



BILLING CODE: 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 319

[Docket No. APHIS-2014-0092]

RIN 0579-AE17

Importation of Lemons From Northwest Argentina

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the fruits and vegetables regulations to allow the importation of lemons from northwest Argentina into the continental United States. As a condition of entry, lemons from northwest Argentina would have to be produced in accordance with a systems approach that includes requirements for importation in commercial consignments; registration and monitoring of places of production and packinghouses; pest-free places of production; grove sanitation, monitoring, and pest control practices; treatment with a surface disinfectant; lot identification; and inspection for quarantine pests by the Argentine national plant protection organization. Additionally, lemons from northwest Argentina will have to be harvested green and within a certain time period, or treated for Mediterranean fruit fly in accordance with an approved treatment schedule. Lemons from northwest Argentina will also be required to be accompanied by a phytosanitary certificate with an additional declaration stating that the lemons have been inspected and found to be free of quarantine pests and were produced in accordance

with the requirements. This action allows for the importation of lemons from northwest Argentina into the United States while continuing to provide protection against the introduction of quarantine pests.

DATE: Effective [Insert date 30 days after date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Mr. Juan A. (Tony) Román, Senior Regulatory Policy Specialist, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1236; (301) 851-2242.

SUPPLEMENTARY INFORMATION:

Background

The regulations in “Subpart-Fruits and Vegetables” (7 CFR 319.56-1 through 319.56-75, referred to below as the 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 within the United States.

On May 10, 2016, we published in the Federal Register (81 FR 28758, Docket No. APHIS-2014-0092) a proposal¹ to amend the regulations to allow the importation of commercial consignments of fresh lemons from northwest Argentina into the continental United States, subject to a systems approach.

We solicited comments concerning our proposal for 60 days ending July 11, 2016. We extended the deadline for comments until August 10, 2016, in a document published in the Federal Register on July 11, 2016 (81 FR 44801, Docket No. APHIS-2014-0092). We received 414 comments by that date. They were from domestic and foreign citrus producers, State and

¹ To view the proposed rule and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0092>.

national organizations representing citrus producers, State departments of agriculture, an organization of State plant pest regulatory agencies, Argentina's national plant protection organization, the Argentine embassy, lemon importers and wholesalers, longshoremen, U.S. ports of entry, Senators, Representatives, an Argentine organization devoted to citrus research, and private citizens. Forty-seven commenters supported the rule as proposed. Seventy-six commenters generally opposed the proposed rule but did not address any specific provisions. The remaining commenters raised a number of issues and concerns about the proposed rule. These comments are discussed below by topic.

One commenter stated that the proposed rule failed to comply with the requirements of the National Environmental Policy Act (NEPA). Specifically, the commenter stated that the proposed rule is a major Federal action that significantly affects the human environment, as set forth in 40 CFR 1508.18 and 1508.27, respectively, and that the Animal and Plant Health Inspection Service (APHIS) should have prepared an environmental impact statement or environmental assessment (EA). The commenter further stated that none of the APHIS categorical exclusions set forth in 7 CFR 1b.3 apply, therefore at a minimum, APHIS is obligated to prepare an EA.

APHIS notes that the APHIS NEPA implementing regulations in 7 CFR part 372 specify that additional routine measures used by APHIS are categorically exempt from NEPA, in addition to those measures set forth in 7 CFR 1b.3. The measures in this rule that will occur within the United States fall within the scope of these additional routine measures. Accordingly, a categorical exclusion was prepared.

We do not agree that the rule meets Council on Environmental Quality requirements for a "significant" Federal action, and thus, by definition, cannot be a "major" Federal action (a type

of significant action). The rule is not contextually significant from a policy standpoint because it does not substantially alter existing policy regarding market access requests, and has severity/intensity only if one concedes that the mitigations specified in the rule are ineffective in precluding the introduction of quarantine pests. We consider them effective, for reasons discussed below.

One commenter stated that APHIS must take all available measures to preclude introduction of invasive species into the United States.

APHIS agrees. Under the Plant Protection Act (7 U.S.C. 7701 et seq.), we are responsible for regulating exports, imports, and interstate commerce in agricultural products and other commodities that pose a risk of harboring plant pests or noxious weeds in ways that are based on sound science and that will reduce the risk of dissemination of plant pests or noxious weeds. For this reason we prepared a pest risk assessment (PRA) and assigned mitigations with a proven track record in the risk management document (RMD).

One commenter noted that APHIS has also recently published proposed rules to allow for the importation of citrus from South Africa (79 FR 51273, Docket No. APHIS-2014-0015) and Chile (81 FR 19063, Docket No. APHIS-2015-0051). The commenter stated that because both of those proposals deal with a disease or pest of concern which is also of concern in the Argentine proposal, APHIS should not finalize this rulemaking until we have responded to the comments on the other proposed rules.

We disagree with the commenter that the other rules must be finalized before we can proceed with this rule. APHIS considers each of its rulemakings as a distinct regulatory action. This is consistent both with the language of the Administrative Procedure Act (5 U.S.C. §§ 551-559) and with case history regarding its implementation.

Site Visits

Many commenters stated that APHIS should conduct an additional site visit before the rule is implemented. Many of those commenters also stated that representatives of State governments and subject matter experts should be involved in the site visit.

APHIS conducted an additional site visit to review the details of the draft operational workplan in September of 2016. In addition to APHIS personnel, a representative from the California Department of Food and Agriculture and a former plant pathologist from the United States Department of Agriculture, Agricultural Research Service (ARS) participated in the site visit as observers. The site visit revealed nothing that would require a revision of the PRA.

Some commenters stated that the site visit should include a holistic review of Argentina's production system. Other commenters stated that Argentina's traceability system provides holistic records of their production system.

APHIS conducted a thorough review of Argentina's traceability system. We looked at the requirements for growers signing up, initial site visits of production sites, ongoing oversight during the growing season, field and packinghouse inspection, approval for movement and the final inspection for phytosanitary certificates. We also reviewed the computer system they use, how users are added, who controls movement and harvest approvals, and who issues phytosanitary certificates. Based on that review, we consider Argentina's traceability system to be robust, and we will use it for traceback as necessary. However, as specified in the proposed rule, we also consider it necessary to be able to identify lots of lemons through the export process, from the place of production to arrival at the port of entry. This establishes traceability beyond the scope of the Argentine domestic traceability system.

One commenter stated that Argentina's traceability system will not be able to trace detections of quarantine pests in U.S. orchards or urban areas back to places of production.

APHIS is confident that if the mitigations in the rule are adhered to, quarantine pests will not be introduced into United States orchards or urban areas.

One commenter stated that Argentina's traceability system has limited utility for citrus black spot (CBS), given its prolonged latency period.

As we explained in the PRA, fruit is not a pathway for CBS.

One commenter stated that the site visit should specifically focus on the infrastructure of the national plant protection organization (NPPO) of Argentina. Another commenter stated that the site visit should specifically focus on NPPO oversight of places of production.

The NPPO of Argentina is the Servicio Nacional de Sanidad y Calidad Agroalimentaria (SENASA). During the September 2016 site visit, we looked at SENASA's infrastructure and asked questions to address their capacity to provide oversight. We remain confident that SENASA will be able to adhere to the requirements of the systems approach.

Some commenters stated that the site visit should specifically focus on identifying pest populations in or near production sites.

During the site visit, we asked questions about pest populations, and we looked ourselves at fruit fly traps and at the citrus for signs of pests. We did not discover anything that requires revisions to the PRA.

One commenter stated that the site visit should specifically focus on organic production sites.

APHIS did specifically ask about organic production. Argentina may in the future ship organic fruit, but currently they do not. Current packinghouse practices include chemical

treatments that are not organic, so any fruit that arrived from an organic production site would lose its organic status during packinghouse processing.

We will ask SENASA about organic production in northwest Argentina, as well as pest control guidelines they have developed for organic producers. We note that there are provisions in the systems approach that preclude the commingling of organic lemons and lemons for export to the United States later in the production chain.

One commenter stated that the site visit should be conducted during the summer months in Argentina.

The 2015 site visit occurred in June, during harvest season in Argentina. For this reason, APHIS considered a second site visit during the September/October timeframe to be sufficient.

One commenter stated that two additional site visits are needed. Specifically, the commenter stated that after the September site visit, a second fact-finding trip should be made to review the harvesting and packing operations in Argentina. The commenter stated that a trip at that time is needed since so many steps in the systems approach take place during the harvesting and packing operations.

APHIS disagrees. As we explained above, the 2015 site visit occurred in June, which is during the harvest season in Argentina. For this reason, we do not consider two additional site visits to be necessary.

Two commenters stated that industry stakeholders should be allowed to consult with trip members on their findings.

APHIS prepared a site visit report outlining the findings of the visit. The site visit report is available on the APHIS Web site at

<https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/proposal-import-lemons-argentina>.

Many commenters expressed concern that the findings of the 2007 site visit are outdated.

