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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: Proposed rule.

SUMMARY: We are proposing to amend our regulations governing the importations 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 proposing to remove the region- or commodity-specific phytosanitary requirements currently found in these regulations. Likewise, we are proposing an equivalent revision of the performance standard in our regulations governing the interstate movements of fruits and vegetables from Hawaii and the U.S. territories (Guam, Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands) and the removal of commodity-specific phytosanitary requirements from those regulations. This proposal would 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 would 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: We will consider all comments that we receive on or before [Insert date 60 days after date of publication in the Federal Register].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to
 http://www.regulations.gov/#!docketDetail;D=APHIS-2010-0082.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2010-0082, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at http://www.regulations.gov/#!docketDetail;D=APHIS-2010-0082 or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Ms. Nicole L. Russo, Assistant Director, Regulatory Coordination and Compliance, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1231; (301) 851-2159.

SUPPLEMENTARY INFORMATION:

Background

Foreign Quarantine Notices

Under the regulations in "Subpart—Fruits and Vegetables" (7 CFR 319.56-1 through 319.56-70, 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.

In a final rule published in the <u>Federal Register</u> on July 18, 2007 (72 FR 39482-39528, Docket No. APHIS-2005-0106), and effective on August 17, 2007, we established a process by which we allow certain fruits and vegetables to be approved for importation. That rule established a notice-based process for approving the importation of fruits or vegetables that, based on the findings of a pest risk analysis, can be safely imported subject to one or more of the designated phytosanitary measures listed in § 319.56-4(b) of the regulations. These measures, which are referred to elsewhere in this document as designated phytosanitary measures or designated phytosanitary measures of the fruits and vegetables regulations, are:

- The fruits or vegetables are subject to inspection upon arrival in the United States and comply with all applicable provisions of § 319.56-3;
- The fruits or vegetables are imported from a pest-free area in the country of origin that meets the requirements of § 319.56-5 for freedom from that pest and are accompanied by a phytosanitary certificate stating that the fruits or vegetables originated in a pest-free area in the country of origin;

- The fruits or vegetables are treated in accordance with 7 CFR part 305;
- The fruits or vegetables are inspected in the country of origin by an inspector or an official of the national plant protection organization (NPPO) of the exporting country, and have been found free of one or more specific quarantine pests identified by the risk analysis as likely to follow the import pathway; and/or
 - The fruits or vegetables are imported as commercial consignments only.

Under the notice-based process, amendments to the regulations are not needed, as approval of fruits and vegetables for importation from various countries or regions is accomplished via the publication of notices in the Federal Register (this practice is described in detail below under the heading "Current Processes"). To list approved commodities and the requirements for their importation, APHIS's Plant Protection and Quarantine (PPQ) program developed the Fruits and Vegetables Import Requirements (FAVIR) database, which is accessible via the APHIS Web site. FAVIR includes not only those commodities approved using the notice-based process, but also commodities approved through rulemaking. FAVIR allows individuals to search for authorized fruits and vegetables by commodity or country, and quickly and easily determine the requirements for their importation into the United States. In addition, FAVIR allows APHIS officials and the Department of Homeland Security's Customs and Border Protection agricultural inspectors to quickly determine whether or not a fruit or vegetable is authorized entry into the United States. Approved commodities are also listed in PPQ's Fresh Fruits and Vegetables Import Manual and will continue to be so listed.

¹ You may search FAVIR at http://www.aphis.usda.gov/favir/.

Hawaii and Territories Quarantine Notices

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.

In a final rule published in the <u>Federal Register</u> on January 16, 2009 (74 FR 2770-2786, Docket No. APHIS-2007-0052), we revised those regulations in order to establish a regulatory approach that is similar but not identical to that in the fruits and vegetables regulations discussed above. That final rule established a notice-based process for approving the interstate movement of fruits or vegetables from Hawaii and the territories that, based on the findings of a pest risk analysis, can be safely moved interstate subject to one or more of the designated phytosanitary measures listed in § 318.13-4(b) of the regulations. These measures, which are referred to elsewhere in this document as designated phytosanitary measures or designated phytosanitary measures of the Hawaii and territories regulations, are:

- The fruits and vegetables are inspected in the State of origin or in the first State of arrival;
- The fruits and vegetables originated from a pest-free area in the State of origin and the grower from which the fruit or vegetable originated has entered into a compliance agreement with the Administrator;
- The fruits and vegetables are treated in accordance with 7 CFR part 305 and the treatment is certified by an inspector;

- The fruits and vegetables are inspected and certified in the State of origin by an inspector and have been found free of one or more specific quarantine pests identified by risk analysis as likely to follow the pathway;
 - The fruits and vegetables are moved as commercial consignments only; and/or
- The fruits and vegetables may be distributed only within a defined area and the boxes
 or containers in which the fruits or vegetables are distributed must be marked to indicate the
 applicable distribution restrictions.

