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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 319

[Docket No. APHIS-2011-0007]

RIN 0579-AD42

Importation of Sand Pears from China

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 sand pears (Pyrus pyrifolia) from China into the United States. As a condition of entry, sand pears from areas in China in which the Oriental fruit fly (Bactrocera dorsalis) is not known to exist will have to be produced in accordance with a systems approach that includes requirements for registration of places of production and packinghouses, sourcing of pest-free propagative material, inspection for quarantine pests at set intervals by the national plant protection organization of China, bagging of fruit, safeguarding, labeling, and importation in commercial consignments. Sand pears from areas in China in which Oriental fruit fly is known to exist may be imported into the United States if, in addition to these requirements, the places of production and packinghouses have a monitoring system in place for Oriental fruit fly and the pears are treated with cold treatment. All sand pears from China will also be required to be accompanied by a phytosanitary certificate with an additional declaration stating that all conditions for the importation of the pears have been met and that the consignment of pears has been inspected and
found free of quarantine pests. This action will allow for the importation of sand pears from China into the United States while continuing to provide protection against the introduction of quarantine pests.

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

FOR FURTHER INFORMATION CONTACT: Dr. Farrell Wise, Supervisory Agriculturist, Regulatory Coordination and Compliance, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737; (301) 851-2280.

SUPPLEMENTARY INFORMATION:

Background

The regulations in "Subpart–Fruits and Vegetables" (7 CFR 319.56-1 through 319.56-56, referred to below as the regulations) prohibit or restrict the importation of fruits and vegetables into the United States from certain parts of the world to prevent the introduction and dissemination of plant pests. The regulations currently allow for the importation of both Ya pears (Pyrus bretschneideri) and fragrant pears (Pyrus sp. nr. communis) from China.

The national plant protection organization (NPPO) of China requested that the Animal and Plant Health Inspection Service (APHIS) amend the regulations to allow sand pears¹ (Pyrus pyrifolia) from China also to be imported into the United States.

As part of our evaluation of China's request, we prepared a pest risk assessment (PRA), titled "Importation of Fresh Fruit of Chinese Sand Pear, Pyrus pyrifolia, from China, including the Special Administrative Regions of Hong Kong and Macau, into the Entire United States, Including all Territories" (July 2009). The PRA evaluated the risks associated with the importation of sand pears into the United States from China, and identified 16 pests of quarantine

¹ We previously referred to Pyrus pyrifolia as “Chinese sand pear.” However, we have discovered that the accepted international nomenclature for Pyrus pyrifolia is simply “sand pear.” Hence, throughout this document, we refer to Pyrus pyrifolia as sand pear.
significance present in China that could be introduced into the United States through the importation of sand pears. The PRA presented a number of potential options to mitigate the risks posed by these plant pests. Based on these options, we prepared a risk management document (RMD). The RMD recommended specific measures to mitigate these risks.

Based on the recommendations of the RMD, on December 16, 2011, we published a proposed rule in the Federal Register (76 FR 78168-78172, Docket No. APHIS-2011-0007) to authorize the importation of sand pears from China into the United States. We solicited comments concerning the proposed rule for 60 days ending February 14, 2012. We received five comments by that date. They were from the NPPO of China, a State department of agriculture, an organization representing State departments of agriculture, a technical committee representing the U.S. pear industry, and a private citizen. The comments we received are discussed below, by topic.

Comments Regarding the Pest Risk Assessment

The PRA identified the following pests of quarantine significance as being likely to follow the pathway on imported sand pears from China:

- *Acrobasis pyrivorella*, pear fruit moth.
- *Alternaria gaisen* Nagano, the cause of black spot of pear.
- *Amphitetranychus viennensis* (Zacher), Hawthorn spider mite.
- *Aphanostigma iaksuiense* (Kishida), an aphid.
- *Bactrocera dorsalis*, Oriental fruit fly.
- *Caleptrimerus neimongolensis* Kuang and Geng, a mite.
- *Carposina sasakii* Matsumora, peach fruit moth.
- *Ceroplastes japonicus* Green, Japanese wax scale.
- *Ceroplastes rubens* Maskell, red wax scale.
- *Congothes punctiferalis* (Guenée), yellow peach moth.
- *Grapholita inopinata*, Manchurian fruit moth.

