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## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

#### 7 CFR Parts 318 and 319

[Docket No. APHIS–2010–0082]

RIN 0579–AD71

#### Establishing a Performance Standard for Authorizing the Importation and Interstate Movement of Fruits and Vegetables

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** We are amending our regulations governing the importation of fruits and vegetables by broadening our existing performance standard to provide for approval of all new fruits and vegetables for importation into the United States using a notice-based process. We are also removing the region- or commodity-specific phytosanitary requirements currently found in these regulations. Likewise, we are making an equivalent revision of the performance standard in our regulations governing the interstate movement of fruits and vegetables from Hawaii and the U.S. territories (Guam, Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands) and removing the commodity-specific phytosanitary requirements from those regulations. This action will allow for the approval of requests to authorize the importation or interstate movement of new fruits and vegetables in a manner that enables a more flexible and responsive regulatory approach to evolving pest situations in both the United States and exporting countries. It will not, however, alter the science-based process in which the risk associated with importation or interstate movement of a given fruit or vegetable is evaluated or the manner in which risks associated with the importation or interstate

movement of a fruit or vegetable are mitigated.

**DATES:** Effective October 15, 2018.

#### FOR FURTHER INFORMATION CONTACT:

Regarding the commodity import request evaluation process, contact Mr. Benjamin J. Kaczmarek, Assistant Director, Regulatory Coordination and Compliance, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1231; (301) 851–2127.

Regarding import conditions for particular commodities, contact Mr. Tony Román, Senior Regulatory Policy Specialist, Regulatory Coordination and Compliance, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1231; (301) 851–2242.

#### SUPPLEMENTARY INFORMATION:

##### Background

Under the regulations in “Subpart—Fruits and Vegetables” (7 CFR 319.56–1 through 319.56–83, referred to below as the regulations or the fruits and vegetables regulations), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) prohibits or restricts the importation of fruits and vegetables into the United States from certain parts of the world to prevent plant pests from being introduced into and spread within the United States.

The regulations in 7 CFR part 318, “State of Hawaii and Territories Quarantine Notices” (referred to below as the Hawaii and territories regulations), prohibit or restrict the interstate movement of fruits, vegetables, and other products from Hawaii, Puerto Rico, the U.S. Virgin Islands, and Guam to the continental United States to prevent the spread of plant pests and noxious weeds that occur in Hawaii and the territories.

Under our current process for authorizing importation of fruits or vegetables under the fruits and vegetables regulations or interstate movement under the Hawaii and territories regulations, when APHIS receives a request from a country’s national plant protection organization (NPPO) or a State department of agriculture to allow importation or interstate movement of a fruit or vegetable whose importation or interstate movement is currently not authorized, that NPPO or State department of agriculture must first gather and submit information to APHIS

concerning that fruit or vegetable. In the case of imports, a description of the required information is contained in 7 CFR 319.5(d). This information, in addition to our own research, allows APHIS to conduct a pest risk analysis.

The pest risk analysis usually contains two main components: (1) A pest risk assessment (PRA), pest list, or other pest risk document to determine what pests of quarantine significance are associated with the proposed fruit or vegetable and which of those are likely to follow the import or interstate movement pathway, and (2) a risk management document (RMD), to identify phytosanitary measures that could be applied to the fruit or vegetable and evaluate the potential effectiveness of those measures. When the PRA, pest list, or other pest risk document is complete, if quarantine pests are associated with the fruit or vegetable in the country, State, or other region of origin,<sup>1</sup> APHIS then evaluates whether the risk posed by each quarantine pest can be mitigated by one or more of the designated phytosanitary measures of the fruits and vegetables regulations or the designated phytosanitary measures of the Hawaii and territories regulations. If the designated phytosanitary measures alone are not sufficient to mitigate the risk posed by the importation or interstate movement of the commodity, any further action on approving the fruit or vegetable for importation or interstate movement is undertaken using the rulemaking process, which entails publishing a proposed and final rule. The pest risk analysis is made available to the public for review and comment at the time of the publication of the proposed rule.

However, if APHIS determines in an RMD that the risk posed by each identified quarantine pest associated with the fruit or vegetable in the country, State, or other region of origin can be mitigated by one or more of the designated phytosanitary measures listed in § 319.56–4(b) of the fruits and vegetables regulations or § 318.13–4(b) of the Hawaii and territories regulations (these measures are referred to elsewhere in this document as designated phytosanitary measures or designated phytosanitary measures of

<sup>1</sup> Pest risk assessments can consider a country, part of a country, all or parts of several countries, a State or territory, part of a State or territory, or all or parts of several States or territories.

the fruits and vegetables regulations), the findings are communicated using the notice-based process.

Under the notice-based process, APHIS publishes in the **Federal Register**, a notice announcing the availability of the pest risk analysis for a minimum of 60 days public comment. Each pest risk analysis made available for public comment through a notice specifies which of the designated phytosanitary measures APHIS would require to be applied. APHIS evaluates comments received in response to the notice of availability of the pest risk analysis. In the event that APHIS receives no comments, or in the event that commenters do not provide APHIS with analysis or data that indicate that the conclusions of the pest risk analysis are incorrect and that changes to the pest risk analysis are necessary, APHIS then publishes another notice in the **Federal Register** announcing that the Administrator has determined that, based on the information available, the application of one or more of the designated phytosanitary measures (as specified in a given pest risk analysis) is sufficient to mitigate the risk that quarantine pests could be introduced or disseminated within the United States via the importation or interstate movement of the fruit or vegetable. APHIS then authorizes the importation or interstate movement of the particular fruit or vegetable, subject to the conditions described in the pest risk analysis, on the date specified in the **Federal Register** notice.

In the event that commenters provide APHIS with information that shows that changes to the pest risk analysis are necessary, and if the changes made affect the conclusions of the analysis (e.g., that the application of the identified phytosanitary measures will not be sufficient to mitigate the risk posed by the identified pests), APHIS proceeds as follows:

- If additional phytosanitary measures beyond the designated phytosanitary measures are determined to be necessary to mitigate the risk posed by the particular fruit or vegetable, any further action on the fruit or vegetable follows the rulemaking process.
- If additional risk mitigation measures beyond those evaluated in the pest risk analysis are determined to be necessary, but the added measures only include one or more of the designated phytosanitary measures of the fruits and vegetables regulations or the designated phytosanitary measures of the Hawaii and territories regulations, APHIS may publish another notice announcing that the Administrator has determined that

the application of one or more of the designated phytosanitary requirements will be sufficient to mitigate the risk that quarantine pests could be disseminated within the United States via the importation or interstate movement of the fruit or vegetable. The notice also explains the additional mitigation measures required for the importation or interstate movement of the fruit or vegetable to be authorized and how APHIS made its determination. APHIS then begins allowing the importation or interstate movement of the particular fruit or vegetable, subject to the conditions described in the revised pest risk analysis, beginning on the date specified in the **Federal Register** notice. Alternatively, if APHIS believes that the revisions to the pest risk analysis are substantial, and there may be continued uncertainty as to whether the designated measures are sufficient to mitigate the risk posed by importation of the fruit or vegetable, APHIS may elect to make the revised pest risk analysis available for public comment via a notice in the **Federal Register**, or may make any further action on approving the commodity for importation subject to rulemaking.

When commodities are approved for importation or interstate movement, either through rulemaking or the notice-based process, all permits issued list the commodity-specific importation requirements as determined by the pest risk analyses. Those requirements are also listed in Fruits and Vegetables Import Requirements (FAVIR) database,<sup>2</sup> in the case of imported fruits and vegetables, as well as the appropriate manual, in the case of fruits and vegetables that are moved interstate from Hawaii and the U.S. territories. In order to ensure producer compliance with the listed procedures, an APHIS inspector or an official authorized by APHIS monitors any treatments (e.g., cold treatment, fumigation, irradiation) that are required. Upon arrival, consignments are inspected to ensure compliance with any particular shipping requirements, such as arrangement of fruits or vegetables on pallets or pest-exclusionary packaging, as well as for the presence of any pests of concern. In the event that a pest is discovered upon inspection at the port of first arrival, APHIS works with the inspectors and, in the case of imports, the NPPO of the exporting country, in order to investigate and, if necessary, re-evaluate shipments of the fruit or

vegetable in question from that country or State.