Commodity-Specific Requirements

The notice-based approach described above for imports and for interstate movement from Hawaii and the territories allows us to maintain our science- and risk-based evaluation process and shorten the administrative process involved in approval of new fruits and vegetables, while continuing to provide opportunity for public comment and engagement on the science- and riskbased analysis associated with such imports and interstate movements. It also enables us to adapt our import requirements more quickly in the event of any changes to a country's pest or disease status or as a result of new scientific information or treatment options. One example of this adaptability may be found in a notice entitled "Importation of Garlic From the European Union and Other Countries Into the Continental United States," which was published in the Federal Register on March 21, 2011 (76 FR 15279-15280, Docket No. APHIS-2011-0015). Prior to the publication of that notice, the importation of garlic from these countries was approved only if consignments were first treated using vacuum fumigation with methyl bromide. Based on the conclusions of a commodity import evaluation document, we were able to determine that application of one or more of the designated phytosanitary measures would sufficiently mitigate the pest risk and that the use of methyl bromide was no longer necessary.

Under the notice-based approach, APHIS was able to address this issue within 5 months, while, on average, it takes us 18 months using the traditional rulemaking process.

Both the fruits and vegetables regulations and the Hawaii and territories regulations continue to list certain fruits and vegetables for which additional phytosanitary measures are needed beyond one or more of those designated phytosanitary measures cited in the regulations. Additional phytosanitary measures may include requirements such as limitations on the distribution of the fruits and vegetables and box marking of fruit or vegetable consignments. Certain other fruits and vegetables must meet combinations of requirements (in some cases, called "systems approaches") to be eligible for importation into or interstate movement within the United States. Such measures include sampling regimens, pest surveys, packing requirements, and other measures determined to be necessary to mitigate the pest risk posed by the particular fruit or vegetable. These fruits or vegetables and their importation or interstate movement requirements are listed in §§ 319.56-20 through 319.56-70 of the fruits and vegetables regulations and §§ 318.13-20 through 318.13-26 of the Hawaii and territories regulations, respectively.

These commodity-specific requirements are similar to the designated phytosanitary measures of the fruits and vegetables regulations and the Hawaii and territories regulations in that both the requirements listed in the regulations and those imposed through the notice-based process are established by APHIS using the same rigorous science- and risk-based approach, which begins with the development of the pest risk analysis.

Current Processes

Using 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 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, 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, to identify phytosanitary measures that could be applied to the fruit or vegetable and evaluate the potential effectiveness of those measures. When the pest risk assessment is complete, if quarantine pests are associated with the fruit or vegetable in the country, State, or other region of origin, 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.

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² 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.

However, if APHIS determines in a risk management document 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 requirements, the findings are communicated using 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.

Under the notice-based process, 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 measures described earlier in this document 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 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 FAVIR, in the case of imported fruits and vegetables, as well as the appropriate fruits and vegetables manual, in the case of both fruits and vegetables that are imported and those 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.

Proposed Revisions

The 2007 final rule concerning imports and the 2009 final rule concerning interstate movement from Hawaii and the territories streamlined the authorization process for those fruits or vegetables whose phytosanitary requirements consisted of measures that were used most frequently. The notice-based processes established by those rules are as transparent and accessible to our stakeholders and other interested parties as the rulemaking process, while providing APHIS with the ability to make more responsive decisions on import issues and by reducing the time involved in approving the commodity for importation or interstate movement. For a number of reasons, which are explained below, we are proposing to expand the use of the

notice-based process to all decisions related to the importation and interstate movement of new fruits and vegetables. We are also proposing to remove the remaining region- or commodity-specific phytosanitary requirements currently found in §§ 319.56-20 through 319.56-70, 318.13-16, and 318.13-20 through 318.13-26. As stated previously, those requirements would continue to be listed in FAVIR.