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2 To view the proposed rule, supporting documents, and the comments we received, go to http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0007.
• **Guignardia pyricola** (Nose) W. Yamamoto, a phytopathogenic fungus.
• **Monilinia fructigena** Honey in Whetzel, the cause of brown rot.
• **Phenacoccus pergandei** Cockerell, a mealybug.
• **Planococcus kraunhiae** (Kuwana), a mealybug.
• **Venturia nashicola** Tanaka & Yamamoto, pear scab fungus.

One commenter stated that recent research conducted on diseases of *Malus* spp. has discovered that the causal agent of apple and pear ring spot, which had long been considered to be *G. pyricola* (Nose) W. Yamamoto, is in fact *Botryosphaeria dothidea*. The commenter pointed out that *B. dothidea* is widely prevalent in the United States, and stated that it thus should not be considered a pest of quarantine significance. The commenter also stated that, based on this research, *G. pyricola* should not be considered a pest of quarantine significance for sand pears from China. The commenter cited a peer-reviewed article³ (referred to below as Tang et al.) detailing the research that had been conducted.

We agree that Tang et al. provides evidence in support of *B. dothidea* being a causal agent of apple ring spot. However, we do not consider this evidence sufficient to remove *G. pyricola* from the list of pests of quarantine significance for sand pears from China. The research detailed in Tang et al. appears to have focused primarily on *Malus* spp. Researchers included only a few fungi of *Pyrus* spp. for evaluation, and the discussion section of Tang et al. refers exclusively to fungi isolated from *Malus* spp. It is even unclear whether *B. dothidea* was the only *Botryosphaeria* species that researchers isolated from *Pyrus* spp.

The scope and nature of the research conducted on *Pyrus* spp. is unclear in Tang et al. In order for us to consider removing *G. pyricola* from the list of pests of quarantine significance for sand pears from China, Tang et al. would have to specify that the research conducted on *Malus*

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³ Tang et al., “Phylogenetic and pathogenic analyses show that the causal agent of apple ring rot in China is *Botryosphaeria dothidea*.” *Plant Disease* 4 (April 2012), 486-497.
spp. is directly applicable to *Pyrus* spp. It does not do so; hence we continue to consider *G. pyricola* a pest of quarantine significance for sand pears from China.

Another commenter stated that the list of pests of quarantine significance for sand pears from China should be expanded to include two additional pests, *Alternaria yaliinficiens*, a phytopathogenic fungus, and *Monilia polystroma*, the cause of Asiatic brown rot. The commenter pointed out that *A. yaliinficiens* is frequently detected on Ya pears in China, and *M. polystroma*, a well-documented pest of sand pears, is known to exist in China.

We have been able to find no evidence suggesting that sand pears are a host of *A. yaliinficiens*, and the commenter did not provide any references on this subject. Ya pears are *Pyrus bretschneideri*, a separate species from sand pears.

We agree that *M. polystroma* is known to exist in China, and sand pears are a known host of this pest. However, to date, *M. polystroma* has only been detected in Heilongjiang province. This province does not produce sand pears for export and is geographically isolated from the provinces in China that account for the bulk of pear exports from China, Hebei and Shandong. There is, moreover, no evidence of artificial spread of *M. polystroma* within China. For these reasons, at this time, we do not consider *M. polystroma* likely to follow the pathway of sand pears imported from China. We will, however, continue to monitor the presence of *M. polystroma* in China and, if necessary, take appropriate action to prevent its introduction.

A commenter asked that the PRA be updated to include a list of all pests of quarantine significance that have been detected on sand pears from China exported to other countries.

Foreign countries are free to designate plant pests as being of quarantine significance, without reference to the designations of other countries. Thus, there is no guarantee that a foreign country’s pest list for sand pears is equivalent to our own. Moreover, foreign countries’
conditions for importation of fruits and vegetables often vary significantly from those of the United States. Accordingly, a foreign country’s pest interception data for a particular commodity should not be considered a reliable predictor of possible pest interceptions for that same commodity at ports of entry within the United States. We are therefore not amending the PRA in the manner requested by the commenter.