On September 9, 2014, we published in the **Federal Register** (79 FR 53346–53352, Docket No. APHIS–2010–0082) a proposal<sup>3</sup> to amend the regulations by expanding the use of the notice-based process to all decisions related to the importation and interstate movement of new fruits and vegetables. We also proposed to remove the remaining region- or commodity-specific phytosanitary requirements currently found in §§ 319.56–13, 319.56–20 through 319.56–70, 318.13–16, and 318.13–20 through 318.13–26. Since that time, § 319.56–71 through § 319.56–83 have been added to the regulations. This rule will remove those commodity-specific sections as well.

We solicited comments concerning our proposal for 60 days ending November 10, 2014. We reopened and extended the deadline for comments until January 29, 2015, in a document published in the **Federal Register** on December 4, 2014 (79 FR 71973, Docket No. APHIS–2014–0082) and reopened and extended the deadline for comments a second time ending March 10, 2015, in a document published in the **Federal Register** on February 6, 2015 (80 FR 6665, Docket No. APHIS–2010–0082). We received 22 comments on the proposed rule by that date. They were from representatives of State and foreign governments, industry organizations, importers and exporters, distributors, and private citizens. Two comments were supportive. The remainder of the comments are discussed below by topic.

#### Comments on the Comment Period

Several commenters requested that we extend the comment period for the proposed rule. As stated previously, we extended the comment period twice. Along with the initial comment period on the proposed rule, these extensions gave the public 180 days in which to review the proposal and submit comments.

In addition to the comment period extension, several commenters said that APHIS should issue an additional notice to clarify the scope and application of the proposed rule.

One commenter observed that, in 2006 when we proposed a notice-based process for a limited number of fruit and vegetable import requests, APHIS provided four public field hearings to ensure adequate interested-party input. The commenter said that similar efforts

<sup>2</sup> You may search FAVIR at <http://www.aphis.usda.gov/favir/>.

<sup>3</sup> To view the proposed rule and the comments we received, go to <http://www.regulations.gov/#/docketDetail;D=APHIS-2010-0082>.

were warranted in this case as well. Two commenters suggested that APHIS convene a stakeholder working group in association with the extension of the comment period in order to review the proposed rule. The commenters requested that special attention be paid to addressing significant barriers that impact trade within certain countries. The commenters argued that this working group would allow stakeholders to provide greater input for the proposed action.

While we did not issue an informational notice as suggested by the first commenters or convene a working group, we did host a webinar open to the public. This briefing provided an overview of the proposed changes and gave stakeholders an opportunity to learn more about the rule and to ask questions. Additionally, APHIS published an explanatory questions and answers (Q&A) document on the APHIS website.<sup>4</sup> Unlike our 2006 action, which represented a new rulemaking procedure, we did not hold public meetings in association with the proposed rule because the notice-based process has been successfully employed since that time and the proposed action was merely an expansion of the existing program.

#### General Comments

Several commenters stated that the proposed rule did not make clear which administrative review steps would be eliminated if APHIS adopted a notice-based process.

Since notices are not considered rulemaking documents, we anticipate that the primary administrative time-savings will be a result of procedural steps that apply to rulemaking in the Federal Government, such as the development and publication of a proposed rule or final rule. The notice-based process is an informal adjudication process in that the Code of Federal Regulations (7 CFR parts 318 and 319) sets out general mitigation measures and criteria that will be applied for the interstate movement or importation of fruits and vegetables into the United States. For each interstate movement or import request, the agency will conduct a risk assessment applicable to the specific commodity/place of origin and adjudicate the matter through the publication of a notice

announcing the availability of the risk analysis and the solicitation of comments. The final notice published in the **Federal Register** constitutes a final agency action which may be subject to challenge in court under the Administrative Procedure Act.

Another commenter stated that since the proposed changes would include a broad list of most or all available risk mitigation measures, which is far beyond currently established treatments, inspections, and certifications, APHIS should explain how efficacy and performance will be measured within each commodity import request in order to evaluate whether the notice-based process will enhance trade.

The commenter's characterization of the proposed designated measures as being beyond established treatments is incorrect. Any phytosanitary treatment required must be among those that appear in the Plant Protection and Quarantine (PPQ) treatment manual. Any additions to the listed treatments in the treatment manual are done so only after we provide notice via a **Federal Register** notice and evaluate any comments received on that notice. Mitigations apart from phytosanitary treatments will continue to be recognized as parts of systems approaches via FAVIR, which will include information on all other required mitigations.

One commenter cited the 2010–2015 APHIS Strategic Plan's characterization of the Agency's mission to "Protect the health and value of U.S. agricultural, natural and other resources." The commenter claimed that the proposal was in contradiction with that statement and requested clarification on how the action aligns with the APHIS mission, particularly as it relates to benefits to U.S. agricultural resources.

This rule does not alter the way in which APHIS carries out its mission to protect the health and value of U.S. agricultural, natural, and other resources. Our risk-based decisionmaking will not change as a result of this rule, nor will the level of phytosanitary security provided by the mitigation measures we will assign to address identified risks. U.S. consumers and businesses will benefit from more timely access to fruits and vegetables, and the more timely approval of the interstate movement of fruits and vegetables from Hawaii and the U.S. territories will be beneficial to U.S. producers.

#### Comments on Alternatives and Additions to the Proposed Action

One commenter suggested that, as an alternative approach, APHIS should consider import requests for each commodity in a way that encompasses at least three different perspectives: Pests and diseases, economic impact, and possible environmental impact.

The process for developing PRAs and determining mitigation measures would remain the same, giving the public opportunity to review, evaluate, and comment. Additionally, the requirements of the National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*) will still apply. As such, for each additional fruit or vegetable approved for importation, APHIS will make available to the public documentation related to our analysis of the potential environmental effects of such new imports. This documentation will likely be made available at the same time and via the same **Federal Register** notice as the risk analysis for the proposed new import. Finally, while the notices published using the notice-based approach will not contain economic analyses, we will certainly continue to consider the potential economic consequences of pest introduction in the pest risk analysis. Similarly, we will document our consideration of trade volume and other economic factors. We commit to inclusion of an evaluation of the economic impacts of those actions that would have been deemed "economically significant" under Executive Order 12866 prior to the effective date of this final rule.

Several commenters said that APHIS should consider maintaining a dual track approach to considering import requests. The commenters suggested that requests that depend on a systems approach for risk mitigation be reviewed by APHIS so that APHIS could then make a determination as to whether a notice-based or rulemaking-based decision was appropriate based on a set of criteria that evaluate relative level of risk, the probability of success of the mitigation measures, and the economic impact of the associated pests in the event that an introduction took place. The commenters concluded that APHIS should then make the rationale for that determination available for public comment.

Under the expanded notice-based process, the development of pest risk analyses and determination of mitigation measures would remain the same, giving the public opportunity to review, evaluate, and comment. This action will not alter our science-based

<sup>4</sup> You may view the Q&A document as well as slides from the webinar on the internet at [http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/planthealth/sa\\_import/sa\\_permits/sa\\_plant\\_plant\\_products/sa\\_fruits\\_vegetables/ct.q56-streamlining-questions-answers/!ut/p/a0/04\\_Sj9CPykssy0xPLMnMz0vMAfGjzOK9\\_D2MDJ0MjDzd3V2dDDz93HwCzL29jAx8TfULsh0VAY\\_1WKE!/](http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/planthealth/sa_import/sa_permits/sa_plant_plant_products/sa_fruits_vegetables/ct.q56-streamlining-questions-answers/!ut/p/a0/04_Sj9CPykssy0xPLMnMz0vMAfGjzOK9_D2MDJ0MjDzd3V2dDDz93HwCzL29jAx8TfULsh0VAY_1WKE!/).

process for approval. If a risk analysis is conducted, the first step of which is typically a PRA or pest list, stakeholders will continue to have 30 days to consult on draft PRAs or pest lists before APHIS initiates the notice-based process. Once APHIS and the foreign NPPO have reached agreement on the PRA, the exporting country will notify APHIS about the mitigation measures they will be implementing. APHIS will then develop an RMD which includes specific requirements for addressing the pests of concern highlighted in the PRA or pest list. Market access requests developed via the notice-based process involving a systems approach will not be any less effective than rulemaking and will not compromise phytosanitary security.