The trip in 2007 was conducted by APHIS risk assessors to evaluate pest complexes in Argentina in order to prepare the PRA. Information from this trip served as a baseline primarily for the pest list in the PRA. The PRA, as other commenters noted, has been continually updated since this trip through means that APHIS routinely uses to update PRAs, such as literature review and ongoing consultation with the NPPO of Argentina. More specifically, the PRA was updated in 2014 after publication of new research results on seed transmission of citrus variegated chlorosis (CVC) in citrus. The PRA was also updated in 2014 in response to a new finding of citrus greening, also known as Huanglongbing (HLB), in Argentina. The PRA was reviewed by APHIS personnel at the same time to address comments from Argentina regarding the pest list. Furthermore, APHIS conducted a site visit just last year, in June of 2015, and the information gathered during that visit was used to update the PRA before the proposed rule was published.

Two commenters stated that the 2015 site visit was not a technical review of Argentina's program.

The commenters are mistaken. The 2015 site visit was a technical review of Argentina's program.

Three commenters stated that APHIS did not provide enough information to the public regarding the 2015 site visit to evaluate its adequacy. Two commenters stated that APHIS' slow response to a Freedom of Information Act (FOIA) request for documents regarding the 2015 site visit is an indication of the inadequacy of the trip.

APHIS has received the FOIA request and is in the process of responding to it. The time taken to respond to the FOIA request is consistent with normal timeframes for such requests and not a reflection of the adequacy of the trip.

One commenter stated that APHIS' willingness to conduct another site visit is an indication of the inadequacy of the 2015 site visit.

Usually, APHIS conducts one site visit as close to the implementation of a new systems approach as possible in order to aid in development of the operational workplan. It was therefore entirely in keeping with APHIS policy to conduct the September 2016 site visit prior to implementing this final rule, and is not indicative of flaws in the 2015 visit.

The 2015 site visit team included several APHIS risk managers who have extensive experience in evaluating foreign production systems to determine the ability of those systems to meet requisite mitigation measures.

Pest Risk Assessment

One commenter stated that updated information appears to have been incorporated into the PRA in a piecemeal fashion, without checking whether any conclusions or assumptions were affected.

APHIS notes that we have updated the PRA several times. Appendix 1 of the PRA summarizes updates to the draft PRA in response to public and peer review comments; Appendix 2 summarizes updates to the PRA made between 2008 and 2015 in response to new scientific information. Any time we incorporated new material into the PRA we reviewed the PRA to check the conclusions.

One commenter stated that information provided by SENASA is unreliable.

We disagree with the commenter. We have conducted two site visits during which we have verified the information provided by SENASA. They have also answered all the questions we have asked and provided all information we have requested.

Two commenters stated that stakeholder comments on the PRA appear to have been ignored.

APHIS posts PRAs and other documents for stakeholder review. As noted on the Web site on which the documents are posted, while stakeholder comments may result in changes to the PRA, as well as the RMD and the rule, it is not APHIS policy to compile or post responses to the comments received. This is because these documents are also made available for review and comment along with the rules and notices that propose to grant market access. Any comments that we receive on the documents during that comment period are addressed in a final regulatory action.

APHIS reviewed all of the comments that we received on the PRA and RMD. Certain comments, such as statements agreeing that Brevipalpus chilensis should be listed as a pest of lemons that is known to exist in Argentina, or that green lemons should not be required to be treated for Mediterranean fruit fly (Medfly), required no changes to the PRA or RMD because the commenters' requests were already reflected in the PRA or RMD. Other comments, such as a request to indicate whether the mites B. californicus, B. obovatus, and B. phoenicis (Brevipalpus spp.) were surface feeders, were incorporated into the PRA and RMD.

Other suggested revisions, such as revising the RMD to prohibit the importation of lemons with leaves attached, would have made the rule more stringent than our domestic requirements for the interstate movement of citrus fruit from areas quarantined for pests and diseases of citrus, and were not incorporated for that reason. Similarly, other revisions would

have made the PRA or RMD inconsistent with how other APHIS documents discuss the same pest of concern or mitigation structure.

Finally, certain comments, such as that the NPPO of Argentina could not be trusted to abide by the systems approach, were reiterated during the comment period and dismissed for reasons discussed below under the heading “Risk Management Document.”

One commenter stated that a footnote in the Executive Summary to the PRA seems to define the term “commercially produced,” but in fact only describes conditions of the fruit after harvest and processing. The commenter stated that the term “commercially produced” should be limited to conditions at places of production.

The term “commercially produced” is equivalent to “commercial consignments.” It includes all aspects of the production system: The manner in which the fruit was grown and harvested, the quality of the fruit, the manner in which it is packaged, the quantities packaged, and the requisite accompanying documentation.

One commenter stated that the PRA and proposed rule did not identify pests of concern for Argentine lemons.

The pest list in the PRA identifies pests of lemons that are known to exist in Argentina.

One commenter stated that four pathogens -- Elsinoë australis, Phyllosticta citricarpa, Xanthomonas citri subsp. citri (Xcc), and citrus leprosis virus -- can all infect fruit and stay viable while on the fruit, even though capacity for transmission from infected fruit may be low. The commenter stated that the answer to the question “Can it follow the pathway?” for all four pathogens should be changed to “yes.”

APHIS notes that, while these could follow the pathway, the capacity for introduction or transmission of disease is so epidemiologically insignificant that further analysis was not warranted.

One commenter stated that citrus leprosis virus should have been selected for further analysis in the PRA as it is a quarantine pest likely to follow the pathway.

Citrus leprosis virus is not systemic and cannot be transmitted apart from viruliferous Brevipalpus spp. mites. It can follow the pathway only if it is vectored by the mites. For this reason we do not consider the virus to be a quarantine pest likely to follow the pathway.

One commenter stated that the citation in the PRA to the APHIS domestic fruit fly quarantine and regulations, which address Medfly was outdated and have been replaced with 7 CFR 301.32. The commenter noted that in the current regulations, only yellow lemons are regulated articles for Medfly.

The commenter is correct; the citations were outdated. However, this does not affect the conclusions of the PRA that green lemons are a poor host for Medfly.

Several commenters stated that the pest risk associated with importation of lemons is too high, and that the domestic citrus industry would suffer as a result of pest introductions.

If the mitigations in the rule are adhered to, this pest risk will be mitigated. Furthermore, some of these commenters appear to have overestimated the likelihood of introduction associated with certain of the pests. For example, Cryptoblabes gnidiella and Gymnandrosoma aurantianum have never been intercepted in commercial shipments of citrus from South America. Both are associated with poorly managed or non-commercial citrus, like backyard fruit.

One commenter stated that B. chilensis should have been rated as high risk in the PRA.

APHIS notes that B. chilensis was in fact rated as high risk in the PRA.

One commenter stated that Brevipalpus spp. mites should all have been rated “High Risk.” The commenter cited a scientific article on Brevipalpus mites and the diseases they transmit² in support of this statement.

In that article, Childers and Rodrigues state that the only confirmed vector of citrus leprosis in the Western Hemisphere is B. phoenicis. The other mites are suspected to be vectors, but are not known vectors. Given that we consider B. californicus, B. obovatus, and B. phoenicis to be quarantine pests only insofar as they may vector citrus leprosis virus, and there is some uncertainty regarding the ability of B. californicus and B. obovatus to vector this disease, we consider a medium risk rating to be appropriate. It is also consistent with how we have rated these pests in other PRAs.

More importantly, a high risk rating would not have changed our mitigations for the pests. Under APHIS policy, both medium risk and high-risk pests are subject to pest-specific mitigations beyond port of entry inspection, and the mitigations we prescribed to address Brevipalpus spp. are based on the possibility that they may vector citrus leprosis virus, rather than the risk rating ascribed to the pests.

One commenter stated that the overall risk rating should have been higher.

As we explained above, a higher overall risk rating would not have changed the mitigation structure.

One commenter asked why, if “not be detected at the port of entry” did not impact risk ratings, port of entry inspection is a component of the systems approach.

“Not be detected at the port of entry” was removed as a criterion in the PRA because APHIS does not have enough information about relative likelihood of detection at the port of

² Childers, C. C. and J. C. V. Rodrigues. 2011. An overview of Brevipalpus mites (Acari: Tenuipalpidae) and the plant viruses they transmit. Zoosymposia 6:180-192.

entry to be able to weight this criterion relative to other elements. As a result, this criterion could not substantially impact the risk ratings.

This does not imply that port of entry inspections are an ineffective component of a systems approach. Port of entry inspections by U.S. Customs and Border Protection (CBP) are, in fact, capable of detecting quarantine pests and are a significant mitigation against pests entering the United States. For example, in December 2015, CBP detections of Medfly larvae on Spanish tomatoes and Moroccan citrus led us to suspend market access for those commodities, pending investigations.

One commenter asked why, if fruit is not an “epidemiologically significant” pathway for E. australis, P. citricarpa, and Xcc, the PRA says “additional specified risk management options may be required.”