The same commenter pointed out that the PRA contained a list of pest interceptions on Ya and fragrant pears from China imported into the United States between 1995 and 2009, but this list did not include information for 2010 or 2011. The commenter also pointed out that the list did not group detections based on the port of entry at which the pest was detected. The commenter asked that the list be updated to include information through 2011 and to sort this information by port of entry.

We do not consider such updates to be necessary. Interceptions in 2010 and 2011 do not disclose any additional pests of quarantine significance that had not previously been detected on the pears. Moreover, the list was provided in order to illustrate the starting point from which we conducted our evaluation of the pests of quarantine significance that could follow the pathway on sand pears from China imported into the United States. Hence, changing the scope of the list or its presentation would not alter the results of our evaluation.

Comments Regarding the Proposed Rule

One commenter stated that, based on the number of pests of quarantine significance likely to follow the pathway on sand pears imported into the United States from China, the plant pest risk associated with the importation of sand pears from China was significant, and we should therefore not authorize such importation.
Similarly, two commenters stated that the proposed conditions for importation of sand pears from China in the proposed rule did not take into consideration the unique climate of Florida, which the commenters asserted is more conducive to the establishment of fruit flies than that of other States. The commenters pointed out that imported fruit containing dead fruit fly larvae had been discovered in Florida, and stated that these detections call into question the efficacy of APHIS’ systems approaches for these pests.

We agree that there are many pests on the pest list for sand pears from China, and one of these, *B. dorsalis*, could become established in Florida, if introduced. However, for the reasons described in the RMD that accompanied the proposed rule, we have determined that the measures specified in the proposed rule will effectively mitigate the risk associated with the importation of sand pears from China into any area of the United States. The commenters did not provide any evidence suggesting that the mitigations are not effective.

To that end, we note that the discovery of dead larvae in imported fruit does not call into question the efficacy of the systems approaches under which the fruit has been imported. Rather, it suggests the systems approaches have been effective in neutralizing the larvae.

A commenter asked whether the proposed rule had provisions that would address the risk that *V. nashicola* or *M. fructigena* would follow the pathway on sand pears from China.

As detailed in the RMD that accompanied the proposed rule, there are several provisions of the proposed rule that address the risk posed by phytopathogenic fungi such as *V. nashicola* and *M. fructigena*. These include: Registration of places of production and packinghouses with the NPPO of China, inspections for quarantine pests at set intervals, bagging of fruit, safeguarding, labeling, and importation in commercial consignments.
One commenter stated that fertility management, that is, the use of nutrient-rich soil composed primarily of decaying organic matter, has been demonstrated to be effective in reducing population densities of certain plant pests on host plants. The commenter suggested that fertility management be explored as an alternative to the systems approach of the proposed rule, or, at least, certain provisions of that approach.

APHIS will continue to monitor the efficacy of this and other possible mitigation measures for sand pears from China. If we determine alternate measures to be effective in reducing the risk associated with the importation of sand pears from China, we may initiate rulemaking to add them to the regulations.

In the proposed rule, we proposed to require all sand pears imported into the United States from China to be grown at places of production that are registered with the NPPO of China. We also proposed that the NPPO of China would have to inspect registered places of production prior to harvest for signs of infestations and allow APHIS to monitor the inspections. Finally, we proposed that, if any of the pests of quarantine significance likely to follow the pathway on sand pears from China were detected at a registered place of production, we could reject individual consignments from that place of production or prohibit the importation of sand pears from the place of production for the remainder of the season.

The NPPO of China stated that it had entered into a memorandum of understanding (MOU) with APHIS regarding inspections of sand pears that would take place at ports of entry in the United States if the proposed rule was finalized. The NPPO stated that it was their understanding that these port-of-entry inspections obviated pre-harvest inspections of registered places of production. Accordingly, the NPPO asked that we modify the proposed rule to remove references to such pre-harvest inspections.
We are making no change in response to this comment. The MOU referenced by the NPPO pertains to general inspections of imported fruits and vegetables thatAPHIS conducts in accordance with § 319.56-3 of the regulations. As specified in the MOU, such inspections are meant to complement, rather than supplant, the provisions of the proposed rule, including pre-harvest inspections of registered places of production. Moreover, we note that such pre-harvest inspections are necessary not only to prevent infested fruit from being imported to the United States, but also so that APHIS has assurances that places of production have implemented and are maintaining all provisions of the proposed rule that pertain to them, such as bagging of sand pears destined for export to the United States.

