

IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF CALIFORNIA

HARLAN LAND CO., LIMONEIRA)
COMPANY, PECHT RANCH, R7)
ENTERPRISES; and U.S. CITRUS)
SCIENCE COUNCIL)
)
Plaintiffs,)
)
vs.)
)
U.S. DEPARTMENT OF)
AGRICULTURE; DANIEL GLICKMAN,)
Secretary of Agriculture; and)
CRAIG A. REED, Administrator,)
Animal and Plant Health)
Inspection Services,)
)
Defendants.)

On May 21, 2001, the court heard the parties’ Cross Motion for Summary Judgment.

Upon due consideration of the oral and written arguments and the record herein, plaintiffs’ motion for summary judgment is granted and defendants’ motion for summary judgment is denied for the reasons set forth herein.

I. Factual Background

In 1993, Argentina officially requested Animal and Plant Health Inspection Service (“APHIS), a division of United States Department of Agriculture, to amend its regulations so that lemons, oranges and grapefruit grown in the Argentine States of Catamarca, Jujuy, Salta, and Tucuman could be imported into the United States. Statement of Stipulated Facts, ¶ 1. Two citrus pests, citrus black spot and sweet orange scab, that exist in these Argentine States are not present in the United States. *Id.* At ¶ 2. APHIS officials visited the Argentina growing areas in May 1994 and determined that they could not fully assess the risk of citrus black spot and sweet orange scab under the protocol proposed by Argentina. 1994 Trip Report, AR 591. In 1995, APHIS denied Argentina’s petition “unless pest free areas can be established or treatments can be approved” for the two diseases. Decision on Entry Status, AR at 2386. Consequently, at the request of APHIS, Argentina conducted research and surveys and submitted reports on the research to APHIS in support of its petition. Statement of Stipulated Facts, ¶ 3.

In September 1997, APHIS prepared a Supplemental Plant Pest Risk Assessment (“Risk Assessment”) to evaluate the likelihood that plant pests and citrus diseases from Argentina would be introduced into the United States if commercial shipments of Argentine citrus to the United States were allowed. *Id.* at ¶ 4, AR at 1-110. The Risk Assessment consists of four basic components:

(1) Scenario Analysis: First, APHIS conceptualized the events (probability nodes-“P”) that must occur before introduction of a quarantine pest. AR at 28-30, 32. The nodes that must take place before a pest is introduced into the United States are that the pest has: infected/infested the harvested fruit (P1), avoided detection at harvest (P2), avoided detection at the packinghouse (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 or life cycle (P8). P1-P4 occur in Argentina. P5-P8 happen in the United States.

(2) Mathematical Model: Second, APHIS constructed a mathematical model to use for the risk assessment. AR at 30. To estimate the annual likelihood of pest introduction, APHIS multiplied together nine numbers – the eight probability nodes above and the estimated annual number of imported boxes of Argentine citrus (F1). To estimate the effect of mitigation, APHIS used the mathematical model separately for all four pests with (“mitigated program”) and without (“baseline program”) specific mitigation measures anticipated to be contained in the proposed rule.

(3) Input Probabilities: Third, APHIS estimated the input values for F1 and P1 through P8 for each pest with and without specific mitigation measures. AR at 30-49, 2022-2052. APHIS used a range of values for F1 and P1 through P8, instead of a single value point because of the uncertainty involved in risk assessment. AR at 5. APHIS based the estimates needed for its input values on data provided by Argentina, pest interception records, the known biology of 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.

(4) Computer Simulations: Finally, the last step involved quantitative analysis with randomly selected values that were entered into a computer program. AR at 30-31.

The Risk Assessment concludes that without using mitigation measures, there is a high likelihood for the introduction into the United States of fruit flies and sweet orange scab, a medium likelihood for citrus black spot, and a low likelihood for citrus canker. AR at 49-50. However, APHIS determined, based on the Risk Assessment, that the likelihood of pest introduction into the United States would be reduced to a negligible level if the mitigation measures set forth in the Argentine Citrus Rule were applied. AR at 1952. APHIS did not establish a level above which the risk would no longer be negligible.

On August 12, 1998, APHIS published a proposed rule to allow the importation of citrus fruit from Catamarca, Jujuy, Salta, and “”Tucuman into the United States in accordance with the provisions of the proposed rule. *See* 63 Fed. Reg. 42117, AR at 111-122. Following a 180 day period for public comment, APHIS published a final rule on June 15, 2000, allowing the importation of lemons, grapefruit,

oranges from Catamarca, Jujuy, Salta and Tucuman in accordance with the provisions of the rule. See 65 Red. Reg. 37608-69, AR at 1951-1981.

APHIS prepared an economic analysis and determined that the rule “[would] not have a significant economic impact on a substantial number of small entities.” 65 Fed. Reg. At 37667, AR 1980B. Based on that determination, APHIS did not prepare a Regulatory Flexibility Analysis for the rule pursuant to 5 U.S.C. § 605. Id. APHIS also prepared an Environmental Assessment and issued a Finding of No Significant Impact, which concluded that the rule “would not have a significant impact on the quality of the human environment.” AR at 2010-11. Based on the finding, APHIS did not prepare an Environmental Impact Statement for the final rule pursuant to. Id.

The final rule proposes a systematic approach to the importation of grapefruit, lemons and oranges from Argentina. The final rule, at 7 C.F.R. § 319.56-2, states:

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 requirements.* The grapefruit, lemons, or oranges must have been grown in a grove located in the region of 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, and 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 Agrealimentaria (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 was obtained 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 the 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. 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 most likely to have infected, symptomatic fruit (i.e., near the outer, upper part of the canopy on the sides of the tree that receives 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 paragraphs (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 damages 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 hypochloride (chlorine) at a concentration of 2000 parts per million for 2 minutes;
 - (ii) Immersion in orthophenilphenate of sodium;
 - (iii) Spraying with imidazole; and
 - (iv) Application of 2-4 thiazailil 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 fruit.
 - (6) The fruit must be packaged 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, and 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 accomplished by a phytosanitary certificate issued by

SENASA that states the grapefruit, lemons, or oranges were produced and handled in accordance with the requirements of paragraph (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 of Argentina of Mediterranean fruit fly (Medfly) (*Ceratitis capitata*) and fruit flies of 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 Section 330.1 of this chapter. The cold treatment must be conducted in accordance with the requirements of Section 310.56-2d of this subpart.

(f) *Disease detection.* If, during the course of any inspection or testing required by this section or Section 319, 56-6 of this subpart, or at any other time, citrus black spot or sweet orange scab is detected in 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 expert 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 200 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 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) *Port 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 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.