While we do not consider fruit to be an epidemiologically significant pathway for these pests, the pests are subject to domestic quarantines within the United States. For the sake of consistency with domestic regulations regarding the interstate movement of fruit from areas quarantined for CBS, sweet orange scab, and Xcc, we would require fruit to be washed, brushed, waxed, and surface disinfected. It is worth noting that such washing, brushing, waxing, and disinfecting are standard packinghouse procedures both domestically and internationally.

Likelihood and Consequences of Establishment

Several commenters stated that citrus-producing areas are particularly at risk for establishment of quarantine pests that could follow the pathway.

Incorporating information regarding likelihood of establishment would not have affected the pest risk ratings or the risk mitigation structure. As we explained above, both medium and high-risk pests are subject to pest-specific mitigations beyond standard port-of-entry inspection.

One commenter stated that the PRA does not acknowledge that backyard citrus in California is in proximity to ports of entry. Other commenters stated that the PRA does not recognize that most quarantine pest introductions first occur in urban areas, and are undetected. Three commenters stated that urban areas in Texas and California abut production areas and expressed concern that pests could become established in urban areas with backyard citrus and then spread into production areas.

As we noted above, incorporating this information into the PRA would not have affected either the pest risk ratings or the risk mitigation structure.

One commenter stated that Climate-Host interaction for Brevipalpus spp. should have been rated “high.” The commenter cited a 2012 reference in the Ninth Report of the International Committee of Taxonomy of Viruses³ that said that citrus leprosis virus was transmitted to several other experimental hosts from other genera including Phaseolus vulgaris in support of this statement.

There is no mention in the report of whether the conditions under which transmission to P. vulgaris occurred could be reduplicated outside of laboratory conditions. The sentence the commenter is referring to is immediately preceded by a sentence referring to mechanically administering inoculum to induce symptoms in articles previously considered non-hosts. This, coupled with the use of “experimental” to describe inoculation of P. vulgaris, suggests the study was not intended to reduplicate actual “field” conditions.

³ “Virus taxonomy: classification and nomenclature of viruses: Ninth Report of the International Committee on Taxonomy of Viruses.” (2012) Ed: King, A.M.Q., Adams, M.J., Carstens, E.B. and Lefkowitz, E.J. San Diego: Elsevier Academic Press.

In the PRA, we identified the dispersal potential of B. chilensis as “medium” and of Brevipalpus spp. as “high.” One commenter stated that the dispersal potential for both B. chilensis and Brevipalpus spp. should be high.

The commenter is correct that the dispersal potential for both B. chilensis and Brevipalpus spp. should be the same; however, we disagree that the rating for both should be high. Based on the work of Childers and Rodrigues, the dispersal potential for both should be medium. Both B. chilensis and Brevipalpus spp. are very unlikely to move from one orchard tree to another. They both tend to aggregate, they move downwind slowly, and they do not balloon – that is, they do not produce streamers of silk and travel with wind currents for longer distances.

One commenter stated that the environmental impact potential for Brevipalpus spp. is low, but the introduction of this pest infected with citrus leprosis virus would stimulate the use of chemical control. The commenter stated that the risk rating should therefore be changed to medium. The same commenter also stated that consequences of introduction for Brevipalpus spp. should have been considered high.

We consider the ratings given to Brevipalpus spp. to be accurate. Under standard commercial packinghouse procedures, the mites would be washed or brushed off, even in the absence of required mitigations. Furthermore, citrus leprosis virus is not a systemic infection, and mites do not feed on harvested fruit unless doing so is absolutely necessary for survival.

Accordingly, for a non-viruliferous Brevipalpus mite in the United States to become a vector of citrus leprosis virus, the infected portions of the fruit would have to have abnormally high levels of inoculum, the mite would have to be on infested fruit, and the mite would have to specifically consume the infected portions of the fruit, climb up a tree, and infect the tree.

Since citrus leprosis virus inoculum is not shed to offspring, this would also have to occur during the infected mite's lifetime. We consider the probability of this occurring to be extremely remote.

One commenter stated that the likelihood of introduction for Medfly should have considered lemons a conditional host, rather than a conditional non-host.

The designation of lemons as a conditional non-host of Medfly was based on research published by ARS scientists⁴ that examined the host status of immature lemons.

One commenter stated that the PRA did not consider introduction via smuggling or diversion. The commenter expressed concern that the fruit could be carried to a home while vectoring a pest or disease.

The PRA addressed the plant pest risk associated with the importation of commercially produced and commercially packed fresh lemon fruit from northwest Argentina into the United States. Fruit that is not commercially grown or packed are outside the scope of the risk assessment.

Risk Management Document

One commenter stated that the RMD requirements are inadequate to eliminate the risk of introduction of the quarantine pests identified in the PRA, but did not provide the basis for their concern.

Some commenters stated that the RMD and rule contain safeguards to address plant pest risk, and one commenter stated that similar systems approaches for citrus from other countries have proven effective. One commenter, however, stated that there are no similar systems

⁴ Spitler, G. H., J. W. Armstrong, and H. M. Couey. 1984. Mediterranean fruit fly (Diptera: Tephritidae) host status of commercial lemon. Journal of Economic Entomology 77(6):1441-1444.

approaches because no other growing area harbors this combination of pests and diseases of citrus, but is still asking to market fresh fruit.

APHIS notes that the PRA for citrus from Uruguay had a very similar quarantine pest list -- they did not have B. chilensis or Brevipalpus spp., but had all other quarantine pests identified in the Argentine citrus PRA. Accordingly, many provisions of the Argentine lemons systems approach were modeled on the Uruguay citrus systems approach, which has been in place for 3 1/2 years now without incident. Furthermore, the Brevipalpus-specific provisions are not new, and have been tested for several different commodities in other countries.

Five commenters expressed concern that Argentina cannot be trusted to abide by mitigations in the RMD and rule. Some of these commenters cited incidents that they believed showed Argentina handling sanitary or phytosanitary issues in deceptive ways. One commenter stated that, as a result of the history of SENASA, APHIS needs to exercise continual monitoring and oversight over the program.

Argentina is a World Trade Organization member country and signatory on the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS agreement). As such, it has agreed to respect the phytosanitary measures the United States imposes on the importation of plants and plant products from Argentina when the United States demonstrates the need to impose these measures in order to protect plant health within the United States. The PRA that accompanied the proposed rule provided evidence of such a need. Argentina has demonstrated the ability to comply with U.S. regulations with respect to other export programs.

We disagree with several of the examples cited as recent prevarication by SENASA. APHIS became aware of the presence of A. fraterculus in blueberries in Argentina because of a scientific paper published by Argentina. The disagreement between APHIS and SENASA

regarding the presence of B. chilensis in Argentina was based on differing opinions regarding whether the pest detected had been identified properly. As such, it indicated a difference of scientific opinion, rather than an act of deception.

That said, the 2015 site visit specifically evaluated SENASA's oversight of the Argentine production system for lemons to determine whether the provisions of the systems approach could be implemented and maintained.

Finally, as provided in paragraph (a) of the proposed rule, APHIS would be directly involved in monitoring and auditing implementation of the systems approach in Argentina. A determination that the systems approach had not been fully implemented or maintained would result in remedial actions, including possible suspension of the export program for Argentine lemons.

One commenter expressed concern that the United States Department of Agriculture (USDA) cannot be trusted to abide by mitigations in the RMD and rule. The commenter referred to a scandal at Hunts Point Terminal Produce Market in the Bronx, NY, as an example of USDA personnel accepting bribes and kickbacks. The commenter stated that even if such events are not commonplace, they still must be factored into the risk assessment.

The bribery and kickback scheme referenced by the commenter was revealed in 1999 after a 3-year investigation by the USDA Inspector General and involved Agriculture Marketing Service personnel, who have no role in the implementation of this rule.

One commenter asked why, if the mitigations in the RMD are effective, the PRA discusses likelihood and consequences of introduction.

The PRA follows our guidelines for PRAs. As such, it discusses the likelihood and consequences of quarantine pests that could follow the pathway on lemons from northwest

Argentina to the United States, in the absence of any mitigations. This assessment is a necessary aspect of our evaluation of the risk rating for the pests.

The RMD lists the mitigations that will be applied to prevent pests from following the pathway and being introduced.

Three commenters stated that European Union (EU) detections of CBS on fruit from Argentina indicate the inability of Argentina to follow a systems approach.

We disagree with the EU regarding the transmissibility of CBS via commercially produced fruit. The point of these statements in the PRA and RMD was to point out that Argentina has been able to implement and abide by a systems approach for lemons that rests on SENASA having the wherewithal to meet phytosanitary requirements. We note that the RMD stated that Argentina proposed the EU systems approach to us in its entirety as a mitigation structure, and that we rejected adopting it outright. Furthermore, the systems approach for Argentine citrus to the EU is the same systems approach applicable to U.S. citrus to the EU, indicating they consider us equivalent in terms of ability to adhere to phytosanitary requirements.

It is also worth noting that the EU audit⁵ attributed the detections to a lack of traceability of individual lots of fruit to the production units in places of production, to some packinghouses commingling lemons destined for export with other fruit, and to some producers not applying pest controls for CBS. These mitigations, which were added to the EU directive following the detections, are all aspects of our systems approach. Our systems approach is, in short, more stringent than the EU directive was prior to the CBS detections.

