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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 319

[Docket No. APHIS-2015-0004]

RIN 0579-AE12

Importation of Fresh Pitahaya Fruit from Ecuador into the Continental United States

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the fruits and vegetables regulations to allow the importation of fresh pitahaya fruit into the continental United States from Ecuador. As a condition of entry, the fruit will have to be produced in accordance with a systems approach that includes requirements for fruit fly trapping, pre-harvest inspections, approved production sites, and packinghouse procedures designed to exclude quarantine pests. The fruit will also be required to be imported in commercial consignments and accompanied by a phytosanitary certificate issued by the national plant protection organization of Ecuador stating that the consignment was produced and prepared for export in accordance with the requirements of the systems approach. This action will allow for the importation of fresh pitahaya fruit from Ecuador while continuing to provide protection against the introduction of plant pests into the United States.

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

FOR FURTHER INFORMATION CONTACT: Ms. Claudia Ferguson, M.S., Senior Regulatory Policy Specialist, Regulatory Coordination and Compliance, Imports, Regulations and Manuals, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1231; (301) 851-2352; e-mail: Claudia.Ferguson@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

Under the regulations in "Subpart-Fruits and Vegetables" (7 CFR 319.56-1 through 319.56-76, referred to below as the regulations), the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture 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.

On April 8, 2016, we published in the *Federal Register* (81 FR 20575-20579, Docket No. APHIS-2015-0004) a proposal¹ to amend the regulations in order to allow fresh fruit of any color of pitahaya (*Hylocereus* spp., *Acanthocereus* spp., *Cereus* spp., *Echinocereus* spp., *Escontria* spp., *Myrtillocactus* spp., and *Stenocereus* spp.) to be imported into the continental United States. (Hereafter we refer to these species collectively as "pitahaya.") We also prepared a pest risk assessment (PRA) and a risk management document (RMD). The PRA evaluates the risks associated with the importation of fresh pitahaya fruit from Ecuador into the continental United States. The RMD relies upon the findings of the PRA to determine the phytosanitary measures necessary to ensure the safe importation into the continental United States of fresh pitahaya fruit from Ecuador.

¹ To view the proposed rule, public comments, and supporting documents, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0004>.

In the proposed rule, we noted that the PRA identified one quarantine pest present in Ecuador that could be introduced into the continental United States through the importation of fresh pitahaya fruit: *Anastrepha fraterculus* (Wiedemann), South American fruit fly.

We determined in the PRA that measures beyond standard port of arrival inspection will mitigate the risks posed by this plant pest and proposed a systems approach that includes requirements for fruit fly trapping, pre-harvest inspections, approved production sites, and packinghouse procedures designed to exclude quarantine pests. The fresh pitahaya fruit will also be required to be imported in commercial consignments and accompanied by a phytosanitary certificate issued by the national plant protection organization (NPPO) of Ecuador stating that the consignment was produced and prepared for export in accordance with the requirements of the systems approach.

We solicited comments concerning our proposal for 60 days ending June 7, 2016. We received 12 comments during the comment period.

Eight commenters, consisting of shippers, growers, and consumers, stated general support for the proposed action. The remaining four commenters did not categorically oppose the rule but did raise questions about its provisions that we address below.

One commenter stated that the proposed rule indicates there is a lack of adequate data that would allow APHIS to determine the economic effects of the rule. The commenter added that additional analysis should be conducted to ensure that small entities, specifically the United States pitahaya growers, should not receive any adverse effects of this rule change.

We note in the final regulatory flexibility analysis prepared for this rule that we received no adverse comments with respect to the specific economic impacts on small entities. Therefore, in the absence of apparent significant economic impacts and based on our review of available

information, APHIS does not expect the proposed rule to have a significant economic impact on small entities and that additional analysis is not necessary.

The same commenter asked why the operational workplan required in proposed § 319.56-77(a)² does not outline any specific requirements for the workplan itself, other than that it must be approved by APHIS.