65 Fed. Reg. At 37688-69, AR 1980C-1981.

Plaintiffs, four California citrus growers and a coalition of more than 5,000 other growers of lemons, oranges and grapefruit in Arizona and California, seek judicial review of the final rule. Both plaintiffs and defendants move for summary judgment.

In connection with defendants' motion for summary judgment, defendants filed a declaration from Dr. Michael Firko and attached the curriculum vitae of four of the five APHIS lead scientists who conducted the Risk Assessment. The lead scientists were Dr. Michael Firko, Dr. Mary Palm, Dr. Edward Podleckis, Dr. Gary Cave and Mr. John Lightfield. Dr. Michael Firko has a PhD in Ecology and Population Biology from the University of Pennsylvania and is currently the Assistant Director of Plant Health Programs for Permits and Risk Assessment at USDA, APHIS, PPQ. Firko Decl. ¶ 1. Dr. Palm has

a PhD in Plant Pathology (Mycology Emphasis) from the University of Minnesota. She is a mycologist with the USDA/APHIS/PPQ Biological Assessment and Taxonomic Support and an associate adjunct professor at Penn State University. *Id.* Dr. Edward Podleckis received his PhD in Plant Pathology/Plant Virology from the University of Maryland. *Id.* He is a senior plant pathologist with the USA/APHIS/PPQ Commodity Risk Analysis Staff. *Id.* Dr. Gary Cave has a PhD in Entomology from Louisiana State University and is a senior entomologist with the USDA/APHIS/PPQ Commodity Risk Assessment Staff. *Id.* Finally, John Lightfield, was a risk analyst with USDA/APHIS. Firko Decl. ¶ 2(b).

Plaintiffs also filed a declaration from their expert, Dr. Edmund Crouch, in connection with their summary judgment motion. Ex. A to Plaintiffs' Summary Judgment Motion. Dr. Crouch is a senior scientist at Cambridge Environmental Inc., a toxicology and risk assessment consulting firm. Crouch Affidavit, ¶ 1. He has a B.A. in Natural Sciences (Theoretical Physics) and a PhD in High Energy Physics -- both from the University of Cambridge, England. He specializes in issues relating to quantitative health and environmental risk assessment. *Id.* at ¶ 2.

II. Standard of Review

Section 706 of the Administrative Procedure Act ("APA"), provides in pertinent part:

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be – (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . [or] (C) in excess of statutory jurisdiction, authority, or limitations . . .

5 U.S.C. § 706. In considering whether an agency's decision is arbitrary and capricious, the court "must determine whether the decision was based on a consideration of the relevant factors or whether there has been a clear error of judgment. This inquiry must be searching and careful, but the ultimate standard of review is a narrow one." Morongo Band of Mission Indians v. Federal Aviation Adm., 161 F.3d 569, 573 (9th Cir. 1998). The standard of review is deferential; thus, the court cannot substitute its judgment for that of the agency. Wetlands Action Network v. United States Army Corps of Eng'rs, 222 F.3d 1105, 1114 (9th Cir. 2000).

"Deference to an agency's technical expertise and experience is particularly warranted with respect to questions involving . . . scientific matters." Friends of the Clearwater v. Dombeck, 222 F.3d 552, 556 (9th Cir. 2000) (quoting United States v. Alpine Land and Reservoir Co., 887 F.2d 207, 213 (9th Cir. 1989)). "When specialists express conflicting views, an agency must have discretion to reply on the reasonable opinions of its own qualified experts even if, as an original matter, a court might find contrary views more persuasive." Greenpeace Action v. Franklin, 14 F.3d 1324, 1332 (9th Cir. 1992) (quoting Marsh v. Oregon Natural Resources Council, 490 U.S. 360, 378 (1989)). Once the court is satisfied that an agency's exercise of discretion is informed, the court must defer to that informed discretion. *Id.*

However, the court evaluates the agency decision based on the record the agency presents to the court. Florida Power v. Light Co. v. Lorion, 470 U.S. 729, 744 (1985). Unless an agency describe the

standard under which it has arrived at its conclusion, the court has no basis for exercising its responsibility to determine whether the agency's decision is arbitrary, capricious, an abuse of discretion, or otherwise in accordance with the law. Ober v. Whitman, 243 F.3d 1190, 1195 (9th Cir. 2001). An agency must cite to information to support its position; without data the court owes no deference to an agency's line-drawing. Id.

Summary judgment is appropriate where there is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter of law. Fed. R. Civ. P. 56(c). The party seeking summary judgment bears the initial burden of proof that there is no genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). However, rule 56(c) requires the nonmoving party to go beyond its pleadings to prove specific facts showing a genuine issue for trial. Id. at 324.

III. Plant Quarantine Act

A. Negligible Risk Term Used by APHIS

The Plant Quarantine Act gives the Secretary of Agriculture authority to restrict importation of fruits from pest-infested localities. 7 U.S.C. § 160 provides in part:

Whenever, in order to prevent the introduction into the United States of any tree, plant, or fruit disease or of any injurious insect, new to or not theretofore widely prevalent or distributed within and throughout the United States, the Secretary of Agriculture shall determine that it is necessary to forbid the importation into the United States of any . . . plants, fruits . . . or other plant products from a country or locality where such disease or insect infestation exists, he shall promulgate such determination, specifying the country and locality and . . . plants, fruits . . . or other plant products which, in his opinion, should be excluded. Following the promulgation of such determination of . . . plants, fruits . . . or other plant products specified in the said promulgation . . . is hereby prohibited.¹

An agency's construction of its governing statute is entitled to deference provided Congress has not directly addressed the precise question at issue. Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 847 (1984). "[I]f the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." Id. The agency's construction need not be the only interpretation that the agency could have

¹ The Plant Quarantine Act was repealed by the Plant Protection Act which Congress enacted on June 20, 2000. See 7 U.S.C. § 7758. However, the Plant Protection Act provides "[r]egulation issued under the authority of a provision of law repealed by subsection (a) shall remain in effect until such time as the Secretary issues regulation under section 7754 of this title that supersedes the earlier regulation." 7 U.S.

permissibly adopted or even the reading he court would have reached if the question initially had arisen in a judicial proceeding. Id. at 843 n.11.