One commenter stated that there is no evidence the EU systems approach for lemons from Argentina is equivalent to the systems approach proposed by APHIS.

⁵ The audit is available online at ec.europa.eu/food/audits-analysis/act_getPDF.cfm?PDF_ID=12522.

The two systems approaches are not equivalent, and we did not suggest they were. Rather, we made reference to the EU systems approach to illustrate that Argentina has the capacity to adhere to a stringent systems approach, so that it is plausible that they could adhere to our systems approach as well. We state in the RMD that Argentina proposed that we simply adopt the EU systems approach, and we rejected that proposal.

One commenter stated that, because of proximity of ports of entry to urban areas, and urban areas to citrus production in the United States, any lapses from systems approach will have dire consequences.

The commenter seems to be assuming that, if infested or infected fruit is shipped to the United States, it will not be detected at a port of entry inspection, and will necessarily result in the introduction of quarantine pests into the United States. This assumption is, in essence, that port of entry inspections are ineffective at detecting plant pests. We disagree with this assumption; port of entry inspections are an effective mitigation and have precluded two potential introductions of Medfly in the last year alone.

One commenter stated that there is no definition or list of criteria for pests of “quarantine significance” in either the PRA or RMD. The commenter asked what the criteria are for determining what pests are of quarantine significance.

The PRA, RMD, and rule use the terms “quarantine significance” and “quarantine pest” interchangeably. In § 319.56-2 of the regulations, we define a quarantine pest as “[a] pest of potential economic significance to the area endangered by it and not yet present there, or present but not widely distributed there and being officially controlled.”

One commenter noted that the RMD says 9 pests of quarantine significance were identified, but the PRA lists 10. The commenter asked for an explanation of this apparent discrepancy.

The PRA acknowledges that CBS could follow the pathway, and is a quarantine pest, but then cites the 2010 PRA, which determined that, even in the absence of packinghouse procedures, fruit is an “epidemiologically insignificant” pathway for CBS, and the conditions that would allow for transmission from fruit are nearly impossible to occur, even in the absence of standard packinghouse procedures. The RMD looked at commercially produced fruit, that is, fruit subject to packinghouse procedures and standard industry practices. This led us to drop CBS from the list of quarantine pests.

One commenter noted that in section 1 of the RMD, guidelines for growers participating in the program are mentioned as needing to be followed. The commenter asked what these guidelines are.

In the RMD, we explain that these are pest control guidelines that a place of production may need to meet in order to qualify for registration with SENASA.

One commenter asked if the operational workplan will contain only SENASA’s requirements.

Generally, the operational workplan pertains to APHIS, the NPPO of the exporting region, and growers, packinghouses, and persons commercially involved in chain of production. It contains details that are necessary for day-to-day operations needed to carry out provisions of the rule and RMD. This one will be no different.

One commenter asked what SENASA’s requirements are under the operational workplan.

SENASA's requirements include everything specified within the RMD: Registration; regular inspections; pest control guidelines; and inspections to determine that treatment guidelines are being adhered to.

Additionally, Argentina has place of production requirements apart from APHIS' requirements that pertain to all citrus groves in the country. These include sanitary guidelines that are developed in consultation with Argentine subject matter experts and address regulated nonquarantine pest populations that could affect marketability of the citrus.

One commenter noted that the RMD specifies that SENASA must ensure that growers are following the "export protocols." The commenter asked what those protocols are, and stated that they should be made available for public review and comment.

The protocols are conditions for export established by APHIS in the operational workplan. The RMD and the regulatory requirements derived from it include a general description of all the phytosanitary measures necessary to mitigate pest risk. The operational workplan specifies details that are necessary for day-to-day operations needed to carry out provisions of the rule and RMD. Operational workplans are available to the public upon request only after a rule has been finalized and the operational workplan has been signed by APHIS and the NPPO of the exporting country. With respect to consulting with stakeholders, APHIS typically conducts outreach and consultation during the risk assessment and management phases.

One commenter stated that section 16 of the RMD should specify that fruit fly detections must fall below a threshold before a registered place of production can resume shipping.

Immature lemons are a poor host of Medfly. Because of this, prevalence levels at a place of production are not germane to whether Medfly are more likely to follow the pathway on

immature Argentine lemons, and it would be incommensurate with risk to cut off a place of production based on Medfly detections.

This policy is consistent with our existing importation requirements for lemons from other countries that have Medfly. We have no reason to believe these existing requirements have been ineffective.

One commenter stated that places of production should be suspended if B. chilensis is found on the lemons during NPPO inspections.

In the RMD, we said place of production “may be suspended” and are “subject to suspension” out of recognition that the investigation could determine that the fruit was clean when it left the orchard, and the pest was introduced later in the production chain.

Two commenters noted that the rule doesn’t contain mitigations for CVC and its vectors. The commenters expressed concern that potential vectors could transmit CVC if they were allowed to hitchhike on exports.

Glassy-winged sharpshooters are the vector of concern for CVC. They are the subject of consistent surveys and are not in northwest Argentina. Were they to spread into northwest Argentina, the sharpshooters would be removed by washing and brushing and standard packinghouse procedures. Additionally, as external feeders, they are easy to detect during phytosanitary inspections and/or port of entry inspections. Finally, CVC cannot follow the pathway of lemons in the absence of a vector.

One commenter noted that the RMD concludes that seeds are unable to transmit CVC directly. The commenter stated that this directly contradicts the regulations in 7 CFR 319.37-2, which consider CVC to be seed-transmitted.

A Federal Order published on May 19, 2016, relieved restrictions on citrus seed for CVC. The Federal Order is available on the APHIS Web site at https://www.aphis.usda.gov/import_export/plants/plant_imports/federal_order/downloads/2016/2016-31.pdf. A rule codifying this Federal Order is in development. The citrus seed pest list prepared in November 2015 is referenced in this Federal Order. The pest list contains our current thinking about the transmissibility of CVC and other citrus diseases via seed.

Four commenters expressed concern that the rule does not contain mitigations for HLB.

APHIS has examined whether fruit is a pathway for HLB, and determined that HLB is not transmitted via fruit. Therefore, mitigations for HLB are not necessary.

One commenter stated that APHIS should not trust SENASA on the scope of the HLB outbreak in Argentina.

Neither the severity of the HLB outbreak in Argentina, nor its distribution, affect whether HLB-specific mitigations need to be included in the rule. As we explained above, HLB is not transmitted via fruit.

The same commenter stated that APHIS should not trust SENASA on distribution of Asian citrus psyllid (ACP), a vector of HLB, in Argentina.

The distribution of ACP in Argentina is not necessary for us to evaluate the risk of it following the pathway via the importation of lemons. As documented in the PRA, standard packinghouse procedures will remove ACP from the fruit. Only commercially produced fruit, which is subject to such procedures and will therefore be free of ACP, can be exported to the United States.

One commenter stated that the PRA should include information about distribution of HLB in Argentina.

APHIS does not consider this information to be necessary, given that HLB is not transmitted via fruit.

One commenter expressed several concerns about CBS. The commenter stated that CBS is impossible to eradicate once introduced, that it can have a lengthy latency period, and that trees infected with CBS are unmarketable.

APHIS notes that we never questioned the quarantine significance of CBS, just its ability to become established via fruit.

One commenter stated that justifications in the PRA for why CBS will not follow the pathway are not accurate. The commenter stated that the PRA assumes farmers in Argentina all farm in the same intensive manner.

The commenter is mistaken. In the systems approach for Argentina lemons, we have incorporated the same mitigations for CBS for that we are using for Florida citrus. These mitigations are based on a separate scientific review, which can be viewed on the APHIS Web site at https://www.aphis.usda.gov/plant_health/plant_pest_info/citrus/downloads/black_spot/cbs-risk-assessment.pdf.

Several commenters stated that APHIS erred in determining that CBS cannot follow the pathway on fruit. Another commenter expressed concern that CBS could become established in Southern California if infected fruit arrived at and were distributed through the Port of Long Beach.

Both Paul et al.⁶ and Magarey and Holtz⁷ ran infection models which found California's climate, including that of Southern California, unsuitable for establishment of CBS. While isolated microclimates in Southern California could result in small pockets of CBS infection, the overall climatic conditions are unsuitable to establishment and spread.

One commenter stated that APHIS did not take into account either the reality of the residential yards in Southern California, or the numerous interceptions of Argentine citrus for CBS symptoms in shipments to the EU in the years since 2010.

These two facts do not affect the conclusion on the 2010 PRA that the establishment of the disease via the movement of fruit requires a combination of biological and climatic conditions that are unlikely to occur.

One commenter stated that the spread of CBS in Florida could be indicative of errors in the 2010 PRA.

The PRA found Florida's environment to be conducive to the spread of CBS, and examined only transmission via fruit. The spread of CBS within Florida could have occurred through a pathway other than fruit, and is not in itself indicative of errors in the 2010 PRA.