Section 319.56-77(a) does in fact outline specific requirements that must be met by the operational workplan. The workplan provided to APHIS by the NPPO of Ecuador must detail activities that the NPPO of Ecuador will, subject to APHIS' approval of the workplan, carry out to meet the requirements of the section.

Four commenters communicated concerns about the risk of introducing *A. fraterculus* into the continental United States via the pathway of fresh pitahaya imported from Ecuador.

One commenter representing the State of Florida stated that an introduction of *A. fraterculus* would severely impact Florida's \$8.25 billion dollar agricultural industry. The commenter stated that fruit infested with internal *A. fraterculus* larvae are highly likely to escape detection during culling and recommended that shipments of pitahaya from Ecuador not be allowed into Florida.

Another commenter representing an organization of State plant regulatory agencies was not opposed to the proposed systems approach as long as there is full adoption of the control measures identified in the RMD to manage *A. fraterculus* and strict monitoring and enforcement of the systems approach. The commenter noted Florida's recommendation to prohibit shipments of pitahaya from Ecuador into Florida but did not state a position on the recommendation.

² In the proposed rule, the section number we proposed to include in the Code of Federal Regulations was § 319.56-76. As another rulemaking was published between the proposed and final versions of this rule, we have adjusted the number for this rulemaking accordingly.

We acknowledge the commenters' concerns over the risk of introducing *A. fraterculus* into the continental United States via the pathway of fresh pitahaya from Ecuador, particularly in areas of the southern United States that could sustain permanent *A. fraterculus* populations. However, we have determined that the production and inspection practices contained in the systems approach, which include requirements for fruit fly trapping, pre-harvest inspections, and packinghouse pest exclusion procedures, will sufficiently mitigate the risk of *A. fraterculus* in imports of fresh pitahayas from Ecuador.

Moreover, during a 2016 site visit to Ecuador conducted after publication of the proposed rule, we determined the host population of *A. fraterculus* in pitahaya areas of production to be negligible with respect to pest risk, rendering unnecessary the proposed requirement prohibiting other host crops of *A. fraterculus* to be grown within 100 meters of pitahaya fields. Therefore, we are removing the requirement by amending proposed § 319.56-77(c)(2) accordingly.

One commenter noted that proposed § 319.56-77(e)(2) states the action that must be taken if a single larva of *A. fraterculus* is found in a shipment. The commenter asked if more than a single larva is found, whether further action will be taken regarding the remaining shipment of pitahaya fruit on lots other than that in which the larva was discovered.

The requirement in § 319.56-77(e)(2) states that if a single larva of *A. fraterculus* is found in a shipment from a place of production (either by the NPPO in Ecuador or by inspectors at the continental United States port of entry), the entire lot of fruit will be prohibited from import into the United States and the place of production of that fruit will be suspended from the export program until appropriate measures agreed upon by the NPPO of Ecuador and APHIS have been taken. In other words, all lots comprising that shipment will be prohibited from import into the United States regardless of whether one or more larvae of *A. fraterculus* are

found. Furthermore, suspension of the place of production from the export program will allow the NPPO and APHIS to take appropriate measures to mitigate the risk of future detections in shipments of pitahayas from that place of production.

Another commenter, concerned by the risk posed by *A. fraterculus*, stated that APHIS is over-relying on the NPPO of Ecuador to enforce pest control protocols and that measures should be adopted for additional review of the NPPO's enforcement actions.

We consider APHIS' oversight of the NPPO of Ecuador's enforcement of the systems approach to be adequate to mitigate the risk of *A. fraterculus* following the pathway of fresh pitahaya from Ecuador to the continental United States. Under § 319.56-77(a), the NPPO of Ecuador must provide an operational workplan to APHIS that details activities that the NPPO of Ecuador will, subject to APHIS' approval of the workplan, carry out to meet the requirements of this section. In addition, each consignment of pitahaya fruit must be accompanied by a phytosanitary certificate issued by the NPPO of Ecuador stating that the consignment was produced and prepared for export in accordance with the requirements of the systems approach in § 319.56-77.

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

Executive Orders 12866 and 13771 and Regulatory Flexibility Act

This final rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget. Further, because this rule is not significant, it does not trigger the requirements of Executive Order 13771.