In Ober v. Whitman, the Ninth Circuit reviewed the EPA's authority to exempt de minimis sources of pollution from the Clean Air Act. 243 F. 3d at 1193. The court concluded that the "EPA, in discharging its duty to enforce the Act, is permitted under Chevron to exempt de minimis sources of PM-10 from pollution controls." Id. at 1195. Next, the court addressed the selection of the de-minimis levels. Id. "Although EPA has the authority to exempt de minimis sources of PM-10, the selection of de minimis levels does not escape judicial scrutiny." Id. The court stated, "We therefore defer to the agency's judgment only if EPA has provided a full explanation of its de minimis levels and its application of those levels to sources of pollution." Id. Because the EPA defined a de minimis source of PM-10 pollution in the Phoenix area as any source that contributed less than one microgram per cubic meter of PM-10 for the annual standard and less than five micrograms per cubic meter to a location for the 24-hour standard, the court denied review of the EPA's final action. Id. at 1198.

Plaintiffs argue that by applying an undefined standard of "negligence risk," APHIS acted arbitrarily and capriciously. Plaintiffs maintain that APHIS did not define what it meant by "negligible level" even though some commentators told APHIS that negligible risk was undefined and impossible to determine. Plaintiffs further argue that the undefined negligible risk standard exceeded APHIS' statutory authority and effected an unconstitutional delegation of legislative power. According to plaintiffs, the Secretary's quarantine regulations should "prevent dissemination into the United States of plant pests, plant diseases, or insect pests." Plaintiffs contend that the negligence risk standard used by APHIS does not related to the statutory standard of preventing the dissemination of plant pests, plant diseases or insect pests into the United States. Plaintiffs argue that the risk assessment does not address how the pest risk potential becomes "negligible" if mitigation measures are followed. Plaintiffs seek to have the court declare that APHIS exceeded its authority by applying an undefined standard of "negligible risk" that allows it to exercise arbitrary discretion without meaning and that differs from the more protective standard Congress intended to apply – i.e., to prevent the introduction of exotic plant pests and diseases.

.C. § 7758 (c). The court discusses the Plant Quarantine Act rather than the Plant Protection Act because APHIS issued the final rule in 1998, prior to the enactment of the Plant Protection Act.

Defendants maintain that APHIS routinely permit the importation of agricultural commodities where the risk of pest introduction has been reduced to an insignificant or negligible level rather than a zero level. Defendants also contest plaintiffs' reading of the Plant Quarantine Act. Defendants contend that nothing in the statute itself, the legislative history, or case law supports plaintiffs' position that the Plant Quarantine Act precluded APHIS from allowing agricultural products to be imported into the United States unless APHIS finds that there is no risk of plant pest introduction. Defendants cite to an unpublished opinion, Oregon Natural Resources Council v. APHIS, Nos. C95-4066 and C96-1541 (N.D. Cal. Feb. 27, 1997), for the proposition that Congress delegated discretion to the Secretary to determine what level of risk is consistent with the Plant Quarantine Act's goals of preventing the introduction and dissemination of plant pests from abroad.

The court finds that the Plant Quarantine Act permits the Secretary of Agriculture to determine whether and when to impose restrictions on importation to protect United States.

Whenever, in order to prevent the introduction into the United States of any tree, plant, or fruit disease or of any injurious insect, new to or not theretofore widely prevalent or distributed within and throughout the United States, the Secretary of Agriculture shall determine that it is necessary to forbid the importation into the United States of any . . . fruit . . . from a country or locality where such disease or insect infestation exists, the Secretary shall promulgate such determination.

The statute authorizes the Secretary of Agriculture to prohibit or restrict the importation of plants and plant products in order to prevent the introduction of any plant pest new to the United States or not known to be widely prevalent or distributed within the United States. See The Prof'l Plant Growers Ass'n v. Dep't of Agric., 942 F. Supp. 27, 28 (D.D.C. 1996). Thus, APHIS has authority under the Plant Quarantine Act to permit, prohibit, or restrict the importation of fruit from other countries.

However, although APHIS has the implicit authority to permit the importation of citrus from other countries, APHIS exceeded this authority by failing to define "negligible risk" in the context of the Argentine Citrus Rule. Unlike the court in Ober, this court has no basis for determining whether APHIS' decision is arbitrary, capricious or an abuse of discretion because APHIS does not describe the standard under which it concluded that citrus could be imported from the four Argentine States of Catamarca, Jujuy, Salta, and Tucuman. While the EPA in Ober defined the de minimis level at one microgram per cubic meter for the annual standard and five micrograms per cubic meter for the 24-hour standard, here, APHIS did not

provide a negligible risk threshold for each of the four pests. This failure is of particular concern given that the risk increased significantly when APHIS reevaluated its risk assessment.

Therefore, the court remands the final rule to APHIS so that APHIS may develop a specific negligible risk level for each of the four pests.

B. Systems Approach

Plaintiffs contend that the final rule is arbitrary, capricious and an abuse of discretion because APHIS' conclusion that the risk of pest introduction is negligible is not supported by the administrative record. Plaintiffs criticize the systems approach used by APHIS to reach its conclusion that the risk of sweet orange scab and citrus black spot is negligible. Plaintiffs contend that the systems approach will not be as effective as the agency hopes because there are problems to the system approach. According to plaintiffs, the problems include:

Focus on Individual Groves: The rule requires that any grove in which fruit Destined for export to the U.S. is grown must be registered and surrounded by a 150-meter buffer zone within which grove cleaning and fungicide requirements apply. These requirements apply to individual groves, not large geographically defined regions. This grove-specific approach is one that APHIS scientists earlier (in the 1994 trip report) had said could not be considered for fear that disease pathogens from the non-registered grove in the same region will be able to move across the buffer zone and infect a registered grove.

Grove Cleaning: Under the rule, grove cleaning must be carrier out before the trees in the grove blossom. The rule does not require that grove cleaning continue after the trees blossom, even though the data Argentina submitted show that leaf fall may continue to a significant extent after that time. Dampened fallen leaves may be a fertile source of citrus black spot infection.

Holding Period for Packing House Inspections: The rule provides that after a Four-day holding period at room temperature in the packing house, the fruit Must be inspected to verify its freedom from citrus black spot and sweet orange Scab. However, as APHIS concedes, fruit with latent citrus black spot inspection Is not likely to develop symptoms during a four-day holding period, particularly In a cool packing house, so these inspections are very unlikely to detect infected Fruit.

Packing House Chemical Treatments: The rule provides that the fruit is to be subjected to certain chemical treatments at the packing house. However, as APHIS acknowledges, Argentine data show that these post-harvest treatments have little to no effect in killing the citrus black spot fungus or preventing symptom development.