One commenter stated that the EU Food Safety Commission in 2014 issued a scientific opinion which deemed the risk of entry of the causal agent of CBS as moderately likely for citrus fruit without leaves.

APHIS notes that the proposed conditions for importation of lemons from northwest Argentina are the same as the conditions we apply to export citrus from the United States. We

⁶ Paul, I., van Jaarsveld, A. S., Korsten, L., & Hattingh, V. (2005). The potential global geographical distribution of citrus black spot caused by Guignardia citricarpa Kiely: likelihood of disease establishment in the European Union. Crop Protection, 24, 297–308

⁷ Magarey, R., Chanelli, S., & Holtz T. (2011). Validation study and risk assessment: Guignardia citricarpa, (citrus black spot). USDA-APHIS-PPQ-CPHST-PERAL/NCSU.

also note that the causal organism of CBS has two life cycle stages: A sexual stage represented by the ascospores of Guignardia citricarpa Kiely and an asexual stage represented by the pycnidiospores of P. citricarpa (McAlpine). These two stages are produced at different times, under different environmental conditions, at different locations on the plant and result in different epidemiological dynamics. The sexual stage of the disease may be found in plants and leaves; the asexual stage of the disease is found on fruit. The correlation between ascospore discharge and infection onset showed that pycnidiospores, the asexual stage, do not play a significant role in the disease cycle. For this reason fruit is not considered to be a pathway for CBS.

Several commenters asked how, if we do not know how CBS got into Florida, we know it cannot follow the pathway on fruit.

The PRA examined the biological and climatic conditions necessary for establishment of CBS through infected fruit, and determined that “the establishment of the disease via this pathway [the movement of fruit] requires a combination of biological and climatic conditions that are unlikely to occur.” It is important to acknowledge, as the EU scientific opinion did, that there are many possible pathways for the introduction of CBS, with some (such as smuggling of nursery stock) significantly more likely to result in establishment.

One commenter asked what circumstances would compel APHIS to require further mitigations for CBS in Argentina’s packinghouses, and what mitigation steps it would be willing to institute in those circumstances.

We have considered the risk of CBS and how to mitigate it. Standard packinghouse procedures, including washing, brushing, disinfecting, treating, and waxing, address that risk effectively. Under the circumstances, we do not believe further mitigations are needed.

One commenter stated that the rule should restrict exports to areas of northwest Argentina that are free of CBS.

For the reasons discussed above, we do not consider this necessary.

Comments on Specific Provisions of the Proposed Rule

One commenter asked why the Provinces of Catamarca and Jujuy were included in the rule when they are not major lemon-producing regions.

As we explained in the proposed rule, SENASA asked for market access for these provinces. We therefore included them in the PRA and found that lemons could be safely exported from these provinces subject to the conditions described in the proposed rule.

One commenter stated that Brevipalpus spp. should not be listed as quarantine pests, but that citrus leprosis virus should be listed as a quarantine pest.

Citrus leprosis virus is not systemic. It could not be introduced into the United States, unless vectored by Brevipalpus spp. mites. For this reason we consider the mites to be quarantine pests.

One commenter stated that the details of the operational workplan need to be included in the regulations or otherwise made publicly available.

As we explained above, the mitigations in the operational workplan are the same as in the RMD and the rule. The operational workplan specifies details for day-to-day operations that are needed to carry out provisions of the rule and the RMD. As a result, operational workplans are living documents that change periodically to reflect new technologies and operational realities in the field.

One commenter asked what constitutes “direct involvement” in implementation and monitoring of the operational workplan.

The operational workplan provides APHIS with the standard operating procedures that the NPPO, places of production, packinghouses, and others involved in the production of the fruit will follow as part of the export program. Our oversight will include routine reviews and inspections of the program, but not continual oversight. That would be tantamount to mandatory preclearance program, which we do not consider necessary. The frequency with which we conduct site visits and review export program records will increase if any pest concerns are identified.

One commenter stated that a trust fund agreement to pay for APHIS personnel may be necessary.

A trust fund agreement is associated with preclearance programs in which there is continual APHIS oversight, which we do not consider warranted here.

One commenter stated that registration requirements should extend to contiguous orchards to mitigate the chance of contamination of the place of production during harvest after the initial freedom certification.

APHIS does not consider this to be necessary. As discussed above, the Brevipalpus spp. mites that exist in Argentina do not balloon – that is they do not produce streamers of silk and travel with wind currents for longer distances -- and have limited mobility. It is unlikely that they could infest contiguous orchards after the initial freedom certification.

One commenter stated that registering small places of production may increase pest risk.

We disagree that small places of production may represent a higher pest risk than large ones. In order to be registered with the NPPO and participate in the export program, the NPPO (and, as warranted, APHIS) must determine that the place of production or packinghouse is able to adhere to the systems approach. This is true regardless of the size of the place of production

or packinghouse. Routine inspections by the NPPO, and the possibility of monitoring by APHIS, will corroborate ongoing maintenance of systems approach provisions at registered places of production and packinghouses.

We proposed to require lemons from Argentina to be harvested green and within the time period of April 1 and August 31. If the lemons are harvested yellow or harvested outside of that time period, they would have to be treated for Medfly in accordance with 7 CFR part 305 and the operational workplan. Two commenters asked how we would determine whether a lemon was green or not.

In the ARS study that determined that lemons are a conditional non-host of Medfly, the term “yellow” was used interchangeably with “mature.” Immature lemons were considered to be a poor host. For purposes of the systems approach, we consider any lemon that is not green as ripe enough to require cold treatment. We are using additional ARS research⁸ and a market standard on lemon color to determine if lemons are green.

Two commenters asked who will determine whether a lemon is green or yellow. One commenter asked where this determination will be made. That commenter also stated that APHIS employees should make the determination.

In Argentina, lemons are evaluated for color and graded as part of packinghouse procedures. The determination for color and grade is made by graders employed by SENASA.

One commenter stated that the finding that green fruit is harvested from March to May in Argentina appears to be based on 2007 information, which is outdated.

⁸ Jang, E. B., R. L. Mangan, D. M. Obenland, M. L. Arpaia, and R. Rice. (undated). Defining Host Status of California Grown Lemons to Fruit Fly Infestation (PowerPoint Presentation). USDA- Agricultural Research Service and University of California. 8 pp.

When green fruit is harvested in Argentina is irrelevant to the conclusions of the PRA. As we explained in the proposed rule, lemons that are harvested yellow would have to be treated for Medfly, regardless of the time of year in which they are harvested.

One commenter stated that the RMD and rule should be consistent with regard to when lemons do not need treatment.

The commenter seems to believe that there is a discrepancy between the RMD and the proposed rule because the requirement is phrased slightly differently, but this is not the case. Both the proposed rule and the RMD specify that a lemon must be green and shipped within the April-August window in order to avoid treatment.

One commenter expressed concern that the use of the term “safeguarded” in § 319.56-76 (a)(8) is too vague. The commenter stated that the words “and protected from fruit fly infestation” should be inserted after the word “safeguarded” in that paragraph.

APHIS disagrees that this addition is necessary. We use the term “safeguarded” throughout the regulations to mean that fruit must be protected from infestation, or, in the case of treated fruit, reinfestation, by quarantine pests.

One commenter asked whether trucks and workers would be sanitized in between uses for U.S. exports and other uses, and if not, why not.

Packinghouse workers are required to wash their hands and wear clean protective clothing every time they enter the packinghouse. The fruit never touches the trucks; it is harvested and brought to the packinghouse in bins that are disinfected after each use. Fruit for export is shipped in clean new boxes. Old shipping boxes are never reused.

Several commenters asked how APHIS will determine pest-free places of production for B. chilensis, given that Argentine production for fresh consumption and processing is intermixed.

While B. chilensis exists in Argentina, there is no evidence that it exists in northwest Argentina. This is based on extensive and ongoing documentation SENASA has provided to APHIS. Due to the absence of B. chilensis in northwest Argentina, the intermixing of fresh and processed production sites in that area does not have a bearing on whether a site is pest-free for B. chilensis.

It is worth noting that we have no evidence that Argentine producers designate specific sites for fresh or processed production and use different production practices based on the intended use of the lemons. Rather, as a result of grading during packinghouse inspections, highly graded lots are designated for the fresh market, while the rest of the fruit goes to processing and other uses.

That being said, the rule specifies that APHIS will monitor implementation of the systems approach. This includes monitoring the distribution of B. chilensis in Argentina. If the distribution changes, we note that there are still several safeguards that would address the commenter's concern. First, the place of production must be inspected regularly by the NPPO of Argentina; these inspections would include inspections for B. chilensis. Second, the place of production must adhere to any pest control or management practices specified by APHIS and/or SENASA. An orchard that was in an area in which B. chilensis is known to occur, and in proximity to an orchard not participating in the export program, would be subject to management practices to address this risk. Finally, registration of places of production allows for traceback and quick remediation if infested fruit is discovered later in the production chain.