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

This rule amends the regulations to allow the importation of fresh pitahaya fruit (of any color) (*Hylocereus* spp., *Acanthocereus* spp., *Cereus* spp., *Echinocereus* spp., *Escontria* spp., *Myrtillocactus* spp., and *Stenocereus* spp.) into the continental United States from Ecuador using a systems approach to pest risk mitigation. The systems approach will integrate prescribed mitigation measures that cumulatively achieve the appropriate level of phytosanitary protection. Entities potentially affected by the rule are U.S. pitahaya fruit growers, of which most, if not all, are small entities.

Pitahaya fruit, or dragon fruit, is produced in Hawaii, California, and Florida. It is estimated that these States produce over 11,000 metric tons of pitahaya fruit per year. The quantity of pitahaya fruit that will be imported from Ecuador is uncertain, but the entire pitahaya export volume of Ecuador is estimated to be 165 metric tons, which is 1.4 percent of U.S. production.

Farms producing pitahaya fruit are classified within the North American Industry Classification System under Other Noncitrus Fruit Farming (NAICS 111339). For this industry classification, a business is considered to be a small entity if its annual receipts are not more than \$750,000. It is probable that most or all U.S. producers of pitahaya are small businesses by the U.S. Small Business Administration standard. We expect any impact of the rule for these entities will be minimal, given Ecuador's expected small share of the U.S. pitahaya market.

Based on our review of available information, APHIS does not expect the rule to have a significant economic impact on small entities. In the absence of significant economic impacts, we have not identified alternatives that will minimize such impacts.

Executive Order 12988

This final rule allows fresh pitahaya fruit to be imported into the continental United States from Ecuador. State and local laws and regulations regarding fresh pitahaya fruit imported under this rule will be preempted while the fruit is in foreign commerce. Fresh fruits are generally imported for immediate distribution and sale to the consuming public, and remain in foreign commerce until sold to the ultimate consumer. The question of when foreign commerce ceases in other cases must be addressed on a case-by-case basis. No retroactive effect will be given to this rule, and this rule will not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this final rule, which were filed under 0579-0447, have been submitted for approval to the Office of Management and Budget (OMB). When OMB notifies us of its decision, if approval is denied, we will publish a document in the *Federal Register* providing notice of what action we plan to take.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and

for other purposes. For information pertinent to E-Government Act compliance related to this rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2483.

Lists of Subjects in 7 CFR Part 319

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

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

PART 319—FOREIGN QUARANTINE NOTICES

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

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

2. Section 319.56-77 is added to read as follows:

§ 319.56-77 Pitahaya from Ecuador.

Fresh pitahaya (*Hylocereus* spp., *Acanthocereus* spp., *Cereus* spp., *Echinocereus* spp., *Escontria* spp., *Myrtillocactus* spp., and *Stenocereus* spp.) from Ecuador may be imported into the continental United States only under the conditions described in this section. These conditions are designed to prevent the introduction of the following quarantine pest: *Anastrepha fraterculus* (Wiedemann), South American fruit fly.

(a) *General requirements.* The national plant protection organization (NPPO) of Ecuador must provide an operational workplan to APHIS that details activities that the NPPO of Ecuador will, subject to APHIS' approval of the workplan, carry out to meet the requirements of this section. The operational workplan must include and describe the specific requirements as set forth in this section.

(b) *Commercial consignments.* Pitahaya from Ecuador may be imported in commercial consignments only.

(c) *Production site requirements.* (1) All production sites that participate in the pitahaya export program must be approved by and registered with the NPPO of Ecuador in accordance with the operational workplan.

(2) Trees and other structures, other than the crop itself, must not shade the crop during the day. Pitahaya fruit that has fallen on the ground must be removed from the place of production at least once every 7 days and may not be included in field containers of fruit to be packed for export. Harvested pitahayas must be placed in field cartons or containers that are marked to show the place of production so that traceback is possible.