Supervision: APHIS states that "strict adherence to risk mitigation measures" is Required to provide "an appropriate level of protection," and it "agree[s] that an effective verification and enforcement system is essential to the success of any systems approach." Yet the rule does not require any "APHIS supervision of the activities of the citrus export program carried out in Argentina, where virtually

all steps of the Systems Approach occur. This contrast with other cases, where the rule provide for on-site monitoring by APHIS inspectors.

Plaintiffs contend that the systems approach is also questionable because it relies on survey data submitted by Argentina and on a flawed risk assessment.

With respect to the survey data from Argentina, plaintiffs argue that the data is inadequate and inconclusive. Plaintiffs maintain that the survey provide little data on the extent of disease infestation in the growing area and no data whatsoever on the extent of insect infestation. According to plaintiffs, this is of concern because the level of infestation in the host is the key component in the design of the systems approach. Moreover, the effectiveness of the pre-harvest pesticide spaying a step in the Systems Approach – varies with the severity of the disease incidence. Thus, when citrus black spot infection in untreated oranges was 14%, the 0.18% copper oxychloride fungicide treatment reduced the incidence of the infection to 1.2% but when the incidence of CBS in untreated oranges was 82%, the treatment reduced the incidence of CBS to 25%.

Plaintiffs argue that the survey data is insufficient to predict the efficacy of the 0.18% concentration fungicide that will be used by the Argentines. The Argentine data contained only one unreplicated test of the effectiveness of the pre-harvest fungicidal treatment of lemons even though lemons are particularly susceptible to citrus black spot and symptoms can appear in orchards during later stages of fruit development or not until after picking. Plaintiffs maintain that the failure to perform replicate analyses or to conduct studies in different locales and in different years is a significant shortcoming because environmental variable such as different infection rates is not reflected in the study results. With respect to grapefruit, the data provide only one study regarding the pre-harvest fungicide treatment in grapefruit. According to plaintiffs, the black spot symptoms were not eliminated even when the fungicide was applied at a higher concentration than the concentration the Argentines will be using. For oranges, there was survey data for more than one year of pre-harvest treatment. The data showed that citrus black spot infection rates varied from year to year - - 14% in on year and 82% the following year and indicated that when the infection incidence is 82%, the treatment reduced the citrus black spot symptoms to an incidence

of 25%. For sweet orange scab, the data did not evaluate the effectiveness of the pre-harvest fungicidal treatment for lemons or grapefruit and there was only one unreplicated test on oranges.

Plaintiffs also contend that the Argentines did not provide sufficient data to show the efficacy of the post-harvest treatments. No data showed the effectiveness of post-harvest treatments in the case of sweet orange scab. Moreover, the data indicated that the post-harvest treatments had little to no effect in killing the citrus black spot fungus or in preventing the expression of the citrus black spot symptoms.

In response, defendants contend that plaintiffs have ignored the wide range of expert information that was available to APHIS scientists. The scientists had information from scientific literature, site-visits to Argentina and the Argentine citrus groves, information about Argentine exports of citrus around the world (including the citrus producing countries). APHIS also had observational information from U.S. officials who visited the export groves who stated the infestation levels were low and anecdotal information from agricultural officials and growers in Argentina that fruit flies were not a problem. Defendants maintain that APHIS accounted for the lack of field survey data and the resulting uncertainty by constructing input distributions covering nearly the entire range of probability.

Defendants also challenge plaintiff's contention with respect to the pre-and post-harvest fungicide treatments. With respect to pre-harvest fungicidal treatment of lemons, defendants assert that plaintiffs failed to note two earlier pre-harvest studies submitted by Argentina. The efficacy studies of the pre-harvest fungicide treatment were conducted over a variety of locations in different years. With respect to the post-harvest data for citrus black spot disease, APHIS acknowledge that the post-harvest fungicide treatment would have little mitigating effect but retains the step because it is used by the citrus industry to prevent post-harvest decay by other fungi and bacteria.

Defendants further maintain that in 1995 and 1996, Argentina provided no less than six studies and submitted additional data when APHIS requested more information. In addition, Argentina submitted results of studies performed at the request of APHIS to test the overall efficacy of the proposed systems approach for both sweet orange scab and citrus black spot.

Defendants further note that they did not directly use the field survey data to calculate the input values. Rather, the data was indirectly used along with other sources of scientific and regulatory data information to calculate input distributions for probability values, consistent with recognized processes for the preparation of a phytosanitary risk assessment.

Plaintiffs also challenge the Risk Assessment conducted by APHIS. The Risk Assessment consists of eight separate stages (or “nodes”), each of which corresponds to a step in the Systems Approach – e.g. application of fungicides – or to an event independent of the Systems Approach – e.g. the likelihood that pickers will identify and cull infected fruit during harvest. For each node, APHIS assigns a probability value that reflects APHIS’ estimate of the likely probability of events such as the percentage of citrus black spot-infected fruit escaping detection at harvest. The probability values are based on a “risk unit,” which is defined as an 18-kilogram box of fruit. For each node, the assigned probability value is per risk unit. The probability values are multiplied by each other and the product of the multiplication is then multiplied by the number of risk units which APHIS estimates will be shipped from Argentina each year (1.2 million boxes of fruit). The result is an overall estimate of the annual risk of pest introduction for the total number of “risk units” involved. Separate calculations are made for citrus black spot, sweet orange scab, citrus canker and fruit flies.

Plaintiffs criticize the probability values used by APHIS. According to plaintiffs, there was no empirical data to support the input values used for almost every node in the scenarios for sweet orange scab and citrus black spot. In the absence of direct data, APHIS selected input values based on expert judgment or expert information. Plaintiffs contend that APHIS’ failure to document the basis for input value in the Risk Assessment is a critical flaw because it is important to document the basis of the risk assessment so that readers can assess the validity of the information in the risk assessment.

In opposition, defendants contend that plaintiffs’ criticism is misguided. Defendants argue that many nodes do identify data and other information in a sufficiently transparent manner for the public to understand how the input values were adopted. For example, the input values of the black spot inspection rate after mitigation measures (P1) were based on several sets of field

survey data showing the effect of the treatment measures on the infection rates. In four sets of data, no indication of citrus black spot was detected in two cases, 1.85% of treated grapefruit was detected in the third case and, in a year that was particularly favorable to disease detection, 11% of oranges were found to be infected. The input value for each node was not a single number but a range of values that took into consideration variations that might occur due to differences in rainfall, humidity, and temperature in order to account for all possibilities. The values were estimated using data, published information, and professional judgment as to all components that could affect the particular node. The Risk Assessment cite to 162 separate documents from primary scientific literature. Another 13 other documents (e.g. regulatory documents, memos and letters) were cited in the Additional Information provided by the final rule. Where there was no field survey data, APHIS scientists relied on their expert judgment to select a reasonable range of values as input values for the nodes.