Another commenter recommended that APHIS apply the expanded notice-based approach only to the importation of fruits and vegetables authorized after the regulations are finalized. The commenter added that market access requests currently under review should remain subject to the existing rulemaking process as transferring those requests from the existing rulemaking process into the new notice-based process could result in possible lost opportunities for the industry to review and provide comment. A second commenter wanted to know if the notice-based process would apply to pending decisions where draft PRAs have already been issued for public comment or only to new requests.

We disagree with the first commenter's suggestion. As stated in the proposed rule, initial notices in the **Federal Register** will be available for review and comment for a minimum of 60 days, which is identical to the comment period we typically set out for proposed rules. We also have the option of extending that comment period if necessary. This provides ample time for stakeholder review and engagement. As to the second commenter's question: This rule will be applied to all pending requests. If an importation or interstate movement request has already been submitted and the results of our pest risk analysis lead us to conclude that the commodity can be safely imported or moved interstate under one or more designated measures, then we will follow the notice-based approach. The final notice published in the **Federal Register** constitutes a final agency action which may be subject to challenge in court under the Administrative Procedure Act.

One commenter stated that APHIS should provide annual reports to the House and Senate Committees on Agriculture detailing import requests

petitions addressed and granted each calendar year under the notice-based process. The commenter stated that these reports should be provided either annually or bi-annually.

While APHIS does not supply such reports currently, if either committee were to request documentation along these lines, we would supply it.

#### Comments on Notice-Based Process

One commenter asked if rulemaking would still be an option after this final rule became effective, and, if so, what the threshold would be for initiating rulemaking.

As stated in the proposed rule, we are removing the region- or commodity-specific phytosanitary requirements currently found in the regulations concerning importation or interstate movement from Hawaii and the Territories. The rulemaking process regarding importation or interstate movement of commodities will be replaced by the notice-based process.

Two commenters asked if the notice-based process would apply only to amendments of existing importation and interstate movement requirements or to all decisions related to the importation and interstate movement of fruits and vegetables.

The notice-based process will apply to all decisions related to the importation and interstate movement of fruits and vegetables, both to changes in requirements for those already allowed under the regulations and new requests for importation or interstate movement.

One commenter stated that it is unclear how the process will work if the new approval of a commodity or a change in requirement involves a phytosanitary measure that is listed in the proposed list of designated phytosanitary measures, but is not aligned to some other subpart elsewhere in the APHIS regulations.

Under the revised regulations, all phytosanitary measures pertaining to the importation of fruits and vegetables would be removed from the regulations. As stated previously, importation and interstate movement requirements would be found in FAVIR, in the case of imported fruits and vegetables, as well as the appropriate manual, in the case of fruits and vegetables that are moved interstate from Hawaii and the U.S. territories. Treatments would continue to be listed in the PPQ Treatment Manual and new treatments would continue to be approved in accordance with 7 CFR part 305.

The same commenter asked for clarification regarding reference to treatments within the CFR. As an example of this scenario, the commenter

wondered whether the acceptance of a new phytosanitary treatment depends on the availability of this treatment option under the treatments listed in 7 CFR part 305.

Section 305.3 of the regulations sets forth a notice-based process for adding, revising, and removing treatments contained in the PPQ Treatment Manual. Under those regulations, APHIS will publish in the **Federal Register** a notice describing our reasons for adding, revising, or removing a treatment schedule and provide for public comment on the action. After the close of the comment period APHIS will publish a notice announcing our final determination and, if appropriate, make available the final treatment schedule if any changes were made as a result of public comments.

One commenter suggested that communication regarding import requests in the form of notices might not receive the same careful attention from industry representatives as is currently given to proposals issued under the traditional rulemaking process.

We disagree. Stakeholders and other interested parties have reason to attend to any potential changes in their industries or other areas of interest. We will continue to provide our draft PRAs on the APHIS website for review and comment before publication of an initial notice. We will also continue to provide alerts via the PPQ Stakeholder Registry and issue press releases. Finally, the initial notice will include a comment period of at least 60 days. These actions provide the public ample opportunity to submit opinions and information on any given action.

Another commenter said that statements by APHIS personnel made in the webinar described previously appeared to indicate that the notice-based process will be of use for revisions to existing regulations that are minor in nature. The commenter also cited the questions and answers document as supporting this impression. The commenter was therefore puzzled by the broad scope of the process as described in the proposal.

We proposed to use the notice-based approach for all commodity import requests. Any reference to the time it takes APHIS to address minor changes to the regulations under traditional rulemaking was intended to serve as an example of how even a straightforward alteration to the regulations may end up taking a very long time under the current system. More complicated rulemakings are typically even more time-consuming. It is the success of our more limited notice-based process that

indicates that this broad process may be successfully implemented.

One commenter stated that we should expand upon our explanation of which measure out of the previous list of designated measures APHIS no longer finds sufficient to mitigate the phytosanitary risk posed by importation or interstate movement and how this will affect existing approved measures.

We believe the commenter misunderstood our characterization of the action as it was set out in the proposed rule. None of the five designated phytosanitary measures that had been previously approved for use with the notice-based process were determined to be inadequate to mitigate the pest risks for which they have been used, we instead proposed to expand and reorganize the categories of designated measures in conjunction with an expanded notice-based process.

Another commenter asked how APHIS intends to handle importation situations that include a disease or pest not previously dealt with in connection with the commodity under consideration for importation or interstate movement.

The same commenter wanted to know how APHIS will address a situation where a substantial importation volume of a given commodity is expected when the commodity originates in an area where one or more pests and diseases of quarantine significance exist. The commenter observed that high volumes of an export put pressure on both the exporter to adhere to the required systems approach, and on inspections in the exporting country and the United States.

Systems approaches allow for flexibility in modifying mitigation requirements when evolving pest situations both in the United States and in exporting countries occur. As stated previously, the scientific basis for the application of mitigations will not change. A novel or high import volume situation such as the one described by the commenter would be thoroughly analyzed in the PRA and RMD prior to the approval of any importation or interstate movement. APHIS considers that market access requests through notice-based process involving a systems approach will not be any less effective than rulemaking and will not compromise phytosanitary security.

One commenter wanted to know when the proposed systems approach would be described under the notice-based process in order to allow for stakeholder input. As described in the proposed rule, the process for developing PRAs and determining mitigation measures will remain the

same, giving the public opportunity to review, evaluate, and comment. PPQ will continue to make the draft PRAs, pest lists, or other pest risk documents available for review and comment by stakeholders upon completion. After incorporating any changes to the draft PRA, APHIS will then publish in the **Federal Register**, a notice announcing the availability of the pest risk analysis for a minimum of 60 days public comment. Each pest risk analysis made available for public comment through a notice specifies which of the designated phytosanitary measures APHIS would require to be applied, giving interested parties a chance to specifically comment on those measures. As previously mentioned, the final notice published in the **Federal Register** constitutes a final agency action which may be subject to challenge in court under the Administrative Procedure Act.

The same commenter stated that the operational workplans developed for use by APHIS and the NPPO of the exporting country are documents that can be changed quickly if the need arises. The commenter said that operational workplans are therefore not legally binding documents, particularly as compared to the weight and authority of traditional rulemaking. The commenter asked what the consequences would be if an exporting country were to violate the terms of the operational workplan.

Contrary to the commenter's assertion, operational workplans are binding documents. Every operational workplan includes a detailed description of the objectives, proposed activities, and expected results and benefits of the importation of a specific commodity and the related roles responsibilities, and resources contributed by each signatory. Penalties for violations of the terms of an operational workplan vary depending upon the violation in question, but can include such things as temporary or permanent ban on the importation of the commodity from the violating country.

The same commenter observed that the proposed rule did not address the way in which APHIS intends to handle or incorporate treatment of pest free areas under the expanded notice-based process.

The requirements regarding pest free area recognition are found in § 319.56–5 of the regulations and remain unchanged by this rule.

The same commenter asked what the principle source of information regarding a given commodity would be under the expanded notice-based system. The commenter hypothesized that this information would be kept in

FAVIR and asked if that database would be updated and kept current with the issuance of final notices regarding imports.

As stated in the proposed rule, fruits or vegetables approved for import under this approach will be listed in FAVIR, which is available on the APHIS website. Similarly, approved fruits and vegetables from Hawaii and the territories and their corresponding movement requirements will be listed in APHIS' Hawaii and Puerto Rico/U.S. Virgin Islands manuals, which are available for viewing and download on APHIS' website. All information in these sources will be updated as new commodities are approved for import or interstate movement.