Miscellaneous

In our December 2011 proposed rule, proposed paragraph (f)(1) of § 319.56-55 contained minimum requirements for the trapping systems that places of production and packinghouses would need to have in place for *B. dorsalis* in order to export sand pears from areas in China south of the 33rd parallel to the United States. Additionally, proposed paragraph (f)(4) proposed to require pears from such areas to be treated in accordance with 7 CFR part 305, which contains our requirements governing approved treatments of imported commodities.

Since the proposed rule was issued, we have adopted a general Agency policy of adding minimum trapping requirements to operational workplans. Among other reasons, this allows us to change the frequency and distance at which traps must be placed in response to changes in population densities for *B. dorsalis* in an exporting region. We have also begun to add standards for application of treatments to operational workplans; among other reasons, this allows us to prescribe in greater detail best practices for the application of various treatments.
Hence, in this final rule, we are amending paragraph (f)(1) to specify that the trapping systems must meet the requirements of the operational workplan, and (f)(3) to specify the treatments must be applied in accordance with not only 7 CFR part 305 but also the operational workplan.

In the proposed rule, we proposed to add the conditions governing the importation of sand pears from China as § 319.56-55. In this final rule, they are added as § 319.56-57.

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 Order 12866 and Regulatory Flexibility Act

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

In accordance with 5 U.S.C. 604, we have performed a final regulatory flexibility analysis, which is summarized below, regarding the economic effects of this rule on small entities. Copies of the full analysis are available on the Regulations.gov Web site (see footnote 2 in this document for a link to Regulations.gov) or by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

This rule will amend the regulations to allow, under certain conditions, the importation into the United States of sand pear from China. This fruit is produced in the United States in limited quantities, primarily in Illinois, Virginia, West Virginia, and Maryland.

Farms producing pears are classified within the North American Industry Classification System under Other Noncitrus Fruit Farming. The average 2007 market value of crops sold by farms classified within the industry Fruit and Tree Nut Farming (which includes Other Noncitrus Fruit Farming) was less than $188,000, an amount well below the Small Business
Administration’s small-entity standard of annual receipts of not more than $750,000. We infer that the majority of farms producing pears, including sand pears, are small entities.

China is expecting to export 24,000 metric tons of sand pear annually to the United States. This amount is less than 5 percent of average annual production of all varieties of pear produced in the United States. We do not know the quantity or value of sand pear produced in the United States, or the quantity or value of sand pear imported from other countries. Nor do we know the substitutability of sand pear for other types of pears produced domestically. While the United States is a net exporter of pears overall, it is likely that the U.S. supply of sand pear is largely imported. Without information on the domestic and foreign quantities supplied and the substitutability of sand pear for other pear varieties, we are unable to evaluate potential effects of the rule for U.S. producers.

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.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the information collection or recordkeeping requirements included in this rule have been approved by the Office of Management and Budget (OMB) under OMB control number 0579-0390.

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 Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851-2908.

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:


2. A new § 319.56-57 is added to read as follows:

§ 319.56-57 Sand pears from China.

Fresh sand pears (Pyrus pyrifolia) from China may be imported into the United States from China only under the conditions described in this section. These conditions are designed to prevent the introduction of the following quarantine pests: Acrobasis pyrivorella, pear fruit moth; Alternaria gaisen Nagano, the cause of black spot of sand pear; Amphitetranychus viennensis (Zacher), Hawthorn spider mite; Aphanostigma iaksuiense (Kishida), an aphid; Bactrocera dorsalis, Oriental fruit fly; Caleptrimerus neimongolensis Kuang and Geng, a mite; Carposina sasakii Matsumora, peach fruit moth; Ceroplastes japonicus Green, Japanese wax scale; Ceroplastes rubens Maskell, red wax scale; Conogothes punctiferalis (Guenée), yellow peach moth; Grapholita inopinata, Manchurian fruit moth; Guignardia pyricola (Nose) W.
Yamamoto, a phytopathogenic fungus; *Monilinia fructigena* Honey in Whetzel, the cause of brown fruit rot; *Phenacoccus pergandei* Cockerell, a mealybug; *Planococcus kraunhiae* (Kuwana), a mealybug; and *Venturia nashicola* Tanaka and Yamamoto, pear scab fungus. The conditions for importation of all fresh sand pears from China are found in paragraphs (a) through (e) of this section; additional conditions for sand pears imported from areas of China south of the 33rd parallel are found in paragraph (f) of this section.