Plaintiffs also challenge the risk unit used by APHIS. They argue that APHIS' use of a 18-kilogram "box of fruit" (which consist of 150 lemons, 100 oranges, or 50 grapefruit) as a risk unit does not correspond to physical reality because the fruit is not in boxes for six out of the eight nodes in the Risk Assessment. Moreover, an 18-kilogram box holds differing amounts of fruit, depending on whether lemons (150), oranges (100), or grapefruit (50) are placed in the box. Plaintiffs also maintain that the probability values describing the probability of infestation was per fruit, not per box. Plaintiffs also maintain that the probability values describing the probability of infestation was per fruit, not per box. They contend that the data regarding the black box infection incidence ranging from 14% to 82% must have been on a per fruit basis because a predicted infection rate of 0.003 per fruit ($0.5 \text{ infection rate per box} \div 150 \text{ lemons/box} = 0.003 \text{ infection rate per lemon}$) at Node P1 makes no sense. Thus, plaintiffs infer that the 0.5 infection rate must have been per fruit rather than per box. Plaintiffs argue that because the risk unit is per fruit rather than per box, the risk is 150, 100 or 50 times higher than the risks APHIS reported, depending on the fruit being imported. They contend that the per fruit risk unit would alone increase all annual risks of pest introduction calculated in the risk unit by a factor of 150, 100 or 50 depending on the fruit.

Plaintiffs argue that the same is true for Node P2, where APHIS estimates that fruit infected with citrus black spot will escape detection at harvest is 50% in the baseline scenario (i.e., without application of the systems approach). Plaintiffs argue that this percentage implies that an individual black spot infected lemon has only a 0.3% probability of escaping detection at harvest (50% per box divide 150 lemons/box = 0.3% per lemon). Because the result makes no sense to plaintiffs, they contend that the probability value in Node P2 must be per fruit and not per box.

In opposition, defendants maintain that APHIS used the proper risk unit. They argue that plaintiffs' arguments are premised on a misinterpretation of the scientific data and a baseline refusal to accept APHIS' statements, both in the Risk Assessment and the supplemental material. Defendants contend that plaintiffs' extrapolation of a 0.3% detection per fruit derived from APHIS' estimate of a 50% detection per box in the baseline scenario is wrong because it is based on the assumption that every fruit in a grove is infected. Defendants maintain that even in citrus black spot infected orchards, diseased fruit will be rare. Where infection is detected, growers will promptly treat the orchard to abate the problem. Moreover, defendants point out that Argentina has been shipping lemons and other citrus to other citrus-producing countries such as Spain for decades without the protection of the systems approach used for the citrus exported to the United States; yet, no disease introductions have occurred in those countries. Defendants also criticize plaintiffs for ignoring the fact that the risk assessment is a probability assessment. A distribution with a mean of 0.5 has values that range from 0.06 to 0.94. The distribution curve takes into account that in some years and for some groves, infection rates will be relatively high.

With respect to the systems approach, diseased fruit allegedly will be even more rare than the baseline scenario. Defendants point to a 1996 test that showed the effectiveness of the systems approach after a grove was subject to the systems approach. After packing, 300 boxes of oranges and 300 boxes of lemons were selected and examined for both sweet orange scab and citrus black spot. None of the roughly 30,000 oranges and 45,000 lemons that were examined showed disease symptoms. Defendants also note that after the first year of importation of Argentine citrus into the United States, not a single diseased fruit has been detected at the points of entry.

Plaintiffs also contend that the risk assessment is confusing and internally inconsistent. For example, Node P1 and Node P3 both refer to the 20-day pre-harvest sampling, incubation and laboratory analysis of fruit to detect citrus black spot infection; thus, according to plaintiffs, it is unclear whether the 20 day pre-harvest sampling was for Node P1, P3 or both. Additionally, in Node P2, the baseline scenario assumes a detection rate of 0.5 at harvest and a 0.1 rate under the mitigated scenario. According to plaintiffs, this makes no sense because there is no mitigation for citrus black spot in P2 since P2 involves the baseline culling of blemished fruit in the field. Moreover, culling is not required under the final rule and is not likely to be effective in identifying citrus black spot infection because the symptoms of citrus black spot tend to be latent until after harvest and thus would not be obvious to pickers.

Furthermore, plaintiffs contend that the nodes do not appear to be independent because APHIS states that the reduced frequency of the latent infection in Node P1 of the mitigation scenario for citrus black spot results in fewer diseased fruit escaping detection in Node P2. According to plaintiffs, APHIS appears to have considered expert information relevant to Node P6 (i.e. likelihood that infected fruit will be introduced into a citrus producing area with a summer rainfall climate) and P7 (i.e. the likelihood that the infected fruit will be in very close proximity to hanging fruit) when it estimated Node P8 (i.e. the likelihood that citrus black spot pathogen will be able to complete its disease cycle). Moreover, plaintiffs contend that the fruit fly mitigation scenario, P8 (i.e. the likelihood that fruit flies completing their life cycle), also shows dependence on P5 (i.e. cold treatment administration). APHIS assumed that the likelihood of fruit flies being able to complete their life cycle was lower in the mitigation scenario than in the baseline scenario because the cold treatment administered in P5 would reduce the number of live fruit flies entering the U.S. and available for mating.

Defendants concede that the APHIS scientists made a mistake when they failed to assume that only groves that had passed the 20 day pre-harvest test were being considered as sources of fruit in the mitigated scenario when they estimated the input values in P1, P2 and P3. When estimating P1, the team wrongly considered all export groves wishing to participate in the U.S. export program; thus, the failure rate at P1 was overestimated. At P2 and P3, the experts

incorrectly considered the results of the 20-day pre-harvest incubation as a factor for why fruit would be identified and removed, leading to an underestimation of the failure in P2 and P3. Although APHIS assumed that the mistakes were minor, it reconvened the scientists. Working with the correct assumptions, the team re-estimated the affected input values. The mean value for the risk of citrus black spot infection increased from one chance in 3.2 million to one chance in 763,000. The 95% percentile chance increased from one chance in 840,000 to one chance in 189,000. Defendants contend that the risk is still appreciably lower than the risk of fruit fly introduction, where there is one chance in 350,000 for the mean and one chance in 93,000 for the 95% percentile value. Because the risk level for fruit fly introduction was acceptable to APHIS, defendants argue that the new risk estimate for citrus black spot infection does not warrant remand of the case to APHIS because the citrus black spot risk is still lower than the risk of fruit fly introduction.