The same commenter said that we did not specify when a preclearance program in the exporting country would be required. The commenter observed that preclearance is an important aspect of import requests, made more so as systems approaches become more complex.

Under some circumstances, we find that inspection prior to exportation is a necessary part of mitigating pest risk and the exporting country would need to inspect the commodity. Such an inspection requirement would be one of the mitigations included in the pest risk analysis and determination of need would be made on a case-by-case basis.

#### Comments on Pest Risk Analyses

One commenter observed that the PRA is simply a list of the pests and diseases present in the country requesting access to the U.S. market, while the more important issue for U.S. growers concerns the mitigation measures that will be required to address those pests and diseases. The commenter stated that this information should be made available in detail at the same time as the draft PRA is released for comment. The commenter also stated that, even if the RMD were to be released simultaneous to the draft PRA, it is fairly general in nature and does not provide details about the proposed systems approach.

As the commenter noted, mitigation measures for the pests of concern identified in the PRA are addressed in the RMD that is made available with the initial notice. This document is then subject to public comment for at least 60 days. As stated previously, we will continue to provide our draft PRAs on the APHIS website for review and comment before publication of an initial notice. Comments submitted during the 30 day review period for the draft PRA will be considered and may result in changes to the final PRA. The PRA also

informs the process of country consultation, which occurs after development of the PRA. The RMD is drafted after this consultation has concluded. Generally, the measures included in the RMD are those that have been certified as effective, standardized, and proven via use on similar or identical pest complexes. Information on the specific steps necessary to meet the requirements of the systems approaches are located in the operational workplan established between APHIS and the exporting country. Copies of the operational workplan may be requested from APHIS.

The same commenter said that the removal of the PRA from the APHIS website after the close of the comment period makes no sense to stakeholders and industry observers. The commenter suggested that all PRAs remain available on the APHIS website for all interested parties to access.

The PRA to which the commenter refers is a draft document. We post all draft PRAs on the APHIS website for comment for 30 days prior to finalizing the PRA and RMD and subsequently publishing any rule or notice concerning those PRAs. After the close of the comment period we remove the PRA from the APHIS website in order to make any necessary changes. Subsequent versions of the PRA are made available for review and comment in association with the **Federal Register** notice on *Regulations.gov*. The draft PRA and a summary of any comments we received are preserved and are available upon request.

The same commenter noted that it is impossible to determine the priority assigned by APHIS to any specific import request, and thus the PRA that addresses that request, from the information available on the APHIS website. The commenter asked that APHIS provide some indication of the order in which the PRAs are being considered.

APHIS handles market access requests in the order that they are received. However, issues such as the need for additional information from the requesting country may delay a given request, at which point we often move on to the next request while awaiting necessary information.

Another commenter said that we should make the data underlying PRAs and RMDs more readily available to stakeholders. The commenter suggested that, where proprietary data issues occur, data summaries or other forms of explanation should be provided to stakeholders.

We disagree. PRAs and RMDs represent a synthesis of research, knowledge, and experience. As such, they offer the most complete picture of the pest and disease situation in any potential production area as well as the best representation of the measures APHIS believes will mitigate any phytosanitary risks. We do note that we include references in the completed documents, which interested parties may examine if they so choose.

Two commenters asked if details such as the credibility of the foreign NPPO, infrastructure of programs, and facilities being employed would be made available. The commenters particularly cited the State of Florida as having requested on many occasions to have the opportunity to work more closely with APHIS to lend expertise and increase their level of knowledge regarding import programs. The commenters concluded that it is not acceptable for the State of Florida to concur with a list of phytosanitary measures without knowing firsthand what is being done to assure compliance.

PPQ and the National Plant Board work together to utilize our respective Federal and State authorities, assets, and expertise to safeguard plant health and enable safe trade. While it is not appropriate from a policy standpoint nor practicable from a scheduling standpoint for individual States to directly participate in such activities on a regular basis, we do note that representatives from the State of Florida accompanied APHIS on a site visit to Peru in November 2014 in order to examine the cold treatment program for citrus from that country. In past years, representatives of other States such as California have been included in similar visits.

One commenter said that we should develop procedures for facilitating stakeholder consultation into the process prior to publication of the draft PRA, including a defined period for review and public comment on pest and disease lists.

With respect to allowing the public to comment on pest and disease lists during the drafting phase of the pest risk analyses, such a process would have a serious adverse impact on the timely preparation of these documents. We believe a process in which an analysis is prepared, reviewed, and brought to a point where wider circulation and publication for comment is appropriate yields constructive comments that can be considered before any analysis is finalized. Therefore, we do not plan to take comments on pest and disease lists while they are under development.

The same commenter suggested we include regulated non-quarantine pests and other pests of concern in the PRA in addition to pests of quarantine significance.

The pests described by the commenter are currently included in every PRA prepared by APHIS.

Another commenter observed that the expanded notice-based process will not provide time efficiencies in the pest risk analysis development process, which is responsible for long delays in the processing of pending import applications for fruit and vegetables. The commenter suggested that APHIS consider this part of the approval process with the goal of identifying options to create further efficiencies.

In 2011, APHIS began a business process improvement initiative to identify and ameliorate inefficiencies in the manner in which we evaluate and respond to import applications for fruits and vegetables. While this initiative does not pertain solely to pest risk analyses, we have been working on an ongoing basis to improve the pest risk analysis development process since the initiative began.

One commenter expressed concern that the time reduction associated with the notice-based process may negatively impact the scientific scrutiny needed for the assurance of safety against potential exotic pests and diseases. The commenter urged APHIS to ensure that any time reduction does not also include a less thorough review of the scientific and technical review process.

We agree with the commenter's point that APHIS should ensure that any time reduction does not result in a less thorough review. As stated in the proposed rule, we will continue our specific reviews following market access requests as we have always done and provide the public opportunity to review and comment on the documents produced as a result of those reviews. The amount of time we devote to developing these pest risk analyses will not change. The shortened time period discussed in the proposed rule was in reference to that portion of the rulemaking process that begins after the pest risk analysis is finalized.

Another commenter stated that the proposed expansion of the notice-based process increases the types of measures that may be used as part of approved systems approaches. The commenter questioned whether the additional measures, either alone or in concert, would maintain the efficacy of the more limited notice-based system currently in use. The commenter asked that APHIS clarify how a given performance standard would be set and where

stakeholders would look in order to understand how the efficacy of these standards was measured. The commenter concluded that, while the RMD is supposedly where some of this information will be located, such documents do not necessarily include all of the data required for stakeholders to evaluate efficacy.

The documentation provided in support of an acceptable level of phytosanitary risk reduction will not change under the new process. The RMDs used for noticed-based process are identical to those used in traditional rulemaking. For new treatments we will also utilize a Treatment Evaluation Document, which specifically addresses the efficacy of those treatments with which we have less experience. We would note, however, that most treatments and mitigations required by APHIS are not novel. Various types of treatments (e.g., fumigation, heat treatment, and irradiation) and mitigations (e.g., pest-exclusionary structures, use of clean boxes for transit, and waxing) are effective against a wide variety of pests and diseases.

One commenter stated that we should consider limiting consignments of fruits and vegetables into States that have crops that are highly susceptible to infestation by pests and diseases from countries which do not have equivalent plant pest agencies. The commenter also stated that pest and risk information should be supplied to regulatory officials in those vulnerable States and regions.

We will continue to consider limiting distribution of imports on a case-by-case basis when the findings of pest risk analysis indicate that such an action might be necessary and if it is operationally feasible. Limited distribution is specifically cited as an example of a safeguarding and movement mitigation that may be applied. We provide our expertise via analysis in the form of pest risk assessments and other risk documentation, which is available to all interested parties via publication of material in the **Federal Register** as well as through PPQ's stakeholder registry.

#### Comments on Other Supporting Analyses

Several commenters asked if economic impact studies and determinations of significance or economic significance would remain part of the streamlined process.

Our determination as to whether a new agricultural commodity can be safely imported is based on the findings of the pest risk analysis, not on economic factors. However, we will

continue to consider the potential economic consequences of pest introduction in the PRA. Similarly, we will document our consideration of trade volume and other economic factors.

