



BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2019-0057]

Decision to Authorize the Importation of Fresh Sand Pears From Japan Into the United States

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our decision to authorize importation of sand pears from all production areas of Japan into the United States and to revise the conditions under which they may be imported. Based on the findings of a commodity import evaluation document, which we made available to the public for review and comment through a previous notice, we have concluded that the application of one or more designated phytosanitary measures will be sufficient to mitigate the risks of introducing or disseminating plant pests or noxious weeds via the importation of fresh sand pears from all production areas of Japan.

DATES: The articles covered by this notice may be authorized for importation after [Insert date of publication in the Federal Register].

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

SUPPLEMENTARY INFORMATION:

Under the regulations in “Subpart L—Fruits and Vegetables” (7 CFR 319.56-1 through 319.56-12, referred to below as the regulations), the Animal and Plant Health Inspection Service (APHIS) 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.

Section 319.56-4 of the regulations contains a notice-based process based on established performance standards for authorizing the importation of fruits and vegetables. Paragraph (c) of that section provides that the name and origin of all fruits and vegetables authorized importation into the United States, as well as the requirements for their importation, are listed in APHIS’ Fruits and Vegetables Import Requirements database (FAVIR) on the internet at <https://epermits.aphis.usda.gov/manual>. It also provides that, if the Administrator of APHIS determines that any of the phytosanitary measures required for the importation of a particular fruit or vegetable are no longer necessary to reasonably mitigate the plant pest risk posed by the fruit or vegetable, APHIS will publish a notice in the *Federal Register* making its pest risk analysis and determination available for public comment.

In accordance with that process, we published a notice<sup>1</sup> in the *Federal Register* on September 23, 2019 (84 FR 49709-49710, Docket No. APHIS-2019-0057) announcing the availability, for review and comment, of a pest list and a commodity import evaluation document (CIED) prepared relative to revising the conditions for the importation of fresh sand pears (*Pyrus pyrifolia*) from Japan into the United States. The notice proposed both to revise the conditions for the importation of sand pears from Japan into the United States and to authorize their importation from all prefectures of Japan (excluding the Amami, Bonin, Ryukyu, Tokara, and Volcano Islands) rather than from certain

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<sup>1</sup> To view the notice, pest list, CIED, economic evaluation assessment, and the comments that we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2019-0057>.

authorized areas of production. We noted in the CIED that no quarantine pests have been intercepted on sand pear at the ports of entry into the United States since market access was granted to Japan in 1985.

We solicited comments on the pest list and CIED for 60 days ending on November 22, 2019.

We received five comments by that date. They were from State departments of agriculture, an organization representing tree fruit growers, and the public. The comments that we received are discussed below by topic.

### General Comments

One commenter representing a State government expressed concern that there were no mitigations in the revised requirements for importation of sand pears from Japan other than phytosanitary inspection.

We have determined, for the reasons described in the CIED that accompanied the notice, that the conditions in place will effectively mitigate the pest risk associated with the importation of fresh sand pear from Japan. The commenter did not provide any evidence suggesting that the mitigations are not effective. Therefore, we are not taking the action requested by the commenter.

A commenter recommended that APHIS deregulate the importation of sand pear from Japan to a greater extent than as currently proposed, adding that many studies on which we have based our import requirements are outdated and do not account for advancements in selective breeding by the National Agriculture and Food Research Organization of Japan. The commenter noted that, with respect to future breeding, marker-assisted selection for each trait, genome-wide association studies, and genomic selection analyses are currently in progress. The commenter also noted that experimental breeding is underway in Japan to produce disease-resistant cultivars, some of which are being harvested for consumption.

We acknowledge the work underway in Japan to develop disease-resistant varieties of sand pear. However, as the commenter noted, much of this work is experimental or at the research stage and the commenter did not indicate how widely it had been adopted within the Japanese sand pear industry. As the possibility still exists of pests following the pathway of sand pears from Japan to the United States, APHIS will continue to require phytosanitary inspections and other mitigations as necessary to reduce pest risk. Regarding the commenter's interest in relieving import restrictions, we note that the changes we are making to the import conditions lift restrictions on areas of production in Japan and remove the additional declaration currently required for the phytosanitary certificate. These changes relieve regulatory burden by facilitating market access for consumers of sand pear in the United States while adequately managing plant pest risk.