Defendants also challenge plaintiffs' assertion that some of the nodes are dependent. Defendants contend that plaintiffs misquoted APHIS' Risk Assessment by stating that "APHIS says that 'reduced frequency of latent infection [from node P1] would result in fewer citrus black spot diseased fruit escaping detection' in node P2." Defendants maintain that the bracketed statement was added by plaintiff and that the statement is false because APHIS' statement was meant to compare the mitigated scenario with the baseline scenario. Defendants further contend that APHIS was comparing between the baseline scenario and mitigated scenario when it concluded that fewer number of fruit flies in the mitigated scenario would reduce the likelihood of fruit flies completing their life cycle at Node P 8.

Plaintiffs also criticize defendants for not dispersing the preliminary risk assessment for peer review. Plaintiffs acknowledge that the drafts were circulated to state agriculture officials for comment but argued that this did not amount to a complete and thorough peer review. Plaintiffs maintain that APHIS should have sought review from professional risk analysts.

In opposition, defendants contend that the Risk Assessment and its methodology were subject to peer review. The Harvard Center for Risk Analysis Expert Workshop reviewed and

praised APHIS' risk assessment model for the importation of Japanese Unshu oranges as its case study – the same risk assessment model used in the Argentine citrus Risk Assessment.

Defendants also maintain that APHIS solicited and received extensive scientific comment on the application of its risk assessment model. The first draft of the preliminary risk assessment focused on the identification of quarantine pests and was sent to state and federal agricultural officials in all citrus-producing states (Arizona, California, Florida, Louisiana, Texas and Hawaii) for their comment in October 1996. The second draft, which included the probability portion of the analysis, was sent in May 1997. APHIS encouraged recipients to share the draft with entomologists and plant pathologists. In addition, risk analysts were included in the distribution list to citrus-producing states and provided technical feedback to APHIS. Defendants also noted that during the 180 day comment period, a number of risk analysts and the general public commented on the Risk Assessment. APHIS responded to the comments in the preamble to the final rule and prepared 41 pages of additional information regarding the preparation of the Risk Assessment.

Plaintiffs argue that APHIS' decision should be given more exacting scrutiny by the court because APHIS has not previously allowed the importation of fresh fruit from a region infested with citrus diseases. Plaintiffs noted that in recent years, APHIS has allowed imports of citrus fruit from Australia and South Africa only when the fruit is growing in areas free of citrus black spot. In opposition, defendants contend that the systems approach has been used to allow the importation of Japanese Unshu oranges and Chinese Ya pears.

In reply, plaintiffs distinguish the Unshu oranges from the Argentine citrus arguing that the Unshu oranges are known to be resistant to citrus canker whereas lemons (which will constitute more than 99% of Argentine citrus exports to the United States) are particularly susceptible to citrus black spot. In addition, the Unshu oranges are excluded from citrus-growing areas of the United States, while the present rule will allow the Argentine citrus to be distributed anywhere in the continental United States within a few years. Plaintiffs also contend that the reliance on the Ya pear regulation as precedent for the Argentine citrus rule is misplaced because

the disease infecting the Ya pears shows signs of rot or scabbing while citrus black spot infested fruit may be symptomless through packing and shipping.

In response, defendants argue that each system approach for each commodity is unique and designed to address the particular pest/host/area problem; thus, one systems approach cannot be directly compared with another systems approach. Furthermore, defendants state that the USDA has used a systems approach to mitigate diseases and plant pests in a dozen cases without having any diseases being introduced into the United States. Defendant maintain that the systems approach has been used frequently for plant propagative material, like nursery stock, which as a commodity category, has a significant higher intrinsic risk for the introduction of plant pests than consumption items like fruits or vegetables.

The court finds that the systems approach has been used on previous occasions and is an acceptable method for phytosanitary regulation to protect the agricultural economy. Additionally, it makes sense to have a different systems approach for each different imported fruit; thus, a comparison between the approach used in the importation of Unshu oranges and Ya pears with the approach for Argentine citrus is not meaningful. Moreover, the risk assessment was subject to peer review because it was calculated to state and federal agriculture officers in citrus producing states and the risk assessment model was used at a Harvard risk analysis workshop.

Furthermore, while more field data certainly would have made the Risk Assessment more accurate, APHIS did not need additional fields studies before they could conduct the risk assessment. The Risk Assessment was conducted precisely because there was little direct empirical data.² Risk assessment is not a science; rather, it is a way of organizing and using scientific data to support decisions.³ Here, the APHIS scientists who conducted the Risk Assessment are knowledgeable about both the risk assessment process and the relevant sciences underlying he risk assessment. Four of the five lead scientists work as professional biological

² At the Harvard Center for Risk Analysis Expert Workshop, the participants agreed that there was no single approach to be uniformly applied to pest problems. Ex. C to Plaintiffs' Summary Judgment Motion, Gray, et al. , "Principles for Conduct of Pest Risk Analysis: Report of an Expert Workshop," 18 Risk Analysis 775 (Society of Risk Analysis, Nov. 6, 1998). The report also noted that risk assessments relied heavily on expert judgment. Given the data-sparse situation for many pest risk analyses and the fact that decisions often cannot wait for new science to be developed, the value of expert judgment for qualifying key factors was emphasized." Id. at 775-76.

research scientists in areas directly pertinent to the Risk Assessment: Firko (Entomology/Population Biology); Palm (Mycology/Plant Pathology), Rodleckis (Plant Virology/Pathology) and Cave (Entomology). The scientists reviewed the science literature on sweet orange scab and citrus black spot, the field survey data and the regulatory documents relevant to the Argentine citrus. They considered the probability of adverse effects and the consequences should the event occur by using a mean for the input value at each node and running computer simulations to test the input values. They also properly exercised their judgment in choosing the risk unit as per box rather than per fruit and in determining the independent event at each node.