One commenter said that the proposal appeared to create disparity in the consideration of the importation of fruits and vegetables versus other commodities, such as meat, citing a lack of interagency review and economic analysis as two such examples. The commenter stated that the import review process for all commodities should currently be of equivalent depth and rigor. Finally, the commenter concluded that the rulemaking process across all of APHIS' activities, not only those concerning the importation of fruits and vegetables, must be similarly time-consuming and therefore all in need of streamlining so that importations of all commodities may be treated equivalently.

We disagree with the commenter that market access requests for fruits and vegetables would be subject to less rigor and interagency review under the proposed rule than market access requests for other agricultural commodities, live animals, or animal products. As we stated previously in this document, we will continue to conduct PRAs, and these PRAs will continue to evaluate the potential economic consequences of pest introduction associated with the importation of the fruit or vegetable.

We agree with the commenter, however, regarding the need to evaluate and, if possible, streamline our processes regarding the importation of other agricultural commodities, live animals and animal products. Indeed, there is an ongoing APHIS initiative to do precisely that. The initiative has yielded a final rule<sup>5</sup> (83 FR 11845–11867, Docket No. APHIS–2008–0011) to restructure our plants for planting regulations to make them less cumbersome to change, and we are currently evaluating our regulations regarding the importation of live animals and animal products to identify how they could potentially be streamlined.

Another commenter said that it is crucial to maintain a review of specific varieties of fruits and vegetables in connection with the origin of the commodity in order to properly analyze the risks associated with exporting the commodity to the United States. The

commenter stated that each region and crop variety poses different risks and should be reviewed separately in order to identify proper phytosanitary mitigation measures and receive relevant public comment.

We agree with the commenter. Our proposal was not to eliminate review of specific varieties of fruits and vegetables in connection with those varieties' country or region of origin, it was merely to remove those specific references from the regulations. We will continue our specific reviews following market access requests as we have always done and provide the public opportunity to review and comment on the documents produced as a result of those reviews. However, the requirements for the importation of specific commodities will no longer be found in the regulations themselves. The requirements will continue to be located in the FAVIR database or APHIS' Hawaii and Puerto Rico/U.S. Virgin Islands manuals.

One commenter cited the World Trade Organization's (WTO) Article 5, "Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection," which states: "In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks." The commenter argued that the elimination of the economic impact analysis is in conflict with the WTO mandate, as it will impact APHIS' ability to consider such consequences. The commenter concluded that, given the rapid changes to global fruit and vegetable production patterns, it is not reasonable for APHIS to make a blanket determination that the future economic impact of unspecified foreign imports entering the United States will always be of little significance.

We disagree that our actions are in conflict with WTO Article 5. As stated previously, we will continue to consider the potential economic consequences of pest introduction in the PRAs. This shift to a fully notice-based system will not alter that approach.

<sup>5</sup> To view the final rule, its supporting documents, or the comments that we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0011>.



### Comments on Phytosanitary Security

One commenter expressed concern regarding the varying capabilities of countries seeking to export fruit and vegetables to the United States to meet the proposed expanded mitigation measures APHIS may recommend. The commenter recommended that APHIS proceed cautiously on approving new market access from countries with regulatory agencies that have questionable capacity in meeting the scientifically based import requirements needed to ensure the phytosanitary security of U.S. produce.

Several commenters noted that the more steps that are included in a systems approach, the more chance that exists for error in its application. One of the commenters suggested that, therefore, particular attention should be paid to the way in which systems approaches are designed, executed, and enforced.

We disagree with the commenters that the number of steps in a systems approach is necessarily correlated to the likelihood of error in its application. Most mitigation measures that are included in systems approaches, such as packinghouse inspections, follow generally applicable standard operating procedures that typically do not vary significantly from systems approach to systems approach or country to country. In our experience, a systems approach that consists solely of such routine measures is unlikely to encounter errors in its application.

Rather, in our experience, the likelihood of error in the application of mitigation measures most often occurs in those relatively rare instances where the application of a mitigation measure in the systems approach does vary from country to country or site to site, with the chance for error increasing relative to the degree to which those measures differ from more routine measures. In such instances, to address this possibility for error, we exercise a higher degree of APHIS oversight to implement those particular mitigation measures. We also are more likely to conduct a follow-up site visit in the exporting country to monitor the implementation of the operational workplan.

The same commenter stated that it is impossible to test systems approaches designed to address complex pest and disease situations, some of which are being used for the first time, until a considerable volume of fruits or vegetables are imported under the requirements.

Many of these systems are already utilized by U.S. domestic producers to

meet requirements required by our trading partners when exporting commodities from the United States. Further, as stated above, very few if any of the elements of the systems approaches will be novel; their effects are well known to APHIS and backed by years of research, knowledge, and experience.

Another commenter said that part of the reduction in the overall timeframe for consideration of import requests comes from the elimination of the Office of Management and Budget's (OMB's) ability to review APHIS rules. The commenter asked how APHIS will ensure that adequate resources are being devoted to mitigation measures in exporting countries or that the appropriate standards for approval of import requests are being achieved if OMB is precluded from undertaking a review of APHIS' actions.

As stated previously, the standards set by APHIS are phytosanitary in nature and, as such, are solely based on sound science. APHIS generally reviews its operational workplans and importation agreements on a yearly basis to ensure that exporting countries are able to continue to meet those requirements. In addition, APHIS will continue to apprise OMB of all notice-based import or interstate movement actions.

### Comments on Stakeholder Engagement

One commenter stated that the domestic industry must be provided sufficient time for review and evaluation of any importation request and questioned whether the reduced timeframe afforded by the proposed streamlining process would provide adequate time for APHIS to properly conduct a pest risk analysis. The commenter also noted the absence of OMB review from the streamlined process.

Another commenter proposed that the expanded notice-based process would create a need for increased communication with U.S. stakeholders, specifically when those stakeholders are potentially impacted by specific commodities imported subject to phytosanitary mitigations. The commenter supposed that there would be an increased need for extended public comment periods as well as greater opportunity for stakeholders to evaluate the risk assessment process, including the data supporting inclusion of a given action within the required systems approach.

Another commenter questioned whether 60 days is sufficient time for the industry and other stakeholders to adequately review the science behind the PRA and risk mitigation document.

The commenter argued that, depending upon the time of year that the notice is provided, the ability to gather adequate stakeholders with the technical expertise to provide useful input on APHIS' documents may be limited. The commenter asked whether APHIS intends to formally notify the industry upon receipt of a market access request and the beginning of the pest risk analysis development process. If not, the commenter wanted to know if an extension beyond the 60-day review period will be possible. A second commenter stated that stakeholders should be provided opportunities for comment and consultation prior to publication of the draft PRA.

In addition to the draft PRA review period of 30 days, the notices would provide for a comment period of at least 60 days, which would give interested parties a total of 90 days to review and comment on various aspects of the proposed action. While we will not be issuing notification when we first receive a market access request, as the pest risk analysis development process can be quite lengthy depending on the country, the pest situation, and the commodity, the notice-based process does not preclude us from extending the comment period when necessary. During the comment period for the initial notice, stakeholders will have further opportunity to comment on any aspect of the PRA they deem necessary. We have no plans to incorporate stakeholder review and consultation into the process prior to posting the draft PRA. The time savings and regulatory flexibility we anticipate as a result of this change will be realized only through shortening of the rule development process. We will continue to prepare scientific documentation with the same rigor as we have always utilized. In addition to the economic considerations required to be included in the PRA, APHIS will continue to apprise OMB of all notice-based import or interstate movement actions. Further, if the information that will be disseminated in a pest risk analysis is determined to be "influential" or "highly influential" as those terms are used in the Office of Management and Budget's "Final Information Quality Bulletin for Peer Review," (see 70 FR 2664–2667, published January 14, 2005), then a peer review will be conducted in accordance with USDA's peer review guidance (see <http://www.ocio.usda.gov/document/usdas-peer-review-guidelines>).

The same commenter requested clarification of the current criteria for stakeholder notification in the event that a phytosanitary mitigation measure



is no longer sufficient. The commenter also wanted to know how APHIS reaches such a conclusion via evaluation or review of technical data.

Interception of even one target quarantine pest for a commodity (usually those pests rated high or medium risk in the PRA) at a port of entry triggers an immediate review of the risk mitigations for that commodity. Other factors that may trigger review are an increase in the pest population in the exporting country and reports of a new pest in the exporting country. The procedures for adding or removing measures would be the same regardless of whether or not the fruit or vegetable in question was approved prior to the implementation of the proposed process.