One commenter stated that APHIS should ask SENASA to prepare a grid-type schematic that shows the location of processed orchards as compared with orchards where fruit is grown for the fresh export market. The commenter stated that this analysis is essential, and that if SENASA will not prepare it, then APHIS should prepare it.

The grid suggested by the commenter is not possible. Orchards in Argentina are not designated for a particular type of production. Rather, as we explained above, lots are designated based on grading conducted in packinghouses.

Two commenters stated that the biometric sampling protocol for B. chilensis is insufficient.

APHIS disagrees. Mites have limited mobility. The commenters are referring to the fact that some species of mites are known to travel longer distances by ballooning, where the mites produce streamers of silk and travel with wind currents for longer distances. According to Childers and Rodrigues (2011), Brevipalpus mites do not produce silk and therefore are not capable of ballooning. Childers and Rodrigues indicate there is some evidence that these mites can blow from heavily infested plants downwind to nearby plants. They do not present evidence of long distance movement of Brevipalpus mites by the wind.

B. chilensis mites in Argentina are associated with the wine grape industry in the state of Mendoza (approximately 1,000 miles south of the region where lemons are produced). They are not present in Tucumán where most of the export lemons in Argentina are grown, nor, again, is there any evidence of their presence in the whole northwestern region.

The systems approach for B. chilensis is based on the pest's limited mobility. This systems approach has similarly been used in Chile for citrus for many years without interceptions of this mite in commercial shipments. In addition to the place of production inspection, every

shipment of lemons to be exported will also be inspected for mites with the same wash technique. If mites are found on any shipment, that place of production will be removed for the rest of the export season.

One commenter stated that APHIS only described the B. chilensis protocol, without providing evidence of its adequacy. The commenter further stated that the lack of interceptions of the mite on fruit that has entered the United States from Chile is not sufficient evidence for the effectiveness of the protocol. Another commenter stated that there is no literature of evidence that suggests the protocol is effective.

APHIS disagrees. Mites and other small organisms have been studied by collecting them from their habitat through sieves that concentrate them. Southwood and Henderson in their classic textbook Ecological Methods⁹ devote chapters to this method of sampling.

This method of sampling has been used since the 18th century; use of Berlese funnels and sieves is ubiquitous in sampling mites and other small organisms in various habitats. The agricultural quarantine and inspection data that APHIS collects routinely suggests that this method, which has been used for almost 20 years by APHIS as a mitigation measure, has been very effective in detecting B. chilensis mites on fruit from Chile.

One commenter stated that it is impossible to know whether 100 samples is sufficient without knowing the size of places of production.

Regardless of the size of the orchard, 100 samples provides 95 percent confidence of a 3 percent infestation rate. This confidence level is sufficient given that B. chilensis is not known to exist within 1,000 miles of northwest Argentina and, biologically, tends to aggregate once established. APHIS believes that the overlapping protections of routine visual inspections,

⁹ Southwood, T. R. E., & Henderson, P. A. (2009). Ecological Methods. John Wiley & Sons.

NPPO surveying for B. chilensis spread, and the biometric protocol provide a sufficient degree of phytosanitary protection.

One commenter stated that the B. chilensis biometric sampling protocol is not based on the biology of B. chilensis. The commenter stated that other species of Brevipalpus are known to have particular habitat preferences within a tree, such as the most shaded, humid areas (Childers & Rodrigues 2011). The commenter stated that if something like this is the case for B. chilensis, then a targeted survey, rather than biometric survey of the place of production, is needed to determine prevalence.

APHIS disagrees. Mites, including B. chilensis, reproduce and build up populations in a small area because of their limited dispersal capability. The sampling distribution is based on the premise that if one mite is found, there is a high probability that another mite is nearby. This is called an aggregated distribution. This probability distribution (or variation), is called hypergeometric, or negative binomial, and can be used to model the distribution of most insects and mites.

Very few insects and mites do not have aggregated distributions, and there is no evidence that B. chilensis does not have aggregated distributions. The production site survey is a targeted survey; the samples are taken from the leaves which is where the mite populations are highest. We note, moreover, that this survey is presently strictly precautionary. There is no evidence of B. chilensis in northwest Argentina.

Two commenters stated that biometric sampling may miss immature B. chilensis mites.

The mite exists in populations that contain eggs, immature stages, and adults. Only the adults can be identified reliably through microscopic examination of the filtrate from the sieve. The sieve will collect adult mites. The likelihood of only eggs or nymphs being present is very

low, so APHIS can use the sieve sampling method to reliably detect populations of mites at production sites. APHIS will be requiring a number of samples and the probability that only eggs and larvae of the target mite would be present in all of the samples is very low. Moreover, if one sample detects adult B. chilensis mites, the production site will not be certified B. chilensis free.

One commenter asked how APHIS determined the efficacy of Chilean citrus protocol.

As we state in the RMD, our determination was based on the absence of detections of infested fruit in the export pathway over almost 20 years.

One commenter questioned whether it is appropriate to compare the citrus-growing area that exists in Chile to the growing areas in Northwest Argentina for purposes of dealing with Brevipalpus spp. mites. The commenter noted that the growing area in Argentina is much larger than the growing area in Chile, and stated that the growing area in Argentina has high rainfall and high humidity, while the growing area in Chile typically has low rainfall and low humidity. The commenter stated that the difference in climate makes the growing area in Argentina hospitable to certain pathogens, but did not specify which ones.

The commenter is mistaken about the climate in northwest Argentina. The scientists at the Obispo Columbres Agroindustrial Station, SENASA, and the lemon growers in Tucumán told us that northwest Argentina does not have high rainfall. On the contrary, rainfall is low and the lemon groves are often irrigated. Therefore, the mite populations should face similar climates in the citrus growing portions of Chile and the lemon growing parts of northwest Argentina. During the September 2016 site visit, we asked the scientists at the Obispo Columbres Agroindustrial station about the mites. They said that they had found two of the three Brevipalpus mite species (not B. chilensis) in the lemon production areas in northwest Argentina,

but that they were not common. Further, the hot dry conditions favor mites more than rainy humid conditions. The mitigations for Brevipalpus mites should not be affected by any climate differences, which appear to be minimal.

One commenter stated that the protocol for citrus from Chile includes species of citrus that may be less hospitable to B. chilensis.

APHIS notes that the protocol for mites from Chile also includes fruit that are better hosts than lemons. The sampling method for determining low prevalence works regardless of mite populations on the host fruit.

Two commenters stated that surveying for B. chilensis around production sites is necessary because if there are high populations in the vicinity, or if wind is a strong factor in dispersal, mites are likely to be constantly moving into the orchard.

As noted above, B. chilensis are a generalist pest, and tend to aggregate. The likelihood of B. chilensis in a neighboring orchard, without spillover into the registered production site, is low. Accordingly, if mites are in the vicinity, they should be detected through routine place of production inspections and the biometric sampling protocol.

One commenter stated that the B. chilensis-specific protocol should be extended to all Brevipalpus spp. mites.

Currently Argentina is sampling for B. chilensis and the three Brevipalpus spp. mites that are potential vectors for citrus leprosis virus. We are only requiring pest free place of production for B. chilensis, because B. chilensis is itself a quarantine pest. We are requiring consignment freedom (by inspection of harvested fruit) for all of the mites. Brevipalpus species other than B. chilensis are only considered quarantine pests if they are carrying the citrus leprosis virus. The probability of movement of the citrus leprosis pathogen from an infected tree in Argentina to a

suitable host in the United States via a Brevipalpus mite traveling on a lemon fruit is extremely low, and require several additional steps to acquire and spread the pathogen so we are not requiring production site freedom.

One commenter stated that the B. chilensis protocol should be extended to surrounding areas of production.

As we explained above, B. chilensis is not found within 1,000 miles of northwest Argentina, has low powers of mobility, and tends to aggregate. If it is not found in a registered place of production during routine surveys conducted by the NPPO to evaluate pest spread, as well as routine harvest inspections and two separate biometric samples associated with the systems approach, we are confident that it will not be on fruit for export.

One commenter stated that production sites should be inspected for B. chilensis throughout the harvest season.

If mites were found in a consignment at a packinghouse, the originating production site would lose its free status. For this reason it is not necessary to inspect production sites throughout the harvest season.

One commenter stated that the B. chilensis protocol should include surveying for citrus leprosis virus.

Symptoms of citrus leprosis virus are easy to detect, and fruit with such symptoms will be detected during standard packinghouse culling and phytosanitary inspections.

One commenter stated that fallen fruit should be cut and inspected for Medfly.

This effectively calls for place of production freedom for Medfly. APHIS notes that in the RMD, fallen fruit are specifically forbidden from being included in harvested fruit going to

the packinghouse for fresh market. For this reason, we do not consider it necessary to sample fallen fruit for fruit flies or any other pest.

One commenter stated that trapping requirements for Medfly need to be delineated in the rule itself.

Historically, we have put trapping requirements in operational workplans, rather than rules, to allow flexibility in trapping protocols in order to respond to variations in population densities from season to season, as well as the development of new lure and bait technologies.