However, the risk assessment is faulty because APHIS scientists failed to link the documents and data to each of the node. One of the principles of risk assessment is the complete and transparent documentation of data used in the assessment. “Any kind of analysis requires a complete and transparent documentation of data considered and used, models and their assumptions and results, sources and justification of parameter values and all other relevant facts In all cases, the standard should be that anyone could understand and reproduce an analysis based on its documentation.” Gray et al., “Principles for Conduct of Pest Risk Analysis: Report of an Expert Workshop,” 18 Risk Analysis 779 (Society of Risk Analysis, Nov. 6, 1998). Although APHIS refers to 162 documents in the Risk Assessment and 13 additional documents in the Additional Information provided with the final rule, the Risk Assessment does not state what information and data was used at each node. Most of the input values were calculated without data and without reference to scientific or regulatory information. For example, for the Program Citrus Black Spot Scenario, at Node P2 – detection at harvest – APHIS states:

Data: None

Expert information: The proposed systems approach is designed to reduce disease incidence (not suppress symptom expression, per se) and to increase the likelihood that diseased fruit, if present, will be detected. This is accomplished through more rigorous inspections and disincentives (e.g., threat of removal from export programs) to allowing diseased fruit to escape detection. The experts predict that under the proposed work plan, more rigorous export standards would result in fewer CBS [citrus black spot] diseased fruit escaping detection. They estimated that, under the conditions of the proposed work

³ Id. at 778.

plan and on a per hoc basis, the percentage of CBS diseased fruit escaping detection at harvest would range from 1 percent to 40 percent with a most likely value of 10 percent.

Distribution: Beta (3,25); Mean: 0.11, Mode: 0.08. There was no scientific information that could be construed as evidence for any particular central tendency value, distribution range, or distribution type. The experts relied on professional judgment to construct a PDF that accurately and precisely represented their understanding of the available information. After discussing available scientific and other information, the group identified the general shape of the distribution that was needed to account for all identified or assumed variation and uncertainty. A discussion ensued to establish the parameters of the chosen distribution. An interactive process was used 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 group succeeded in producing a beta distribution that represented the expert group's understanding of the available information. A consensus approach was used. The group chose a beta (3, 25) distribution to characterize the estimate for the baseline likelihood that harvested fruit would be infected with the black spot fungus. This distribution has a mean of 0.11 and a mode of 0.08. The 5th and 95th percentile values are 0.01 and 0.21, respectively. The distribution captured the full range of variability and uncertainty considered essential by all experts even though it may have represented more uncertainty that was felt necessary by any single expert. The minimum value used in calculations was 0.00, the mode was 0.08 and the maximum was 0.42.

Because the scientists failed to follow the risk assessment guidelines when they constructed the Risk Assessment, the court cannot defer the APHIS' expert determination with respect to the input values for the eight nodes.

Having reviewed the Risk Assessment, the court concludes that the final rule is arbitrary and capricious because it is based on a faulty risk assessment. The uncertain nature of the Risk Assessment is illustrated by the fact that the risk of citrus black spot introduction increased significantly under the revised Risk Assessment from one chance in 3.2 million to one chance in 763,000 for the mean and from one chance in 840,000 to one chance in 189,000 for the 95th percentile. Although the risk is still lower than the risk of fruit fly introduction, where there is one chance in 350,000 for the mean and one chance in 93,000 for the 95th percentile value, the fact that there was a four and a half fold increase in the risk of citrus black spot introduction at the 95th percentile because of faulty assumptions made by the APHIS scientists suggests that APHIS needs to reevaluate the Risk Assessment.

Accordingly, the court remands the final rule to APHIS.

IV. Reliance on SENASA

Plaintiffs criticize APHIS' reliance on SENASA and the Argentine growers to implement, verify

and enforce the complex and labor intensive requirements of the systems approach. On March 30, 2001, the U.S. Citrus Science Council, a plaintiff in the action, filed a rulemaking petition requesting that defendant APHIS suspend and amend the final rule. Plaintiffs base their request on the fact that SENASA affirmatively concealed a significant outbreak of foot-and-mouth disease in Argentina for several months. Plaintiffs question APHIS' confidence in SENASA. Plaintiffs contend that even if there were sound grounds for APHIS to predict that the risk of pest introduction will be negligible, plaintiffs have good reason to be concern because SENASA cannot be depended on for an effective verification and enforcement system.

Defendants agree that SENASA's failure to report the foot-and-mouth disease is of concern. Defendants contend that SENASA's failure to report the foot-and-mouth disease involves the administration of the Argentine citrus rule and not the efficacy of the systems approach or whether the rule is arbitrary and capricious. Defendants state that both the President and SENASA and the Argentine Minister of Agriculture have been replaced after SENASA failed to report the foot-and-mouth outbreak. In addition, APHIS has taken several new and additional steps beyond those contemplated by the final rule to ensure that SENASA is in full compliance with its obligations under the rule.

From March 28 to March 30, 2001, APHIS personnel conducted an unannounced review of SENASA's citrus program. APHIS visited the SENASA offices in Tucuman. They examined SENASA's records and visited a laboratory to verify the presence of sufficient technical personnel, to review records and to ensure that permanent light, temperature and humidity were in the appropriate parameters. In addition, APHIS personnel reviewed the citrus canker survey activities and APHIS randomly selected a citrus grove for inspection where they verified that the rule's grove requirements were being met – e.g. registration, buffer zones, sanitation, oil-copper oxychloride spraying and fruit sampling. Throughout its three day review, APHIS did not discover any irregularities or violations of APHIS' regulatory requirements.

In addition, on March 29, 2001, APHIS finalized a work plan which will provide active and direct monitoring of the Argentine citrus program by APHIS. Each month, APHIS will review all records of Argentina's citrus canker surveillance program, including all phytosanitary data generated by mobile units and control checkpoints on main roadways into canker-free areas. Moreover, every 45-60 days, APHIS

will review all of SENASA's records relating to the growers and packing houses participating in the expert program. APHIS also will inspect participating groves at random from before bloom to the end of harvest to verify sanitation measures, review fungicidal spray records, and observe fruit sampling. In addition, APHIS will visit laboratories conducting the 20-day incubation to verify procedure, analyses, and documentation. APHIS will also inspect the packing houses at random once to twice a month.

Although the work plan addresses some of the concerns raised by plaintiffs with respect to the supervision of the mitigation steps, the work plan is not part of the final rule. Moreover, SENASA's failure to report the foot-and-mouth outbreak does involve the efficacy of the systems approach because administration of the Argentine citrus program is critical to the success of the systems approach. Although the Risk Assessment take human error into content, it may have understated human error in light of SENASA's failure to report the foot-and-mouth disease. Frankly, the court is concern about whether SENASA can be entrusted to enforce the mitigation measures used by the systems approach. Although the president of SENASA and the Argentine Minister of Agriculture have been replaced, the court is not convinced that other SENASA officials who were involved in the coverup have been removed from office.

On remand, APHIS should determine whether it can reasonably rely on SENASA to implement the systems approach.

V. Regulatory Flexibility Act

The Regulatory Flexibility Act requires agencies like APHIS to prepare an initial and final regulatory economic analysis assessing the negative impact of the rule on small businesses whenever it promulgates a new rule. 5 U.S.C. §§ 603, 604. However, the agency does not need to engage in flexibility analysis if the agency head certifies that the rule will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. § 605(b).