Regarding our current process for notifying stakeholders in the event that we change the risk mitigations for a certain commodity, we issue a Federal Order alerting the general public to the changes in the mitigation measures; this Federal Order is issued through the APHIS Stakeholder Registry, among other means. Federal Orders constitute final agency action under the Administrative Procedure Act and may be subject to challenge in court. A Federal Order is usually accompanied by a letter to State plant regulatory officials regarding its issuance. As soon as possible, we update FAVIR and contact existing permit holders regarding the change. If the change in the mitigation structure will be permanent in nature, we initiate rulemaking to codify that change. The new process will be an initial and final notice regarding any permanent change to established mitigations.

Another commenter wanted to know what the process would be in the event that one or more of the designated phytosanitary measures is found insufficient to mitigate the phytosanitary risk associated with a given commodity or the pest risk analysis requires amendments as a result of stakeholder consultation.

Any necessary changes to the PRA based on stakeholder input would be made either at the end of the 30 day comment period specific to the PRA (prior to the publication of the initial notice) or following the close of the comment period on the initial **Federal Register** notice. Changes to the risk mitigation document would be made following the close of the comment period on the initial **Federal Register** notice. If information is provided during that time that leads us to conclude that the proposed mitigation measures are insufficient to mitigate the phytosanitary risk posed by the pests of

concern, we would have the option of adding additional requirements to mitigate that risk or not finalizing the proposed action. We would notify stakeholders of our decision via **Federal Register** notice as well as other methods such as the PPQ Stakeholder Registry. Likewise, if the mitigation measures assigned to an already approved fruit or vegetable are found to be no longer sufficient, we will take measures appropriate to addressing the risk and communicate them through the same channels. In an emergency situation a Federal Order may be issued to alter the conditions of movement or halt it completely.

One commenter requested that APHIS provide more opportunity for stakeholders to provide input regarding import requests. The commenter argued that, in cases where exporting countries are less sophisticated in their agricultural practices than the United States, U.S. industry expertise would prove vital in designing an effective systems approach.

We disagree with the commenter's suggestion. If, based on the findings of our pest risk analysis, we determine that the fruit or vegetable cannot be imported safely, then we would not propose to allow for its importation. Our analyses have always included not only the efficacy of any required treatments or handling methods, but the ability of the exporting country to meet those standards. As stated previously, after initial approval for importation, we examine each program periodically to ensure that the NPPO and foreign exporters are operating according to established standards. The opportunity for public input, which is at least 60 days, is ample time in which stakeholders may address any concerns, questions, or additional necessary information to APHIS.

#### Comments on Trade Issues

One commenter expressed concern about a potential trade imbalance due to the requirement for cost recovery associated with preclearance and verification inspections through trust fund arrangements. The commenter stated that this obligation creates high administrative cost for U.S. importers and creates an imbalance in relation with trading partners, such as the European Union, that do not engage in cost recovery for phytosanitary inspections undertaken in the United States.

APHIS employs trust fund agreements only for countries that operate under preclearance programs that require APHIS personnel to be stationed in the country. Only a few countries have such

programs, and the programs themselves pertain only to a few commodities exported to the United States from those countries. For these reasons, we believe that the commenter overstated the trade imbalances associated with the use of trust fund agreements and cost recovery.

It is worth noting, moreover, that the United States generally does not require such programs, but enters into them typically at the request of the exporting country or an export group from that country. Countries or export groups that request such programs do so based on a belief that the time and cost savings associated with preclearance inspections, rather than inspection at the port of first arrival into the United States, will justify the costs associated with the preclearance inspections. In instances where concern has been raised about the costs of the preclearance program, APHIS has worked with the NPPO to explore ways to minimize those costs.

Another commenter asked what assurances domestic producers have that facilitating our import approval process will prompt a similar response from foreign countries. The commenter also noted that a review of imports and exports of fruits and vegetables in recent years reveals that while imports into the United States continue to grow, exports of U.S. fruits and vegetables lag at a considerable pace. The commenter stated that this result is in direct opposition to assurances made regarding the United States concurrence with the WTO Sanitary and Phytosanitary (SPS) Agreement.

USDA actively and vigorously pursues foreign market access for U.S. products. These efforts have yielded a significant increase in U.S. exports of agricultural products in recent years; indeed, between 2006 and 2014, U.S. agricultural exports more than doubled. Under the SPS Agreement, signatory countries may set the level of phytosanitary protection that they consider appropriate, as long as there is a scientific justification. The level of phytosanitary protection often has direct bearing on how long it takes to approve a market access request. In some instances, USDA has successfully worked with foreign governments to set new terms for market access, thereby facilitating the import approval process for U.S. products.

The same commenter asked that APHIS provide the number of staff hours currently dedicated to fruit and vegetable importation issues and compare that to the number of staff hours that have been dedicated to working on new export opportunities for the U.S. fruit and vegetable industry.

We cannot provide such an accounting given that a number of APHIS staff members work on multiple import and export requests simultaneously. Without clear benefit to associated with keeping such a record, to do so would be time-consuming and overly burdensome. Streamlining our administrative processes will allow the agency to concentrate its expertise on more complex tasks. As stated previously, we also view this rule as a measure for improving the timeliness of our action on import requests, and of our emphasis on science as a basis for decisionmaking while maintaining the fullest practicable opportunity for all interested parties to participate in the process.

The same commenter stated that APHIS indicated during the December webinar that approximately 34 requests for imports into the United States have been handled under the notice-based process since its inception in 2007. The commenter said that APHIS should provide information on how much progress has been made with respect to exports from the United States in that time.

As noted above, U.S. agricultural exports more than doubled between 2006 and 2014.

Another commenter observed that during the webinar, APHIS indicated that U.S. agricultural export interests would benefit due to future reciprocity from trading partners. The commenter said that domestic fruit and vegetable exporters currently face plant quarantine barriers in foreign markets that appear to have little scientific basis, but there is no basis for the assumption that foreign markets will follow the U.S. lead in facilitating the importation process for U.S. commodities. The commenter inquired if APHIS has undertaken any studies to determine whether this claim involving foreign market reciprocity is correct or if APHIS has received assurances from trading partners that they will provide reciprocal access.

APHIS has not performed any studies analyzing the trade reciprocity factor. As stated previously, we are obligated to follow the principles and procedures of the SPS Agreement, including the obligation to base our regulations on science. Other signatories of the SPS Agreement are obligated to do so as well.

#### Miscellaneous Changes

We note that the proposed rule made reference to the fruit and vegetables manual PPQ maintained related to the importation of fruits and vegetables into the United States. Since the publication

of the proposed rule, we have expanded the scope and detail of FAVIR, which rendered the fruit and vegetables manual unnecessarily duplicative. We have therefore discontinued that manual and removed references to it from this rule.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with that one change.

#### Executive Orders 12866, 13563, 13771 and Regulatory Flexibility Act

This final rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget. APHIS considers this rule to be a deregulatory action under Executive Order 13771 as the action will allow the public faster access to fruits and vegetables not previously approved for importation or movement from Hawaii and U.S. territories. This will benefit importers by allowing more timely access to U.S. markets. Quicker approval of requests to import fruits and vegetables will also benefit consumers. Details are provided in the economic analysis prepared for this rule.

The economic analysis provides a cost-benefit analysis, as required by Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The economic analysis also provides a final regulatory flexibility analysis that examines the potential economic effects of this rule on small entities, as required by the Regulatory Flexibility Act. The economic analysis is summarized below. Copies of the full analysis are available on the *Regulations.gov* website (see footnote 3 in this document for a link to *Regulations.gov*) or by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

Requirements for the importation of fruits and vegetables include risk mitigation measures such as treatments, inspections, and certifications. A fruit or vegetable is not allowed to be imported until APHIS has completed the rulemaking process or the notice-based process to approve entry of the fruit or vegetable, based on specific phytosanitary measures. This rule will

establish a single performance standard that, when met, will allow notice-based approval of fruits and vegetables for importation into the United States. The region- and commodity-specific phytosanitary requirements currently in the regulations will be removed and replaced with this single performance standard. The rule will also establish an equivalent single performance standard that will govern the interstate movement of fruits and vegetables from Hawaii and U.S. territories.