Another commenter stated that the pests we determined to be reasonably likely to follow the pathway should be detected through a phytosanitary inspection upon leaving Japan or entering the United States, and asked if 100 percent of sand pears imported from Japan would receive a phytosanitary inspection upon arrival in the United States.

Among the import requirements, all consignments of sand pears from Japan must be accompanied by a phytosanitary certificate issued by the national plant protection organization (NPPO) of Japan and are subject to inspection at the port of entry into the United States. These are current requirements that have not changed. As we noted above, no quarantine pests have been intercepted on sand pear at the ports of entry into the United States since 1985. As to the commenter's question about whether 100 percent of sand pears would receive an inspection, we are unsure as to whether the commenter is asking if all sand pears would receive an inspection, as opposed to all shipments of sand pears. We note that all shipments of sand pear from Japan receive a phytosanitary inspection and that we have determined this practice to be a sufficient mitigation.

## Comments Regarding the Pest List

The pest list identified nine insects and two plant pathogens associated with the commodity that could potentially follow the pathway of sand pears imported from Japan into the United States.

Two commenters expressed concerns about the risk potential of several pests not included in the list of pests that have a reasonable likelihood of following the pathway.

One commenter stated that eriophyid mites require microscopy for their identification and could be missed in a visual inspection of fruit.

Although we agree that such mites can only be identified through magnification, workplan requirements for orchard fruit bagging and postharvest washing and brushing are effective mitigations for these pests, and we therefore determined that these pests are not likely to follow the pathway of sand pears imported from Japan into the United States. For this reason, we see no reason to make changes in response to the comment.

The same commenter also raised a concern about the pear blister canker, a viroid, noting that if it can be transmitted mechanically, as we indicate in the pest list, then it could be transferred by that means to other *Pyrus* species. The commenter concluded that expansion of the export area in Japan should not be undertaken before this concern is addressed.

We are making no changes in response to the comment. Mechanical transmission refers to transmission by the use of tools contaminated by crop production or grafting. For transmission to occur, a consumer would first have to cut an infected fruit and then cut a pear tree with the same instrument, and do so during a time when optimal environmental conditions are present. We conclude that such a scenario is highly unlikely.

Another commenter stated that four additional pests—*Bactrocera dorsalis* (Hendel), *Botryosphaeria kuwatsukai* (Hara) (syn. *Guignardia pyricola*), *Monilinia polystroma*, and *Venturia*

*naschicola*—are likely to enter the export pathway of sand pears from Japan and should be named in the operational workplan and inspection protocols so that growers and packers in Japan, inspectors in Japan, and APHIS inspection personnel can identify and remove them accordingly.

APHIS developed the pest list based on the scientific literature, port-of-entry pest interception data, and information provided by the Government of Japan. It also follows the International Plant Protection Convention (IPPC) guidance for conducting pest risk analyses for quarantine pests. Our conclusions do not indicate that the four additional pests named by the commenter are likely to enter the export pathway of sand pears imported from Japan, and accordingly we are not adding the pests to the pest list. However, we have responded to the commenter's concerns, included below, for each of the four pests.

The commenter stated that as the oriental fruit fly, *Bactrocera dorsalis* (Hendel), is a pest of concern for movement of apples in international trade, it should be considered in pear as well. The commenter advised that mitigation measures included in the 1998 operational workplan should be maintained against oriental fruit fly and that it should be added to the list of quarantine pests.

As indicated in the CABI Invasive Species Compendium,<sup>2</sup> *B. dorsalis* has been eradicated from Japan. Consequently, we have no scientific reason to conclude that the pest is likely to enter the export pathway of sand pears shipped to the United States from Japan under the revised conditions.

The same commenter noted that *Botryosphaeria kuwatsukai* (Hara) has been reported to cause ring rot of fruit in China and Japan and can be observed on harvested parts.

