court challenging this rule.

National Environmental Policy Act

An environmental assessment and finding of no significant impact have been prepared for this rule. The assessment provides a basis for the conclusion that the importation of grapefruit, lemons, and oranges under the conditions specified in this rule will not present a risk of introducing or disseminating plant pests and would not have a significant impact on the quality of the human environment. Based on the finding of no significant impact, the Administrator of the Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared.

The environmental assessment and finding of no significant impact were prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Copies of the environmental assessment and finding of no significant impact are available for public inspection at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect copies are requested to call ahead on (202) 690–2817 to facilitate entry into the reading room. In addition, copies may be obtained by writing to the individual listed under **FOR FURTHER INFORMATION CONTACT**.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this final rule have been approved by the Office of Management and Budget (OMB). The assigned OMB control number is 0579–0134.

List of Subjects

7 CFR Part 300

Incorporation by reference, Plant diseases and pests, Quarantine.

7 CFR Part 319

Bees, Coffee, Cotton, Fruits, Honey, Imports, Incorporation by reference, Nursery Stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

Accordingly, we are amending title 7, chapter III, of the Code of Federal Regulations as follows:

PART 300—INCORPORATION BY REFERENCE

1. The authority citation for part 300 continues to read as follows:

Authority: 7 U.S.C. 150ee, 154, 161, 162 and 167; 7 CFR 2.22, 2.80, and 371.2(c).

2. In § 300.1, paragraph (a), the introductory text is revised to read as follows:

§ 300.1 Materials incorporated by reference.

(a) *Plant Protection and Quarantine Treatment Manual.* The Plant Protection and Quarantine Treatment Manual, which was reprinted November 30, 1992, and includes all revisions through May 2000, has been approved for incorporation by reference in 7 CFR chapter III by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

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PART 319—FOREIGN QUARANTINE NOTICES

3. The authority citation for part 319 continues to read as follows:

Authority: 7 U.S.C. 150dd, 150ee, 150ff, 151–167, 450, 2803, and 2809; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.2(c).

§ 319.28 [Amended]

4. In Subpart—Citrus Fruit, § 319.28 is amended as follows:

a. In paragraph (a)(1), by adding the words ''Argentina (except for the States of Catamarca, Jujuy, Salta, and Tucuman, which are considered free of citrus canker),'' immediately after the word ''Seychelles,''.

b. In paragraph (a)(2), by adding the words ''(except as provided by § 319.56–2f of this part)'' immediately after the word ''Argentina''.

c. In paragraph (a)(3), by adding the words ''(except for the States of Catamarca, Jujuy, Salta, and Tucuman, which are considered free of Cancrosis B)'' immediately after the word ''Argentina''.

§ 319.56a [Amended]

5. In § 319.56a, paragraph (e), the first sentence is amended by removing the words ''and 319.56–2f to 319.56–2m, inclusive,'' and adding the words '', 319.56–2e, 319.56–2g, 319.56–2k, 319.56–2l, and 319.56–2p'' in their place.

6. In Subpart Fruits and Vegetables, a new § 319.56–2f is added to read as follows:

§ 319.56–2f Administrative instructions governing importation of grapefruit, lemons, and oranges from Argentina.

Fresh grapefruit, lemons, and oranges may be imported from Argentina into the continental United States (the contiguous 48 States, Alaska, and the District of Columbia) only under permit and only in accordance with this section and all other applicable requirements of this subpart.

(a) *Origin requirement.* The grapefruit, lemons, or oranges must have been grown in a grove located in a region of Argentina that has been determined to be free from citrus canker. The following regions in Argentina have been determined to be free from citrus canker: The States of Catamarca, Jujuy, Salta, and Tucuman.

(b) *Grove requirements.* The grapefruit, lemons, or oranges must have been grown in a grove that meets the following conditions:

(1) The grove must be registered with the citrus fruit export program of the Servicio Nacional de Sanidad y Calidad Agroalimentaria (SENASA).

(2) The grove must be surrounded by a 150-meter-wide buffer area. No citrus fruit grown in the buffer area may be offered for importation into the United States.

(3) Any new citrus planting stock used in the grove must meet one of the following requirements:

(i) The citrus planting stock originated from within a State listed in paragraph (a) of this section; or

(ii) The citrus planting stock was obtained from a SENASA-approved citrus stock propagation center.

(4) All fallen fruit, leaves, and branches must be removed from the ground in the grove and the buffer area before the trees in the grove blossom. The grove and buffer area must be inspected by SENASA before blossom to verify that these sanitation measures have been accomplished.

(5) The grove and buffer area must be treated at least twice during the growing season with an oil-copper oxychloride spray. The timing of each treatment shall be determined by SENASA's expert system based on its monitoring of climatic data, fruit susceptibility, and the presence of disease inoculum. The application of treatments shall be monitored by SENASA to verify proper application.

(6) The grove and buffer area must be surveyed by SENASA 20 days before the grapefruit, lemons, or oranges are harvested to verify the grove's freedom from citrus black spot (*Guignardia citricarpa*) and sweet orange scab (*Elsinoe australis*). The grove's freedom from citrus black spot and sweet orange scab shall be verified through:

(i) Visual inspection of the grove and buffer area; and

(ii) The sampling of 4 fruit from each of 298 randomly selected trees from each grove and buffer area covering a maximum area of 800 hectares. If the area to be sampled exceeds 800 hectares, SENASA must contact APHIS for APHIS' determination as to the number of trees to be sampled. The sampled fruit must be taken from those portions of the trees that are mostly likely to have infected, symptomatic fruit (*i.e.* near the outer, upper part of the canopy on the sides of the tree that receive the most sunlight). The sampled fruit must be held in the laboratory for 20 days at 27 °C, 80 percent relative humidity, and in permanent light to promote the expression of symptoms in any fruit infected with citrus black spot.