The rule will benefit both APHIS in its operations and U.S. businesses and consumers. APHIS will be able to use its resources more efficiently and the public will have quicker access to fruits and vegetables newly approved for importation or movement from Hawaii and U.S. territories.

APHIS has already established a notice-based process for allowing the importation or movement from Hawaii and U.S. territories of certain fruits and vegetables, subject to one or more specified phytosanitary measures. For fruits and vegetables for which the risks are not adequately mitigated by these specified measures and thereby do not qualify under the current notice-based process, the rulemaking process can range from 18 months to over 3 years. The time needed for approval under the notice-based process ranges from 6 to 12 months, that is, 6 months to 2.5 years sooner.

Consumers and businesses will benefit from more timely access to fruits and vegetables for which entry or movement approval currently requires rulemaking. While certain businesses will face increased competition at an earlier time for the subject fruits and vegetables, if they are produced domestically, overall economic impacts of the rule will be positive. The rule will not alter the manner in which the risks associated with a fruit or vegetable import or interstate movement request are evaluated and mitigated. Principal industries that could be affected by the rule, fruit and vegetable farms and fruit and vegetable importers, are largely composed of small entities.

As a measure of the net benefit of the rule to U.S. businesses and consumers, we estimate net welfare gains that could have been realized for a set of past import actions (11 import rules allowing 8 commodities from 7 countries or regions, in various combinations) if the quicker, notice-based process for acquiring market access had been possible. The rules were in preparation or promulgated over the 7 year period, 2012 through 2018. The 7 year sum of annual net welfare gains is estimated to range from about \$13.7 million to \$47.5

million, yielding annual average net welfare gains from these import actions of \$2.0 million to \$6.8 million.

Net welfare gains that could have been realized under this rule for this set of import actions range from about \$1 million to \$17 million (calculated as the low-range annual net welfare gain multiplied by half year and the high-range annual net welfare gain multiplied by 2.5 years). These estimates are derived based on the time period and commodities specified, and are considered representative of future welfare gains that will be attributable to the rule. Net welfare gains actually realized will depend on the particular commodities that acquire market access, their source countries, and market conditions at that time.

Interpreting these gains as cost savings accrued by using the quicker notice-based process rather than having to wait for rule promulgation, and in accordance with guidance on complying with Executive Order 13771, the primary cost savings estimate for this rule is \$562,500. This value is the mid-point estimate of cost savings annualized in perpetuity using a 7 percent discount rate.

#### Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

#### Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, "Consultation and Coordination with Indian Tribal Governments." Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

APHIS has assessed the impact of this rule on Indian Tribes and determined that this rule does not, to our knowledge, have Tribal implications that require tribal consultation under Executive Order 13175. If a Tribe requests consultation, APHIS will work

with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions and modifications identified herein are not expressly mandated by Congress.

#### National Environmental Policy Act

The majority of the regulatory changes in this document are nonsubstantive, and would therefore have no effects on the environment. However, this rule will allow APHIS to approve certain new fruits and vegetables for importation into the United States without undertaking rulemaking. Despite the fact that those fruits and vegetable imports will no longer be contingent on the completion of rulemaking, the requirements of the National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*) will still apply. As such, for each additional fruit or vegetable approved for importation, APHIS will make available to the public documentation related to our analysis of the potential environmental effects of such new imports. This documentation will likely be made available at the same time and via the same **Federal Register** notice as the risk analysis for the proposed new import.

#### Paperwork Reduction Act

In accordance with section 3507 (d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), some of the information collection requirements included in this final rule are approved by OMB under control number 0579–0346. In addition, on January 29, 2018, APHIS published a 60-day notice in the **Federal Register** (83 FR 4023–4024, Docket No. APHIS–2017–0108), to reinstate OMB control number 0579–0049 which includes burden activities implemented by this rule. In accordance with the procedure for reinstating an information collection, USDA will be publishing a 30-day notice in the **Federal Register**. Once OMB control number 0579–0049 is approved, as fruits and vegetables are approved for importation or interstate movement based on this rule, their associated burden activities and burden will be added to the information collection via the submission of a quarterly report to OMB.

#### 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

##### 7 CFR Part 318

Cotton, Cottonseeds, Fruits, Guam, Hawaii, Plant diseases and pests, Puerto Rico, Quarantine, Transportation, Vegetables, Virgin Islands.

##### 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 parts 318 and 319 as follows:

#### PART 318—STATE OF HAWAII AND TERRITORIES QUARANTINE NOTICES

■ 1. The authority citation for part 318 continues to read as follows:

**Authority:** 7 U.S.C. 7701–7772 and 7781–7786; 7 CFR 2.22, 2.80, and 371.3.

##### § 318.13–2 [Amended]

■ 2. Section 318.13–2 is amended by removing the definition for "Approved growing media".

■ 3. Section 318.13–4 is revised to read as follows:

##### § 318.13–4 Authorization of certain fruits and vegetables for interstate movement.

(a) *Determination by the Administrator.* No fruit or vegetable is authorized for interstate movement from Hawaii or the territories unless the Administrator has determined that the risk posed by each quarantine pest associated with the fruit or vegetable can be reasonably mitigated by the application of one or more phytosanitary measures designated by the Administrator.

(b) *Designated phytosanitary measures.* (1) The fruits and vegetables are subject to phytosanitary treatments, which could include, but are not limited to, pest control treatments in the field or growing site, and post-harvest treatments.

(2) The fruits and vegetables are subject to growing area pest mitigations, which could include, but are not limited to, detection surveys, trapping requirements, pest exclusionary structures, and field inspections.

(3) The fruits and vegetables are subject to safeguarding and movement mitigations, which could include, but are not limited to, safeguarded transport, box labeling, limited

distribution, insect-proof boxes, and importation as commercial consignments only.

(4) The fruits and vegetables are subject to administrative mitigations, which could include, but are not limited to, registered fields or orchards, registered growing sites, registered packinghouses, inspection in the State of origin by an inspector, and operational workplan monitoring.

(5) The fruits and vegetables are subject to any other measures deemed appropriate by the Administrator.

(c) *Authorized fruits and vegetables—*

(1) *Comprehensive list.* The name and origin of all fruits and vegetables authorized for interstate movement under this section, as well as the applicable requirements for their movement, may be found on the internet at <https://www.aphis.usda.gov/aphis/ourfocus/planthealth/complete-list-of-electronic-manuals>.

(2) *Fruits and vegetables authorized for interstate movement prior to October 15, 2018.* Fruits and vegetables that were authorized for interstate movement under this subpart as of October 15, 2018 may continue to be moved interstate under the same requirements that applied before October 15, 2018, except as provided in paragraph (c)(4) of this section.

(3) *Other fruits and vegetables.* Fruits and vegetables not already authorized for interstate movement as described in paragraph (c)(2) of this section may be authorized for interstate movement only after:

(i) APHIS has analyzed the pest risk posed by the interstate movement of a fruit or vegetable and has determined that the risk posed by each quarantine pest associated with the fruit or vegetable can be reasonably mitigated by the application of one or more phytosanitary measures;

(ii) APHIS has made its pest risk analysis and determination available for public comment for at least 60 days through a notice published in the **Federal Register**; and

(iii) The Administrator has announced his or her decision in a subsequent **Federal Register** notice to begin allowing interstate movement of the fruit or vegetable subject to the phytosanitary measures specified in the notice.

(4) *Changes to phytosanitary measures.* (i) If the Administrator determines that the phytosanitary measures required for a fruit or vegetable that has been authorized interstate movement under this subpart are no longer sufficient to reasonably mitigate the pest risk posed by the fruit or vegetable, APHIS will prohibit or

further restrict interstate movement of the fruit or vegetable. APHIS will also publish a notice in the **Federal Register** advising the public of its finding. The notice will specify the amended interstate movement requirements, provide an effective date for the change, and invite public comment on the subject.

(ii) If the Administrator determines that any of the phytosanitary measures required for a fruit or vegetable that has been authorized interstate movement under this subpart are no longer necessary to reasonably mitigate the pest risk posed by the fruit or vegetable, APHIS will make new pest risk documentation available for public comment, in accordance with paragraph (c)(3) of this section, prior to allowing interstate movement of the fruit or vegetable subject to the phytosanitary measures specified in the notice.

(Approved by the Office of Management and Budget under control number 0579-0346)

#### **§ 318.13-13 [Amended]**

■ 4. Section 318.13-13 is amended by removing the last sentence.