One commenter stated that trapping should be at least 50 percent with trimedlure and the other 50 percent should be baited with either 3-component or protein bait.

APHIS notes that both the 3-component bait and the protein bait are far less powerful lures for fruit flies than trimedlure, a pheromone. The trimedlure will draw flies in from farther away and is a more sensitive detection system. Trimedlure will also attract males and unmated females, which will make up a significant portion of any fruit fly population. The only thing that the protein or 3-component baits will attract is mated females, and if they are present then males and unmated females should also be present and will have already been detected by the more powerful trimedlure.

One commenter asked for greater detail about the requirements for packinghouses. The commenter specifically asked whether an entire facility would be included as a packinghouse, how many facilities would pack lemons for the U.S. market and what volume could a dedicated packinghouse expect to process

A packinghouse has to be an entire facility. APHIS is aware of a few packinghouses that would serve as primary packinghouses; however, all packinghouses would be registered with the NPPO. Both the NPPO and APHIS will monitor packinghouses during routine inspections.

One commenter asked how large a consignment of lemons could be, and if there will be a limit on the size of consignments.

Consignments can vary in size. However, regardless of the size of the consignment, the sampling protocol is aimed at detecting a 3 percent infestation rate with at least 95 percent confidence.

One commenter asked how a biometric sample was defined.

The term ‘biometric sampling’ simply means that the sample size that is smaller than a straight 2 percent sample can be used to detect pests on large consignments of the commodity. Taking a biometric sample is more efficient than taking a straight percentage sample.

One commenter stated that the number of samples inspected should be 600. The commenter stated that this is consistent with what other countries require from U.S. growers.

APHIS disagrees that the number of samples inspected should be 600. One hundred samples is consistent with the Chilean protocol, which has been effective at precluding infested fruit from being shipped. Inspecting an additional 500 fruit per sample does not substantially impact the probability of finding an infestation, and would be significantly more resource-intensive.

One commenter asked if the same method will be used to inspect for B. chilensis as is used for the production site protocol.

Yes, the same method will be used for both production sites and packinghouses.

One commenter asked about the efficacy data for post-harvest inspections.

Post-harvest inspections by the NPPO of an exporting country are a long-standing phytosanitary measure that APHIS employs as part of market access requirements. The safe

importation of thousands of foreign commodities into the United States over a prolonged period of time is an indication of its efficacy as a phytosanitary measure.

One commenter stated that fruit that is infested with Medfly larvae should be prohibited from being shipped.

APHIS disagrees. In the event that a single immature Medfly is found in or with the lemons, then the lemons must be treated in accordance with part 305 of the regulations and the operational workplan using a cold treatment. This cold treatment has been shown to be effective at mitigating the risk of Medfly in lemons. Additionally, the registered place of production that produced the lemons in the consignment may be suspended from the export program, pending an investigation.

One commenter stated that remedial actions should be identical, regardless of quarantine pest detected.

The remedial action when quarantine pests are detected is that the fruit cannot be exported. Some findings of quarantine pests also disqualify production sites because the mitigation requires the production site to be a pest-free place of production.

One commenter noted that the rule referred to CBP inspectors, but the supporting documents refer to APHIS inspectors. The commenter asked for clarification as to who will conduct port of entry inspections.

CBP conducts inspections at ports of entries pursuant to authority delegated to APHIS. The use of CBP employees to carry out functions specifically delegated to APHIS is authorized by the Homeland Security Act of 2002. Because CBP is effectively acting as agents of APHIS for the purposes of these inspections, we use the term “APHIS.” These inspections sample

imported commodities for evidence of pests. If pests are detected, APHIS identifiers will be used to positively identify the pests.

One commenter asked whether port of entry inspections would include biometric sampling for Brevipalpus mites. The commenter also asked how CBP would be able to detect the mites.

The B. chilensis protocol is used to establish place of production freedom, and is also used as part of the phytosanitary inspection by the NPPO. Port of entry inspection for B. chilensis and other Brevipalpus mites will look for the pests, as well as signs and symptoms of infestation, such as bronzing.

One commenter asked why, if information from port of entry inspections is “unreliable,” they can be stated to be effective.

“Not be detected at the port of entry” was removed as a criterion in the PRA because we do not have enough information about relative likelihood of detection at the port of entry to be able to weight this criterion relative to other elements. As a result, this criterion could not substantially impact the risk ratings. This does not imply that port of entry inspections are an ineffective component of a systems approach.

One commenter stated that the rule should specify how APHIS will monitor and enforce the systems approach. The commenter expressed concern that APHIS would have to commit substantial resources to ensure compliance with the operational workplan.

This request is predicated on the stated assumptions that SENASA lacks the ability and intent to abide by systems approach requirements. For reasons discussed above, we disagree with those assumptions.

One commenter stated that APHIS should require cold treatment of lemons from northwest Argentina.

This approach would not impose the least restrictive science-based actions needed to address plant pest risk, and thus would be inconsistent with our obligations under the SPS agreement.

One commenter stated that the rule should prohibit the importation of lemons from northwest Argentina into Florida. The commenter also stated that the rule should limit importation of lemons to areas north of the 38th parallel.

We have determined, for the reasons described in the RMD that accompanied the proposed rule, that the measures specified in the RMD will effectively mitigate the risk associated with the importation of lemons from northwest Argentina. The commenter did not provide any evidence suggesting that the mitigations are not effective. Therefore, we are not taking the action requested by the commenter.

Two commenters expressed concern that Argentine producers may use pesticides or practices that are not authorized in the United States.

We note that the Food and Drug Administration (FDA) of the Department of Health and Human Services regulates the pesticide, herbicide, and fertilizer residues that may be present on imported fruits and vegetables intended for human consumption. If illegal pesticides are detected, FDA will take action to remove them from the marketplace. Additionally, we note that the packinghouse disinfectants and treatments for pathogens that we are proposing for Argentina are the same used domestically.

One commenter stated that importing lemons from Argentina will involve carbon dioxide emissions that should be available to the consumer as they purchase the lemons. The commenter

stated that the lemons should be labeled with the pounds of carbon dioxide emitted per pound of lemons.

This request is outside the scope of APHIS' statutory authority.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with minor editorial changes.

Executive Order 12866 and Regulatory Flexibility Act

This final rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with 5 U.S.C. 604, we have performed a final regulatory flexibility analysis, which is summarized below, regarding the economic effects of this rule on small entities. Copies of the full analysis are available on the Regulations.gov Web site (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

This analysis examines potential economic impacts of a rule that will allow the importation of fresh lemons from a region in Northwest Argentina into the continental United States. A systems approach to pest risk mitigation will provide phytosanitary protection against pests of quarantine concern. Both U.S. producers and consumers will be affected by the rule. While producers' welfare will be negatively affected, welfare gains for consumers will outweigh producer losses, resulting in a net benefit to the U.S. economy.

Commercial lemon production takes place in California and Arizona. For the 2014/15 season, lemon-bearing acres totaled 55,300 (California 47,000, Arizona 8,300). In the same season, the value of U.S. production of lemons was \$694 million. Over the production seasons 2008/09 to 2014/15, U.S. fresh lemon production averaged 535,244 metric tons (MT) per year.

Over the same period, annual imports averaged 49,995 MT and exports averaged 101,849 MT. Because lemons imported from Argentina that are harvested green between April 1 and August 31 will not require treatment for Medfly, we expect that most will be imported during this period, which coincides roughly with the months in which U.S. lemon exports are declining and imports are increasing.

Effects of the rule are estimated using a partial equilibrium model of the U.S. lemon sector. Annual imports of fresh lemon from Argentina are expected to range between 15,000 and 20,000 MT, with volumes averaging 18,000 MT. Quantity, price and welfare changes are estimated for these three import scenarios.

If the United States imports 18,000 MT of fresh lemon from Argentina and there is no displacement of lemon imports from other countries, we estimate that the price (custom import value) of fresh lemon will decrease by about 4 percent. Consumer welfare gains of \$22.4 million will outweigh producer welfare losses of \$19.9 million, resulting in a net welfare gain of \$2.5 million. The 15,000 MT and 20,000 MT scenarios show similar effects.

More reasonably, partial import displacement will occur, and price and welfare effects will be proportional to the net increase in U.S. lemon imports. Assuming as an upper-bound that one-half of the quantity of fresh lemons imported from Argentina displaces U.S. fresh lemon imports from elsewhere, we estimate for the 18,000 MT scenario that the price decline will be about 2 percent; consumer welfare gains and producer welfare losses will be \$11.1 million and \$10.0 million, respectively, yielding a net welfare benefit of \$1.1 million.

The majority of businesses that may be affected by the final rule are small entities, including lemon producers, packers, wholesalers, and related establishments.

Executive Order 12988

This final rule allows lemons to be imported into the continental United States from Argentina. State and local laws and regulations regarding lemons imported under this rule will be preempted while the fruit is in foreign commerce. Fresh lemons are generally imported for immediate distribution and sale to the consuming public, and 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 will not require administrative proceedings before parties may file suit in court challenging this rule.