Under this proposal, the unique requirements currently found in §§ 319.56-20 through 319.56-70 would be replaced by the designated phytosanitary measures listed in § 319.56-4(b) of the regulations. Similarly, we would remove the specific requirements in §§ 318.13-20 through 318.13-26 and replace them with the designated phytosanitary measures listed in § 318.13-4(b) of the regulations. We are also proposing to expand the categories of designated phytosanitary measures from those measures listed previously, which would be found in new § 319.56-4(b)(1) through 319.56-4(b)(5) and 318.13-4(b)(1) through 318.13-4(b)(5) of the regulations. These measures would stipulate that fruits and vegetables may be imported or moved from Hawaii and the territories subject to one or more of the following:

- Phytosanitary treatments, which could include, but are not limited to, pest control treatments in the field or growing site, and post-harvest treatments;
- Growing area pest mitigations, which could include, but are not limited to detection surveys, trapping requirements, pest exclusionary structures, and field inspections;
- 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;
- 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; and

• Any other measures that the Administrator determines are appropriate.

We are also proposing that, in the event that the Administrator determines that the phytosanitary measures required for a fruit or vegetable that has been previously authorized for importation are no longer sufficient to mitigate the pest risk posed by the fruit or vegetable, and the Administrator must take emergency action to protect U.S. agriculture, we will prohibit or further restrict importation of the fruit or vegetable in accordance with our existing standard emergency procedures and importation restriction at the port of entry. We would also publish a notice in the Federal Register advising the public of our findings, specifying any amended import requirements, providing an effective date for the change, and inviting public comment on the subject. In the event that the Administrator determines that any of the phytosanitary measures required for a fruit or vegetable that has been previously authorized for importation are no longer necessary to mitigate pest risk, we would make pest risk documentation available for comment prior to issuing any revised permits. 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.

Using a notice-based process provides several advantages over codifying import requirements in the regulations. The plant health import regulatory system is based on a highly complex and evolving body of scientific information. For example, a single approved commodity may require several mitigations to address the risk posed by one pest or may require one mitigation to address several pests. Some imported fruits and vegetables are subject to a dozen or more distinct conditions of entry, and even a minor change to one of those conditions

requires rulemaking if those conditions are listed in our regulations. New information about pests that affect imports is constantly becoming available, and changes must therefore be made frequently to existing import protocols. Listing requirements in the regulations can impede timely and effective decisionmaking, and in some cases, has costs to the regulated public. For example, new information recently became available which led APHIS to conclude that Hass avocados, under certain conditions, are not a host for Mediterranean fruit fly (Medfly), as was previously believed. The regulations for importing Hass avocados from countries where Medfly is present had previously required a treatment, which APHIS concluded was no longer necessary. Similarly, the interstate movement of avocados from areas quarantined for Medfly was also prohibited unless the avocados were treated.³ To relieve these restrictions, which were codified in our regulations, rulemaking was required. Having import requirements codified in the regulations prevents us from quickly and transparently updating import requirements if a pest expands its distribution to a country, territory, or area approved to export hosts of that pest that was not previously regulated for that pest, or when APHIS needs to eliminate import restrictions pertaining to a given pest because, for example, the pest now exists in the United States and is not under official control. We believe that such revisions can and should be made more efficiently and effectively, with equivalent transparency and public engagement and with the same scientific rigor.

Many of our domestic program regulations are designed and effectively administered to provide the flexibility to adjust promptly to changing phytosanitary information. For example, under the regulations concerning emerald ash borer (EAB), which may be found in 7 CFR 301.53-1 through 301.53-9, regulated articles may move interstate from quarantined areas if certain performance-based criteria are met. Specifically, the EAB regulations in § 301.53-5

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³ To view the rule go to http://www.regulations.gov/#!docketDetail;D=APHIS-2010-0127.

allow articles regulated for EAB to move interstate if they are certified by an inspector or person operating under a compliance agreement to have been grown, produced, manufactured, stored, or handled in a manner that, in the judgment of the inspector, prevents the regulated article from presenting a risk of spreading EAB. The precise requirements for interstate movement of various types of articles are not listed in the regulations, but rather are spelled out in the associated compliance agreements. We believe the EAB regulations provide an effective regulatory process.

Using a notice-based approach allows for prompt communication with the public as well as reduced administrative burden, while carrying out the same rigorous risk analysis process we use to support decisions made via rulemaking. The notice-based process also allows us to enforce phytosanitary requirements in permits in the same manner as is used to enforce requirements codified in the regulations.