(c) *After harvest.* After harvest, the grapefruit, oranges, or lemons must be handled in accordance with the following conditions:

(1) The fruit must be moved from the grove to the packinghouse in field boxes or containers of field boxes that are marked to show the SENASA registration number of the grove in which the fruit was grown. The identity of the origin of the fruit must be maintained.

(2) During the time that any grapefruit, lemons, or oranges from groves meeting the requirements of paragraph (b) of this section are in the packinghouse, no fruit from groves that do not meet the requirements of paragraph (b) of this section may enter the packinghouse. A packinghouse technician registered with SENASA must verify the origin of all fruit entering the packinghouse.

(3) After arriving at the packinghouse, the fruit must be held at room temperature for 4 days to allow bruises or other fruit damage to become apparent.

(4) After the 4-day holding period, bruised or damaged fruit must be culled and the fruit must be inspected by SENASA to verify its freedom from citrus black spot and sweet orange scab. The fruit must then be chemically treated as follows:

(i) Immersion in sodium hypochlorite (chlorine) at a concentration of 200 parts per million for 2 minutes;

(ii) Immersion in orthophenilphenate of sodium;

(iii) Spraying with imidazole; and

(iv) Application of 2–4 thiazalil benzimidazole and wax.

(5) Before packing, the treated fruit must be individually labeled with a sticker that identifies the packinghouse in which they were packed and must be inspected by SENASA to verify its freedom from citrus black spot and sweet orange scab and to ensure that all stems, leaves, and other portions of plants have been removed from the fruit.

(6) The fruit must be packed in clean, new boxes that are marked with the SENASA registration number of the grove in which the fruit was grown and a statement indicating that the fruit may not be distributed in Hawaii, Guam, the Northern Mariana Islands, Puerto Rico, the U.S. Virgin Islands, or in any State (each of which must be individually listed) into which the distribution of the fruit is prohibited pursuant to paragraph (g)(1) or (g)(2) of this section.

(d) *Phytosanitary certificate.* Grapefruit, lemons, and oranges offered for entry into the United States from Argentina must be accompanied by a phytosanitary certificate issued by SENASA that states the grapefruit, lemons, or oranges were produced and handled in accordance with the requirements of paragraphs (a), (b), and (c) of this section and that the grapefruit, lemons, or oranges are apparently free from citrus black spot and sweet orange scab.

(e) *Cold treatment.* Due to the presence in Argentina of Mediterranean fruit fly (Medfly) (*Ceratitis capitata*) and fruit flies of the genus *Anastrepha*, grapefruit, lemons (except smooth-skinned lemons), and oranges offered for entry from Argentina must be treated with an authorized cold treatment listed in the Plant Protection and Quarantine Treatment Manual, which is incorporated by reference at § 300.1 of this chapter. The cold treatment must be conducted in accordance with the requirements of § 319.56–2d of this subpart.

(f) *Disease detection.* If, during the course of any inspection or testing required by this section or § 319.56–6 of this subpart, or at any other time, citrus black spot or sweet orange scab is detected on any grapefruit, lemons, or oranges, APHIS and SENASA must be notified and the grove in which the fruit was grown or is being grown shall be removed from the SENASA citrus export program for the remainder of that year's growing and harvest season, and the fruit harvested from that grove may not be imported into the United States from the time of detection through the remainder of that shipping season.

(g) *Limitations on distribution.* The distribution of the grapefruit, lemons, and oranges is limited to the continental United States (the 48 contiguous States, Alaska, and the District of Columbia.). In addition, during the 2000 through

2003 shipping seasons, the distribution of the grapefruit, lemons, and oranges is further limited as follows:

(1) During the 2000 and 2001 shipping seasons, the fruit may be distributed in all areas of the continental United States except Alabama, Arizona, Arkansas, California, Colorado, Florida, Georgia, Louisiana, Mississippi, Nevada, New Mexico, Oklahoma, Oregon, Texas, and Utah.

(2) During the 2002 and 2003 shipping seasons, the fruit may be distributed in all areas of the continental United States except Arizona, California, Florida, Louisiana, and Texas.

(3) For the 2004 shipping season and beyond, the fruit may be distributed in all areas of the continental United States.

(h) *Ports of entry.* The grapefruit, lemons, and oranges may enter the United States only through a port of entry located in a State where the distribution of the fruit is authorized pursuant to paragraph (g) of this section.

(i) *Repackaging.* If any grapefruit, lemons, or oranges are removed from their original shipping boxes and repackaged, the stickers required by paragraph (c)(5) of this section may not be removed or obscured and the new boxes must be clearly marked with all the information required by paragraph (c)(6) of this section.

(Approved by the Office of Management and Budget under control number 0579–0134)

7. Section 319.56–2i, including the section heading, is revised to read as follows:

§ 319.56–2i Administrative instructions prescribing treatments for mangoes from Central America, South America, and the West Indies.

(a) *Authorized treatments.* Treatment with an authorized treatment listed in the Plant Protection and Quarantine Treatment Manual will meet the treatment requirements imposed under § 319.56–2 as a condition for the importation into the United States of mangoes from Central America, South America, and the West Indies. The Plant Protection and Quarantine Treatment Manual is incorporated by reference. For the full identification of this standard, see § 300.1 of this chapter, ''Materials incorporated by reference.''

(b) *Department not responsible for damage.* The treatments for mangoes prescribed in the Plant Protection and Quarantine Treatment Manual are judged from experimental tests to be safe. However, the Department assumes no responsibility for any damage sustained through or in the course of such treatment.

Done in Washington, DC, this 8th day of June 2000.

Bobby R. Acord,

Acting Administrator, Animal and Plant Health Inspection Service.

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