#### **§ 318.13-16 [Removed]**

■ 5. Section 318.13-16 is removed.

#### **§ 318.13-17 [Redesignated as § 318.13-16]**

■ 6. Section 318.13-17 is redesignated as § 318.13-16.

#### **§ 318.13-16 [Amended]**

■ 7. In newly redesignated § 318.13-16, paragraph (a)(1) is amended by removing the word “under” and adding the words “in accordance with” in its place.

#### **§§ 318.13-18 through 318.13-22 [Removed]**

■ 8. Sections 318.13-18 through 318.13-22 are removed.

#### **§ 318.13-23 [Redesignated as § 318.13-17]**

■ 9. Section 318.13-23 is redesignated as § 318.13-17.

#### **§§ 318.13-24 through 318.13-26 [Removed]**

■ 10. Sections 318.13-24 through § 318.13-26 are removed.

### **PART 319—FOREIGN QUARANTINE NOTICES**

■ 11. 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.

### **Subpart—Citrus Fruit [Removed]**

■ 12. Subpart—Citrus Fruit, consisting of § 319.28, is removed.

#### **§ 319.56-2 [Amended]**

■ 13. Section 319.56-2 is amended by removing the definitions for “Above ground parts,” “Cucurbits,” “Field,” “Place of production,” “Production site,” and “West Indies”.

■ 14. Section 319.56-4 is revised to read as follows:

#### **§ 319.56-4 Authorization of certain fruits and vegetables for importation.**

(a) *Determination by the Administrator.* No fruit or vegetable is authorized importation into the United States unless the Administrator has determined that the risk posed by each quarantine pest associated with the fruit or vegetable can be reasonably mitigated by the application of one or more phytosanitary measures designated by the Administrator and the fruit or vegetable is imported into the United States in accordance with, and as stipulated in, the permit issued by the Administrator.

(b) *Designated phytosanitary measures.* (1) The fruits and vegetables are subject to phytosanitary treatments, which could include, but are not limited to, pest control treatments in the field or growing site, and post-harvest treatments.

(2) The fruits and vegetables are subject to growing area pest mitigations, which could include, but are not limited to detection surveys, trapping requirements, pest exclusionary structures, and field inspections.

(3) The fruits and vegetables are subject to safeguarding and movement mitigations, which could include, but are not limited to, safeguarded transport, box labeling, limited distribution, insect-proof boxes, and importation as commercial consignments only.

(4) The fruits and vegetables are subject to administrative mitigations, which could include, but are not limited to, registered fields or orchards, registered growing sites, registered packinghouses, inspection in the country of origin by an inspector or an official of the national plant protection organization of the exporting country, and operational workplan monitoring.

(5) The fruits and vegetables are subject to any other measures deemed appropriate by the Administrator.

(c) *Authorized fruits and vegetables—*

(1) *Comprehensive list.* The name and origin of all fruits and vegetables authorized importation under this section, as well as the applicable

requirements for their importation, may be found on the internet at <https://epermits.aphis.usda.gov/manual>.

(2) *Fruits and vegetables authorized importation prior to October 15, 2018.*

Fruits and vegetables that were authorized importation under this subpart either directly by permit or by specific regulation as of October 15, 2018 may continue to be imported into the United States under the same requirements that applied before October 15, 2018, except as provided in paragraph (c)(4) of this section.

(3) *Other fruits and vegetables.* Fruits and vegetables not already authorized for importation as described in paragraph (c)(2) of this section may be authorized importation only after:

(i) APHIS has analyzed the pest risk posed by the importation of a fruit or vegetable from a specified foreign region and has determined that the risk posed by each quarantine pest associated with the fruit or vegetable can be reasonably mitigated by the application of one or more phytosanitary measures;

(ii) APHIS has made its pest risk analysis and determination available for public comment for at least 60 days through a notice published in the **Federal Register**; and

(iii) The Administrator has announced his or her decision in a subsequent **Federal Register** notice to authorize the importation of the fruit or vegetable subject to the phytosanitary measures specified in the notice.

(4) *Changes to phytosanitary measures.* (i) If the Administrator determines that the phytosanitary measures required for a fruit or vegetable that has been authorized importation under this subpart are no longer sufficient to reasonably mitigate the pest risk posed by the fruit or vegetable, APHIS will prohibit or further restrict importation of the fruit or vegetable. APHIS will also publish a notice in the **Federal Register** advising the public of its finding. The notice will specify the amended importation requirements, provide an effective date for the change, and will invite public comment on the subject.

(ii) If the Administrator determines that any of the phytosanitary measures required for a fruit or vegetable that has been authorized importation under this subpart are no longer necessary to reasonably mitigate the pest risk posed by the fruit or vegetable, APHIS will make new pest risk documentation available for public comment, in accordance with paragraph (c)(3) of this section, prior to allowing importation of the fruit or vegetable subject to the phytosanitary measures specified in the notice.

(Approved by the Office of Management and Budget under control number 0579-0049)

**§§ 319.56–13 through 319.56–83 [Removed]**

■ 15. Sections 319.56–13 through 319.56–83 are removed.

Done in Washington, DC, this 10th day of September 2018.

**Greg Ibach,**

*Under Secretary for Marketing and Regulatory Programs.*

[FR Doc. 2018–19984 Filed 9–13–18; 8:45 am]

**BILLING CODE 3410–34–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 71

[Docket No. FAA–2018–0328; Airspace Docket No. 18–ASO–7]

**RIN 2120–AA66**

#### Amendment of Class D Airspace and Class E Airspace, and Revocation of Class E Airspace: New Smyrna Beach, FL

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule, correction.

**SUMMARY:** This action corrects a final rule published in the **Federal Register** on August 23, 2018, amending Class D airspace and Class E airspace extending upward from 700 feet or more above the surface at New Smyrna Beach Municipal Airport, New Smyrna Beach, FL. The longitude coordinate symbols for Massey Ranch Airpark listed in Class E airspace areas extending upward from 700 feet were typed as degrees, minutes, minutes instead of degrees, minutes, and seconds. Also, a parenthesis was excluded from the airport's geographic coordinates.

**DATES:** Effective 0901 UTC, November 8, 2018. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

**FOR FURTHER INFORMATION CONTACT:** John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Av., College Park, GA 30337; telephone (404) 305–6364.

#### SUPPLEMENTARY INFORMATION:

##### History

The FAA published a final rule in the **Federal Register** (83 FR 42585, August

23, 2018) for Doc. No. FAA–2018–0328, amending Class D airspace, and Class E airspace extending upward from 700 feet or more above the surface at New Smyrna Beach Municipal Airport, New Smyrna Beach, FL. Subsequent to publication, the FAA found that the symbols of the longitude coordinate for Massey Ranch Airpark, listed in the description under Class E airspace extending upward from 700 feet or more above the surface, was printed incorrectly. Also, a parenthesis was omitted from the geographic coordinates of New Smyrna Beach Municipal Airport. This action corrects these errors.

Class D and E airspace designations are published in paragraphs 5000 and 6005, respectively, of FAA Order 7400.11B dated August 3, 2017, and effective September 15, 2017, which is incorporated by reference in 14 CFR part 71.1. The E airspace designations listed in this document will be published subsequently in the Order.

#### Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, in the **Federal Register** of August 23, 2018 (83 FR 42585) FR Doc. 2018–18035, Amendment of D Airspace and Class E Airspace, and Revocation of Class E Airspace; New Smyrna Beach, FL, is corrected as follows:

#### § 71.1 [Amended]

**ASO FL E5 New Smyrna Beach, FL [Corrected]**

■ On page 42586, column 3 line 53, remove Lat. 29°03'21" N, long. 80°56'56" W) and add in its place (Lat. 29°03'21" N, long. 80°56'56" W).

■ On page 42586, column 3 line 55, remove (Lat. 28°58'44" N, long. 80°55'29" W) and add in its place (Lat. 28°58'44" N, long. 80°55'29" W)

Issued in College Park, Georgia, on September 6, 2018.

**Ken Brissenden,**

*Acting Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.*

[FR Doc. 2018–19978 Filed 9–13–18; 8:45 am]

**BILLING CODE 4910–13–P**

## FEDERAL TRADE COMMISSION

**RIN 3084–AA98**

#### 16 CFR Part 310

#### Telemarketing Sales Rule Fees

**AGENCY:** Federal Trade Commission.

**ACTION:** Final rule.