As we noted above, our conclusions do not indicate that *B. kuwatsukai* is likely to enter the export pathway of sand pears imported from Japan. While the pathogen has been found on apples in China, as noted by the commenter, we have no evidence to support the contention that this disease could

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<sup>2</sup> <https://www.cabi.org/isc/datasheet/17685>.

affect sand pear fruit in the field. Moreover, no harvested parts of *Pyrus pyrifolia* other than the fruit are authorized for import into the United States from Japan.

The commenter also stated that *Monilinia polystroma* is reported on *Pyrus* spp. in Japan and provided a citation as evidence (van Leeuwen et al. 2002). The commenter asked if APHIS reviewed this citation as part of the pest risk assessment.

While APHIS has reviewed the citation noted by the commenter, we found no evidence that this fungus is associated with the particular species of pear (*Pyrus pyrifolia*) that is the subject of the pest list.

The commenter disagreed with our statement that *V. nashicola* and *M. fructigena* can be found visually during the phytosanitary certification inspection when seasonal growing conditions are conducive for infection. The commenter noted that fruit infected with these fungi can appear normal, as latent infections under the calices of fruit and on stems are not easily visible upon inspection and must be identified microscopically. The commenter added that these latent infections can be prevalent depending upon climate and growing season and expressed concern that they may escape detection by packers and government inspectors. Another commenter concurred with respect to *M. fructigena*, noting that we prescribed no treatment for the pathogen and that symptomatic fruit would not be easily visible at the time of packing.

While the possibility exists that latent infections of these fungi may escape detection during inspections, we have determined that the likelihood of establishment of the disease via fruit is low. Should commercial shipments of sand pear latently infected with these fungi escape detection, the fruit would still need to be deposited in an orchard with conditions adequate to allow the fungus to grow and sporulate. We consider such a confluence of conditions to be highly unlikely to occur. Moreover, under the systems approach already in place for export of sand pears from Japan there have been no

significant pest interceptions; the same measures will be in place for fruit from the approved new growing areas in Japan.

Commenters also noted potential risks regarding pests that we included in the list of pests likely to follow the export pathway and suggested that additional mitigations are warranted.

A commenter expressed concern about two pseudococcidae included in the pest list, *Crisicoccus matsumotoi* (Siraiwa) and *Planococcus kraunhiae* (Kuwana). The commenter stated that pseudococcidae, or mealybugs, are strictly regulated in foreign agricultural trade, and that a potential risk exists of mealybug eggs, nymphs, or adult females going undetected in sheltered areas on imported fruit. The commenter noted that because mealybugs have a protective coating, routine packinghouse procedures may not remove all mealybugs from fruit and cited a study showing that infested apples can retain mealybugs, particularly eggs, on stems after washing and brushing. Finally, the commenter added that mealybugs can survive cold storage and transport.

We note that, in addition to visual inspection, orchard fruit bagging is an effective mitigation for mealybugs and is a requirement in the current operational workplan for sand pear from Japan.

Another commenter reviewed the list of pests that we determined to have a reasonable likelihood of following the pathway of sand pears imported from Japan to the United States. The commenter stated that three of these pests—peach fruit moth, yellow peach moth, and Manchurian fruit moth—are of special concern because they are fruit-borers, allowing them to move in fruit consignments and making them hard to detect. One commenter recommended that APHIS require fruit bagging as a mitigation measure against fruit-borers.

As noted above, we require orchard fruit bagging in the operational workplan for sand pear from Japan. Fruit bagging effectively prevents boring insects from boring into the fruit.

A commenter raised a concern about the introduction into the United States of *Alternaria gaisen* via imports of sand pear from Japan, citing evidence of its interception in imports to the United States and Australia. The commenter noted that this fungal disease invades young fruit via lenticels and shows as a black speck on brown fruit, making it hard to detect visually.

While it is possible that signs of *Alternaria gaisen* may go undetected during inspections, the likelihood of the disease becoming established in the United States through the movement of sand pear fruit is low. As with *M. fructigena* and *V. nashicola*, discussed above, shipped fruit infected with *A. gaisen* would have to be exposed to an orchard under conditions optimal for fungal growth and sporulation, which as we noted with the other fungi is an unlikely situation. Moreover, under the systems approach already in place for export of sand pears from Japan, there have been no interceptions of this fungus, and the same fungus mitigation measures will be in place for the new growing areas in Japan approved to export sand pear to the United States.