(a) General requirements. (1) The national plant protection organization (NPPO) of China must provide an operational workplan to APHIS that details the activities that the NPPO of China will, subject to APHIS’ approval of the workplan, carry out to meet the requirements of this section.

(2) The pears must be grown at places of production that are registered with the NPPO of China.

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

(4) Sand pears from China may be imported in commercial consignments only.

(b) Place of production requirements. (1) All propagative material entering a registered place of production must be tested and certified by the NPPO of China as being free of quarantine pests.

(2) The place of production must carry out any phytosanitary measures specified for the place of production under the operational workplan.

(3) When any sand pears destined for export to the United States are still on the tree and are no more than 2.5 centimeters in diameter, double-layered paper bags must be placed wholly
over the pears. The bags must remain intact and on the pears until the pears arrive at the packinghouse.

(4) The NPPO of China must visit and inspect registered places of production prior to harvest for signs of infestations and allow APHIS to monitor the inspections. The NPPO must provide records of pest detections and pest detection practices to APHIS, and APHIS must approve these practices.

(5) If any of the quarantine pests listed in the introductory text of this section is detected at a registered place of production, APHIS may reject the consignment or prohibit the importation into the United States of sand pears from the place of production for the remainder of the season. The exportation to the United States of sand pears from the place of production may resume in the next growing season if an investigation is conducted and APHIS and the NPPO conclude that appropriate remedial action has been taken.

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

(2) Packinghouses must have a tracking system in place to readily identify all sand pears that enter the packinghouse destined for export to the United States back to their place of production.

(3) The NPPO of China or officials authorized by the NPPO must inspect the pears for signs of pest infestation and allow APHIS to monitor the inspections. If any of the quarantine pests listed in the introductory text of this section is detected in a consignment at the packinghouse, APHIS may reject the consignment.
Following the inspection, the packinghouse must follow a handling procedure for the pears that is mutually agreed upon by APHIS and the NPPO of China.

The pears must be packed in cartons that are labeled with the identity of the place of production and the packinghouse.

The cartons must be placed in insect-proof containers, and the containers sealed. The containers of sand pears must be safeguarded during transport to the United States in a manner that will prevent pest infestation.

Shipping requirements. Sealed containers of sand pears destined for export to the United States must be held in a cold storage facility while awaiting export.

Phytosanitary certificate. Each consignment of sand pears imported from China into the United States must be accompanied by a phytosanitary certificate issued by the NPPO of China with an additional declaration stating that the requirements of this section have been met and the consignment has been inspected and found free of quarantine pests.

Additional conditions for sand pears from areas of China south of the 33rd parallel. In addition to the conditions in paragraphs (a) through (e) of this section, sand pears from areas of China south of the 33rd parallel must meet the following conditions for importation into the United States:

The place of production of the pears and the packinghouse in which they are packed must have a trapping system in place for B. dorsalis. At a minimum, the trapping system must meet the requirements of the operational work plan.

The place of production or the packinghouse must retain data regarding the number and location of the traps, as well as any pests other than B. dorsalis that have been caught, and make this information available to APHIS upon request.
(3)(i) The place of production or packinghouse must notify the NPPO of China, and the NPPO of China must notify APHIS, regarding the detection of a single *B. dorsalis* in a place of production, packinghouse, or surrounding area within 48 hours of the detection.

(ii) If a single *B. dorsalis* is detected in a registered place of production, APHIS will prohibit the importation into the United States of sand pears from the place of production until any mitigation measures determined by APHIS to be necessary to prevent future infestations are taken.

(iii) If a single *B. dorsalis* is detected in a registered packinghouse, the packinghouse may not be used to pack sand pears for export to the United States until any mitigation measures determined by APHIS to be necessary to prevent future infestations are taken.

(4) The pears must be treated in accordance with 7 CFR part 305 and the operational workplan.

(Approved by the Office of Management and Budget under control number 0579-0390.)

Done in Washington, DC, this 13th day of December 2012.

Kevin Shea

Acting Administrator, Animal and Plant Health Inspection Service.