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, which were filed under 0579-0448, have been submitted for approval to the Office of Management and Budget (OMB). When OMB notifies us of its decision, if approval is denied, we will publish a document in the Federal Register providing notice of what action we plan to take.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2483.

List of Subjects for 7 CFR Part 319

Coffee, Cotton, Fruits, Imports, Logs, Nursery stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

Accordingly, we are amending 7 CFR part 319 as follows:

PART 319--FOREIGN QUARANTINE NOTICES

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

Authority 7 U.S.C. 450, 7701-7772, and 7781-7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

2. Section 319.28 is amended as follows:

a. In paragraph (a)(1), by removing the words “(except for the States of Catamarca, Jujuy, Salta, and Tucuman, which are considered free of citrus canker)”.

b. In paragraph (a)(2), by removing the word “Argentina,”.

c. By redesignating paragraphs (e) through (i) as paragraphs (f) through (j), respectively, and adding a new paragraph (e).

d. In newly redesignated paragraph (h), the words “paragraphs (b) through (e)” are removed and the words “paragraphs (b) through (f)” are added in their place.

The addition reads as follows:

§ 319.28 Notice of quarantine.

* * * * *

(e) The prohibition does not apply to lemons (Citrus limon (L.) Burm. f.) from northwest Argentina that meet the requirements of § 319.56-76.

* * * * *

3. Section 319.56-76 is added to read as follows:

§ 319.56-76 Lemons from northwest Argentina.

Fresh lemons (Citrus limon (L.) Burm. f.) may be imported into the continental United States from northwest Argentina (the Provinces of Catamarca, Jujuy, Salta, and Tucumán) only under the conditions described in this section. These conditions are designed to prevent the introduction of the following quarantine pests: Brevipalpus chilensis, the Chilean false red mite; B. californicus, the citrus flat mite, B. obovatus, the scarlet tea mite, and B. phoenicis, the false spider mite (referred to in this section as “Brevipalpus spp. mites”); Ceratitis capitata, the Mediterranean fruit fly; Cryptoblabes gnidiella, the honeydew moth; Elsinoë australis, the causal agent of sweet orange scab disease; Gymnandrosoma aurantianum (Lima), the citrus borer; and Xanthomonas citri subsp. citri (ex Hasse) Gabriel et al., the causal agent of citrus canker disease.

(a) General requirements--(1) Operational workplan. The national plant protection organization (NPPO) of Argentina must provide an operational workplan to APHIS that details the activities that the NPPO of Argentina and places of production and packinghouses registered with the NPPO of Argentina will, subject to APHIS' approval of the workplan, carry out to meet the requirements of this section. The operational workplan must include and describe the specific requirements as set forth in this section. APHIS will be directly involved with the NPPO of Argentina in monitoring and auditing implementation of the systems approach.

(2) Registered places of production. The fresh lemons considered for export to the continental United States must be grown by places of production that are registered with the NPPO of Argentina and that have been determined to be free from B. chilensis in accordance with this section.

(3) Registered packinghouses. The lemons must be packed for export to the continental United States in pest-exclusionary packinghouses that are registered with the NPPO of Argentina.

(4) Recordkeeping. The NPPO of Argentina must maintain all forms and documents pertaining to registered places of production and packinghouses for at least 1 year and, as requested, provide them to APHIS for review. Based on APHIS' review of records, APHIS may monitor places of production and packinghouses, as APHIS deems warranted.

(5) Commercial consignments. Lemons from Argentina can be imported to the continental United States in commercial consignments only. For purposes of this section, fruit in a commercial consignment must be practically free of leaves, twigs, and other plant parts, except for stems less than 1 inch long and attached to the fruit.

(6) Identification. The identity of the each lot of lemons from Argentina must be maintained throughout the export process, from the place of production to the arrival of the lemons at the port of entry into the continental United States. The means of identification that allows the lot to be traced back to its place of production must be authorized by the operational workplan.

(7) Harvesting restrictions or treatment for fruit flies. Lemons from Argentina must be harvested green and within the time period of April 1 and August 31. If they are harvested yellow or harvested outside of this time period, they must be treated for C. capitata in accordance with part 305 of this chapter and the operational workplan.

(8) Safeguarding. Lots of lemons destined for export to the continental United States must be safeguarded during movement from registered places of production to registered packinghouses as specified by the operational workplan.

(9) Phytosanitary certificate. Each consignment of lemons imported from Argentina into the continental United States must be accompanied by a phytosanitary certificate issued by the NPPO of Argentina with an additional declaration stating that the requirements of this section have been met and that the consignments have been inspected and found free of Brevipalpus spp. mites, B. chilensis, C. capitata, C. gnidiella, and G. aurantianum.

(b) Place of production requirements. (1) Prior to each harvest season, registered places of production of lemons destined for export to the continental United States must be determined by APHIS and the NPPO of Argentina to be free from B. chilensis based on biometric sampling conducted in accordance with the operational workplan. If a single live B. chilensis mite is discovered as a result of such sampling, the place of production will not be considered free from B. chilensis and will not be able to export lemons to the United States. Each place of production will have only one opportunity per harvest season to be considered free of B. chilensis, and certification of B. chilensis freedom will only last one harvest season.

(2) Places of production must remove plant litter and fallen debris from groves in accordance with the operational workplan. Fallen fruit may not be included in field containers of fruit brought to the packinghouse to be packed for export.

(3) Places of production must trap for C. capitata in accordance with the operational workplan. The NPPO must keep records regarding the placement and monitoring of all traps, as well as records of all pest detections in these traps, and provide the records to APHIS, as requested.

(4) Places of production must carry out any additional grove sanitation and phytosanitary measures specified for the place of production by the operational workplan.

(5) The NPPO of Argentina must visit and inspect registered places of production regularly throughout the exporting season for signs of infestations. These inspections must start no more than 30 days before harvest and continue until the end of the export season. The NPPO of Argentina must allow APHIS to monitor these inspections. The NPPO of Argentina must also provide records of pest detections and pest detection practices to APHIS. Before any place of production may export lemons to the continental United States pursuant to this section, APHIS must review and approve of these practices.

(6) If APHIS or the NPPO of Argentina determines that a registered place of production has failed to follow the requirements in this paragraph (b), the place of production will be excluded from the export program until APHIS and the NPPO of Argentina jointly agree that the place of production has taken appropriate remedial measures to address the plant pest risk.

(c) Packinghouse requirements. (1) During the time registered packinghouses are in use for packing lemons for export to the continental United States, the packinghouses may only accept lemons that are from registered places of production and that have been produced in accordance with the requirements of this section.

(2) Lemons destined for export to the continental United States must be packed within 24 hours of harvest in a registered pest-exclusionary packinghouse or stored in a degreening chamber in the registered pest-exclusionary packinghouse. Lemons must be packed for shipment to the continental United States in insect-proof cartons or containers, or covered with insect-proof mesh or plastic tarpaulin. These safeguards must remain intact until the lemons arrive in the United States, or the consignment will not be allowed to enter the United States.

(3) Prior to packing, the lemons must be washed, brushed, and surface disinfected for E. australis and X. citri and in accordance with the operational workplan, treated with an APHIS-approved fungicide, and waxed.

(4) After treatment, the NPPO of Argentina or officials authorized by the NPPO of Argentina must visually inspect a biometric sample of each consignment for quarantine pests, wash the lemons in this sample, and inspect the filtrate for B. chilensis in accordance with the operational workplan. A portion of the lemons must then be cut open and inspected for evidence of quarantine pests.

(i) If a single C. gnidiella or G. aurantianum in any stage of development is found on the lemons, the entire consignment is prohibited from export to the United States, and the registered place of production that produced the lemons is suspended from the export program until APHIS and the NPPO of Argentina jointly agree that the place of production has taken appropriate remedial measures to address plant pest risk.

(ii) If a single B. chilensis or Brevipalpus spp. mite in any stage of development is found on the lemons, the entire consignment is prohibited from export, and the registered place of production that produced the lemons may be suspended from the export program, pending an investigation.

(iii) If a single immature Medfly is found in or with the lemons, the lemons must be treated in accordance with part 305 of this chapter and the operational workplan. Additionally, the registered place of production that produced the lemons in the consignment may be suspended from the export program, pending an investigation.

(5) If APHIS or the NPPO of Argentina determines that a registered packinghouse has failed to follow the requirements in this paragraph (c), the packinghouse will be excluded from

the export program until APHIS and the NPPO of Argentina jointly agree that the packinghouse has taken appropriate remedial measures to address the plant pest risk.

(d) Port of entry requirements. Consignments of lemons from Argentina will be inspected at the port of entry into the United States. If any quarantine pests are discovered on the lemons during inspection, the entire lot in which the quarantine pest was discovered will be subject to appropriate remedial measures to address this risk.

(Approved by the Office of Management and Budget under control number 0579-0448)

Done in Washington, DC, this 20th day of December 2016.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2016-31013 Filed: 12/22/2016 8:45 am; Publication Date: 12/23/2016]