### Workplan

One commenter noted that the 1998 workplan measures for sand pear exports from Japan to the United States continue to be followed, even though an export conditions document for fresh sand pear dated August 2007 omits many of the mitigations in the workplan. The commenter recommended that we continue to use the workplan measures with the addition of seasonal assessment for fungi and scab.

The operational workplan for exports of sand pears from Japan to the United States has been revised to include the revised pest list. We have also ensured that the necessary mitigations listed in the 1998 workplan are included in the revised workplan to address quarantine pests and diseases of concern. The 2007 export conditions document cited by the commenter was used by exporters, packinghouses, and NPPO officials of Japan as a reference document only. Growers, inspectors, and other involved

parties are required to implement requirements in the operational workplan and meet the conditions described before sand pears can be shipped.

The same commenter recommended that specific weather and seasonal guidelines be considered with respect to mitigating fungi (including scab) infections of fruit. The commenter noted that such infections vary year-to-year and are affected by seasonal rainfall and humidity. Accordingly, the commenter suggested that APHIS add requirements to the operational workplan for orchards to assess weather potential for fungi (including scab) in a given season and to assess the fruit for fungi and scab symptoms after an appropriate incubation period has passed. The commenter stated that APHIS could decide at that time whether to allow the block to be part of an export program rather than using inspection of packed fruit.

Scab was not reported as of quarantine concern for sand pears from Japan in the updated pests list. The mitigation measures already in place show efficacy in mitigating fungi (including scab) diseases throughout all seasons of sand pear production in Japan and should continue to be equally efficacious with respect to our proposal to allow export of sand pears from additional growing areas in Japan. For this reason, we are making no changes in response to the commenter.

#### Site Visits

One commenter stated that after completion of the operational workplan, APHIS should conduct a site visit to regions in Japan to confirm the operational viability of the mitigation measures.

We are making no changes in response to the commenter. In December 2019, APHIS reached an agreement with the NPPO of Japan regarding details of the systems approach in an operational workplan. The NPPO of Japan is obligated to fulfill its responsibilities under the systems approach as a signatory to the IPPC. We have determined that it is not necessary for us to monitor program activities on site unless we have reason to believe that such activities may not be adequately mitigating pest risks.

Thus, we do not plan to make periodic site visits. This is consistent with our practice in other import programs. We will, however, provide program oversight by conducting audits if quarantine pests are intercepted or as otherwise warranted. By conducting joint orchard audit inspections with the NPPO of Japan, APHIS reserves the right to verify if the growing conditions of the production areas have been satisfied.

Therefore, in accordance with § 319.56-4(c)(4)(ii) of the regulations, we are announcing our decision to revise the requirements for the importation of fresh sand pears from Japan into the United States. The revised conditions are as follows:

- All sand pears must be bagged on trees to exclude pests in accordance with the operational workplan.
- The sand pears must be accompanied by a phytosanitary certificate (PC) issued by the NPPO of Japan.<sup>3</sup>
- The sand pears are subject to inspection at the port of entry into the United States.
- Only commercial consignments of Japanese sand pears may be imported into the United States.
- The sand pears must be imported under permit.

These revised conditions will be listed in the Fruits and Vegetables Import Requirements database (available at <https://epermits.aphis.usda.gov/manual>). In addition to these specific measures, fresh sand pears from Japan will be subject to the general requirements listed in § 319.56-3 that are applicable to the importation of all fruits and vegetables.

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<sup>3</sup> We note that sand pears from Japan may continue to be imported into Hawaii under permit, and subject to inspection in Hawaii, without any further phytosanitary requirements.

### Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the reporting and recordkeeping requirements included in this notice are covered under the Office of Management and Budget control number 0579-0049.

### 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 notice, please contact Mr. Joseph Moxey, APHIS' Information Collection Coordinator, at (301) 851-2483.

### Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. § 801 *et seq.*), the Office of Information and Regulatory Affairs designated this action as not a major rule, as defined by 5 U.S.C. § 804(2).

Authority: 7 U.S.C. 1633, 7701-7772, and 7781-7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 1st day of April 2020 .

Michael Watson,

Acting Administrator, Animal and Plant Health Inspection Service.

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