The process for developing pest risk assessments and determining mitigation measures (as detailed above under the heading "Current Processes") would remain the same, giving the public opportunity to review, evaluate, and comment. In addition, in order to further engage the public in the decisionmaking process, as well as to increase the transparency of our regulatory approach, PPQ has established a process that makes the draft risk assessments or pest lists available for review by stakeholders upon their completion and prior to being made available formally through a Federal Register notice. PPQ also maintains a Stakeholder Registry on the Internet⁴ that allows anyone to register to receive information on a specified area of interest.

As indicated earlier, if this proposed process is adopted for use by APHIS, we would remove all commodity-specific requirements from both the fruits and vegetables regulations and

15

⁴ You may sign up for PPQ's Stakeholder Registry at https://public.govdelivery.com/accounts/USDAAPHIS/subscriber/new.

the Hawaii and territories regulations. Fruits or vegetables approved for import under this approach would be listed in FAVIR, which is available on the APHIS Web site, as well as in PPQ's Fresh Fruits and Vegetables Import Manual, which is available for viewing and download on APHIS's Web site.⁵ Similarly, approved fruits and vegetables from Hawaii and the territories and their corresponding movement requirements would be listed in APHIS's Hawaii and Puerto Rico/U.S. Virgin Islands fruits and vegetables manuals, which are available for download on APHIS's Web site.⁷ Fruits or vegetables approved prior to the institution of the proposed process would continue to be allowed to be imported under the same requirements under which they were approved.

Definitions

As a result of the changes we are proposing to the Hawaii and territories regulations and the fruits and vegetables regulations, a number of the definitions currently found in §§ 318.13-2 and 319.56-2 would no longer be necessary because the terms would no longer be used in the regulations in those subparts. We are therefore proposing to remove the definitions for approved growing media from the regulations in § 318.13-2 and the definitions for above ground parts, cucurbits, field, place of production, production site, and West Indies from the regulations in § 319.56-2.

⁵ The PPQ Fresh Fruits and Vegetables Import Manual may be found on the Internet at http://www.aphis.usda.gov/import_export/plants/manuals/ports/downloads/fv.pdf.

⁶ Currently, APHIS does not maintain fruits and vegetables manuals for Commonwealth of the Northern Mariana Islands (CNMI) and Guam because there are no regulated articles being moved from those areas. If it becomes necessary to maintain a list of fruits and vegetables from CNMI or Guam, APHIS would list such information on its Web site at http://www.aphis.usda.gov/import_export/plants/manuals/online_manuals.shtml.

⁷ The Puerto Rico and the U.S. Virgin Islands fruits and vegetables manual may be found on the Internet at

http://www.aphis.usda.gov/import_export/plants/manuals/ports/downloads/puerto_rico.pdf. The Hawaii fruits and vegetables manual may be found on the Internet at http://www.aphis.usda.gov/import_export/plants/manuals/ports/downloads/hawaii.pdf.

Frozen Fruits and Vegetables

The regulations in § 318.13-13 concern requirements for the movement of frozen fruits and vegetables from Hawaii and the territories into or through any other territory, State, or District of the United States. We are proposing to remove the last sentence of that section because it contains a reference to the regulations in 7 CFR 305.17, which no longer exist due to a prior change to that section.

Citrus Fruit

We are also proposing to remove Subpart—Citrus Fruit from the regulations. This subpart, consisting of § 319.28, imposes specific requirements on a certain type of fruit. Given that we are proposing to remove other specific requirements from the regulations, removal of the citrus fruit subpart would be consistent with those actions. The specific requirements would continue to apply and would be listed in the FAVIR database and PPQ's Fresh Fruits and Vegetables Import Manual.

Executive Orders 12866 and 13563 and Regulatory Flexibility Act

This proposed 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.

We have prepared an economic analysis 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 an initial 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 by contacting the person listed under FOR FURTHER INFORMATION CONTACT or on the Regulations.gov Web site (see ADDRESSES above for instructions for accessing Regulations.gov).

Based on the information we have, there is no reason to conclude that adoption of this proposed rule would result in any significant economic effect on a substantial number of small entities. However, we do not currently have all of the data necessary for a comprehensive analysis of the effects of this proposed rule on small entities. Therefore, we are inviting comments on potential effects. In particular, we are interested in determining the number and kind of small entities that may incur benefits or costs from the implementation of this proposed rule.

The proposed rule would benefit both APHIS in its operations and U.S. businesses and consumers. APHIS would be able to use its resources more efficiently and the public would have more timely access to many of the fruits and vegetables for which importation or movement from Hawaii and the U.S. territories has yet to be approved.