(3) The production sites must be inspected prior to each harvest by the NPPO of Ecuador or its approved designee in accordance with the operational workplan. An approved designee is an entity with which the NPPO creates a formal agreement that allows that entity to certify that the appropriate procedures have been followed. If APHIS or the NPPO of Ecuador finds that a place of production is not complying with the requirements of the systems approach, no fruit from the place of production will be eligible for export to the continental United States until APHIS and the NPPO of Ecuador conduct an investigation and appropriate remedial actions have been implemented.

(4) The registered production sites must conduct trapping for the fruit fly *A. fraterculus* at each production site in accordance with the operational workplan. Personnel conducting the trapping and pest surveys must be hired, trained, and supervised by the NPPO of Ecuador. The trapping must begin at least 1 year before harvest begins and continue through the completion of harvest.

(5) If more than an average of 0.07 *A. fraterculus* per trap per day is trapped for more than 2 consecutive weeks, the production site will be ineligible for export until the rate of capture drops to less than that average. If levels exceed that average per trap per day, from 2 months prior to harvest to the end of the shipping season, the production site will be prohibited from shipping under the systems approach until APHIS and the NPPO of Ecuador both agree that the pest risk has been mitigated. As conditions warrant, the average number of *A. fraterculus* per trap per day may be raised or lowered if jointly agreed to between APHIS and the NPPO of Ecuador in the operational workplan.

(6) The NPPO of Ecuador must maintain records of trap placement, checking of traps, and any quarantine pest captures in accordance with the operational workplan. Trapping records must be maintained for APHIS review for at least 1 year.

(d) *Packinghouse requirements.* (1) The NPPO of Ecuador must monitor packinghouse operations to verify that the packinghouses are complying with the requirements of the systems approach. If the NPPO of Ecuador finds that a packinghouse is not complying with the requirements of the systems approach, no pitahaya fruit from the packinghouse will be eligible for export to the continental United States until APHIS and the NPPO of Ecuador conduct an investigation and both agree that the pest risk has been mitigated.

(2) All packinghouses that participate in the pitahaya export program must be registered with the NPPO of Ecuador.

(3) The pitahaya fruit must be packed within 24 hours of harvest in a pest-exclusionary packinghouse. The pitahaya shipment must be safeguarded by an insect-proof mesh screen or plastic tarpaulin while in transit to the packinghouse and while awaiting packing. These

safeguards must remain intact until arrival in the continental United States or the consignment will be denied entry.

(4) During the time the packinghouse is in use for exporting pitahaya fruit to the continental United States, the packinghouse may only accept pitahaya fruit from registered production sites.

(e) *Phytosanitary inspection.* (1) A biometric sample of pitahaya fruit (jointly agreed upon by APHIS and the NPPO) must be inspected in Ecuador by the NPPO of Ecuador following post-harvest processing. The biometric sample must be visually inspected for any quarantine pests, and a portion of the fruit will be cut open if signs of *A. fraterculus* are observed.

(2) Pitahaya fruit presented for inspection at the port of entry to the United States must be identified in the shipping documents accompanying each lot of fruit to specify the production site or sites, in which the fruit was produced, and the packinghouse or houses in which the fruit was processed, in accordance with the requirements in the operational workplan. This identification must be maintained until the fruit is released for entry into the continental United States. The pitahaya fruit are subject to inspection at the port of entry for all quarantine pests of concern, including *A. fraterculus*. If a single larva of *A. fraterculus* is found in a shipment from a place of production (either by the NPPO in Ecuador or by inspectors at the continental United States port of entry), the entire lot of fruit will be prohibited from importation into the continental United States, and the place of production of that fruit will be suspended from the export program until appropriate measures agreed upon by the NPPO of Ecuador and APHIS have been taken.

(f) *Phytosanitary certificate*. Each consignment of pitahaya fruit must be accompanied by a phytosanitary certificate issued by the NPPO of Ecuador stating that the consignment was produced and prepared for export in accordance with the requirements of § 319.56-77.

(Approved by the Office of Management and Budget under control number 0579-0447.)

Done in Washington, DC, this 14th day of June 2017.

Michael C. Gregoire,

Acting Administrator, Animal and Plant Health Inspection Service.

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