With respect to the Argentine Citrus Rule, APHIS determined that it did not need to prepare a regulatory flexibility analysis for the rule even though about 97 percent of U.S. citrus farms considered to be small entities.

Plaintiffs contend that APHIS' certification that the rule would not have significant economic impact is premised on the assumption that the results of the Risk Assessment are reliable. Because

plaintiffs feel that the assumption is false, they request that the court set aside the determination as being arbitrary and capricious.

In opposition, defendants argue that APHIS' determination that there would be no economic impact on small businesses is entitled to deference. Moreover, defendant argue that because the Risk Assessment is a valid basis for APHIS' determination that the risk of pest introduction is reduced to negligible level through the systems approach, plaintiffs' claim with respect to the Regulatory Flexibility Act must fail as a matter of law.

Defendants also maintain that APHIS did evaluate the economic impact of Argentine citrus imports on the U.S. citrus markets. APHIS concluded that consumers, importers and brokers would benefit from the entry of Argentine citrus because the Argentine citrus will be imported during the months when domestic production in the United States is at its lowest. The consumer gains would be equal to or greater than grower losses.

In reply, plaintiffs argue that defendants miss the point when they cite to the economic analysis contained in the final rule. The economic analysis focused on the impact that the Argentine imports would have on the supply and prices of citrus fruit in the United States and the resulting costs and benefits to domestic growers, brokers, importer, and consumers.

Unfortunately, the economic analysis failed to consider what the costs would be if Argentine plant pests were introduced into U.S. citrus orchards.

APHIS determination that the final rule would not have a significant economic impact on a substantial number of small entities is based on its conclusion that there is a negligible risk of pest introduction. Because the court finds the Risk Assessment to be flawed, it remands the final rule to defendants for consideration of the economic impact that the importation of Argentine citrus will have on small businesses.

VI. National Environmental Policy Act

Section 10 of NEPA, 42 U.S.C. § 4332, requires that an environmental impact statement ("EIS") be prepared for every major federal action that significantly affect the quality of the human environment. "An agency must prepare an EIS if 'substantial questions are raised as to whether a project . . . may cause significant degradation of some human environmental factor.'" Greenpeace

Action, 14 F.3d at 1332 (quoting LaFlamme v. FERC, 852 F.2d 389, 397 (9th Cir. 1988)). NEPA's goals are "(1) to ensure the agency will have detailed information on significant environmental impacts when it makes its decision; and (2) to guarantee that this information will be available to a larger audience." Inland Empire Public Lands v. United States Forest Service, 88 F.3d 754, 758 (9th Cir. 1996). NEPA exists to ensure a process, not a result. Id. They agency's decision not to prepare an EIS is evaluated under an "arbitrary and capricious" standard of review. Northern Env'tl. Def. Ctr. V. Bonneville Power Admin., 117 F.3d 1520, 1536 (1997). Using this standard, the court considers whether the agency's decision is based on a "reasoned evaluation of the relevant factors" and the court will overturn the decision only if the agency committed a "clear error in judgment." Id. APHIS decided not to prepare an EIS based on its finding that the rule will not significantly impact the quality of the human environment.

Plaintiffs contend that the finding of no significant impact rests on the faulty premise that the risk assessment provides a reliable assessment of the risk of pest introduction. Plaintiffs argue that APHIS cannot claim to have taken a hard look at environmental consequences when it has wholly ignored the very significant consequences of pest introduction; thus, its failure to prepare an EIS is arbitrary and capricious and a violation of NEPA. Plaintiffs are particularly troubled because they feel that it is reasonably foreseeable that other countries with disease-infested citrus growing area (like Australia and South Africa) will submit petitions requesting that fruit be allowed to enter the United States under a systems approach similar to what has been approved for Argentina.

In opposition, defendants contend that APHIS clearly has addressed the reasonably foreseeable actions under NEPA.⁴ In the final rule, APHIS acknowledged that the overall pattern

⁴ Regulations promulgated under NEPA state that an EIS must consider impacts, which may be (1) direct; (2) indirect; or (3) cumulative. 40 C.F.R. § 1508.25(c). A "direct effect" is an effect "caused by the action and occur[ring] at the same time and place." 40 C.F.R. § 1508.8(a). An "indirect effect" is an effect which is both: caused by the action and . . . later in time or farther removed in distance, but [is] still reasonably foreseeable. Indirect effects may include growth inducing effects and other effects related to induced changes in the pattern of land use, population density or growth rate, and related effects on air and water and other natural systems, including ecosystems. 40 C.F.R. § 1508.8(b). A "cumulative impact" is defined as the impact on the environment which results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (federal or non-federal) or person undertakes such other actions. Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time. 40 C.F.R. § 1508.7.

of growth in trade and travel could increase the risk of pests entering the United States. APHIS then focused on the risk that Argentine citrus posed and concluded that importation would not “substantially elevate” the risk in pest outbreaks. APHIS noted that illegal smuggling posed a greater risk of pest introduction than the importation of Argentine citrus under the systems approach.

In addition, defendants argue that plaintiffs’ speculation regarding other countries seeking a systems approach like the one used for Argentina is too remote a possibility to qualify as a “reasonably foreseeable” action.

In reply, plaintiffs argue that their assumption regarding other countries requesting a systems approach similar to that approved for Argentina is reasonably foreseeable. Plaintiffs cite to the WTO Agreement on the Application of Sanitary and Phytosanitary Measures, art. 2.3, which states: “Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail.”

The court cannot determine whether the conditions in Australia and South Africa are similar or identical to the conditions in the Argentine States of Catamarca, Jujuy, Salta, and Tucuman; thus, it cannot say whether the petitions from Australia and South Africa would be reasonably foreseeable or highly speculative. However, the court need not address the cumulative impact issue because APHIS’ did not prepare an EIS based on its conclusion that the importation of Argentine citrus would have no significant impact on the environment since the risk of pest introduction was “negligible.”

As discussed above, the court finds the Risk Assessment to be faulty. Thus, the court cannot give deference to APHIS’ decision not to issue an EIS. Because APHIS’ finding of no significant impact is based on its questionable conclusion that the risk of pest introduction is negligible, APHIS’ decision not to issue an EIS violates NEPA and was arbitrary and capricious.

ACCORDINGLY, IT IS SO ORDERED that plaintiffs be granted summary judgment and defendants be denied summary judgment.

IT IS FURTHER ORDERED that the Argentine citrus rule is suspended until a new rule is in place. The final rule is remanded to APHIS to address the concerns raised by the court.