APHIS has already established a notice-based process for allowing the importation or movement from Hawaii and the U.S. territories of 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 for the notice-based process, the rulemaking process can range from 18 months to over 3 years; using the notice-based process, the average time has been reduced to 6 to 12 months.

Consumers and businesses would benefit from the more timely access to fruits and vegetables for which entry or movement would currently require rulemaking. This benefit would be reduced to the extent that certain businesses would face increased competition for the subject fruits and vegetables sooner due to their more timely approval. APHIS has not identified other costs that may be incurred because of the proposed rule. The rule would not alter the manner in which the risks associated with a fruit or vegetable import or interstate movement request are evaluated and mitigated.

The proposed rule is expected to result in more efficient use of APHIS resources and more timely approval for importation or interstate movement of fruits and vegetables from Hawaii and the U.S. territories. Principal industries that could be affected by the proposed rule, which are fruit and vegetable farms and fruit and vegetable importers, are largely composed of small entities.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

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

This proposed rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

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 propose to amend 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) <u>Determination by the Administrator</u>. 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 mitigated by the application of one or more phytosanitary measures designated by the Administrator.
- (b) <u>Designated phytosanitary measures</u>. (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) <u>Authorized fruits and vegetables</u>. (1) <u>Comprehensive list</u>. 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 http://www.aphis.usda.gov/import_export/plants/manuals/ports/index.shtml.

- (2) <u>Fruits and vegetables authorized for interstate movement prior to [EFFECTIVE DATE OF FINAL RULE]</u>. Fruits and vegetables that were authorized for interstate movement under this subpart as of [<u>EFFECTIVE DATE OF FINAL RULE</u>] may continue to be moved interstate under the same requirements that applied before [<u>EFFECTIVE DATE OF FINAL RULE</u>], 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) <u>Pest risk analysis and mitigations</u>. 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 mitigated by the application of one or more phytosanitary measures.
- (ii) Opportunity for public comment. 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.
- (iii) <u>Administrator's decision</u>. The Administrator has announced his or her decision in a subsequent <u>Federal Register</u> notice to begin allowing interstate movement of the fruit or vegetable subject to the phytosanitary measures specified in the notice.
- (4) <u>Changes to phytosanitary measures</u>. (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 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 <u>Federal Register</u> 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 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 is removed.
- § 319.56-2 [Amended]
- 13. Section 319.56-2 is amended by removing the definitions for <u>Above ground parts</u>, <u>Cucurbits</u>, <u>Field</u>, <u>Place of production</u>, <u>Production site</u>, and <u>West Indies</u>.
 - 14. Section 319.56-4 is revised to read as follows:
- § 319.56-4 <u>Authorization of certain fruits and vegetables for importation</u>.
- (a) <u>Determination by the Administrator</u>. 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 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) <u>Designated phytosanitary measures</u>. (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) <u>Authorized fruits and vegetables</u>. (1) <u>Comprehensive list</u>. 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 http://www.aphis.usda.gov/import_export/plants/manuals/ports/downloads/fv.pdf or http://www.aphis.usda.gov/favir.
- (2) <u>Fruits and vegetables authorized importation prior to [EFFECTIVE DATE OF FINAL RULE]</u>. Fruits and vegetables that were authorized importation under this subpart either directly by permit or by specific regulation as of [EFFECTIVE DATE OF FINAL RULE] may continue to be imported into the United States under the same requirements that applied before [EFFECTIVE DATE OF FINAL RULE], 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) <u>Pest risk analysis and mitigations</u>. 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 mitigated by the application of one or more phytosanitary measures.
- (ii) Opportunity for public comment. 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.
- (iii) <u>Import authorization</u>. The Administrator has announced his or her decision in a subsequent <u>Federal Register</u> notice to authorize the importation of the fruit or vegetable subject to the phytosanitary measures specified in the notice.
- (4) <u>Changes to phytosanitary measures</u>. (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 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 <u>Federal Register</u> 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 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 0579-0293) §§ 319.56-13 through 319.56-69 [Removed]

15. Sections 319.56-13 through 319.56-69 are removed.

§ 319.56-70 [Removed]

16. §319.56-70, as added at 79 FR 52543, September 4, 2014, and effective October 6, 2014, is removed.

Done in Washington, DC, this 2nd day of September 2014.

Gary Woodward,

Deputy Under Secretary for Marketing and Regulatory Programs.

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