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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2018–0078]

Decision To Revise the Requirements for the Importation of Fresh Citrus Fruit From Australia Into the Continental United States

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our decision to revise the requirements for the importation of citrus from Australia in order to authorize the importation into the continental United States of citrus from additional areas of production. Based on the findings of a pest risk analysis, which we made available to the public for review and comment through a previous notice, we have determined 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 citrus from these additional authorized areas of production in Australia.

DATES: The articles covered by this notification may be authorized for importation under the revised requirements beginning August 18, 2021.

FOR FURTHER INFORMATION CONTACT: Mr. Tony Román, Senior Regulatory Policy Specialist, Regulatory Coordination and Compliance, PPQ, APHIS, 4700 River Road, Unit 133, Riverdale, MD 20737–1231; (301) 851–2242.

SUPPLEMENTARY INFORMATION:

Background

Under the regulations in “Subpart 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) of the U.S. 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.

Section 319.56–4 of the regulations provides the requirements for authorizing the importation of fruits and vegetables into the United States, and it revises existing requirements for 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 their importation requirements, are listed on the internet in APHIS’ Fruits and Vegetables Import Requirements database, or FAVIR (<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 risk posed by the fruit or vegetable, APHIS will publish a notice in the **Federal Register** making its pest risk documentation and determination available for public comment.

In accordance with that process, we published a notice¹ in the **Federal Register** on December 17, 2020 (85 FR 81869–81871, Docket No. APHIS–2018–0078), in which we announced the availability, for review and comment, of a pest risk analysis that evaluated the risks associated with the importation into the United States of citrus from three additional areas of Australia: The inland region of Queensland, the regions that compose Western Australia, and the shires of Bourke and Narromine within New South Wales District. The pest risk analysis consisted of a pest risk assessment (PRA) identifying pests of quarantine significance that could follow the pathway of importation of citrus from these regions of Australia into the United States and a commodity import evaluation document (CIED), a type of risk management document, that identified phytosanitary measures to be applied to that commodity to mitigate the pest risk. The national plant

protection organization (NPPO) of Australia also asked us to reevaluate whether *Epiphyas postvittana* (light brown apple moth, also known as LBAM) could follow the pathway of citrus fruit from Australia into the United States. Currently, consignments of citrus fruit imported from Australia must be accompanied by a phytosanitary certificate with an additional declaration stating that the fruit in the consignment was subject to phytosanitary measures to ensure the consignment is free of LBAM. As a result of this reevaluation, we found that LBAM does not follow the pathway of citrus fruit from Australia into the United States, and we announced our intention to remove the additional declaration requirement. This change would affect both the currently authorized importations of citrus fruit from Australia and the importations from the additional production areas authorized by this notice.

We solicited comments on the notice for 60 days ending February 16, 2021. We received seven comments by that date. They were from producers, exporters, researchers, and representatives of State and foreign governments. Three of the commenters supported authorizing citrus imports from the additional regions of Australia as described in the notice and supporting documents. One commenter supported authorizing these imports with some revisions to the PRA. Two commenters opposed authorizing these imports. The commenters also raised a number of questions and concerns about the pest risk assessment and the conditions under which citrus could be imported from these additional regions in Australia.

Pest Risk Assessment

The PRA and CIED that we prepared in response to the Government of Australia’s request evaluated the pest risk associated with the importation of citrus fruit from the inland region of Queensland, the regions that compose Western Australia, and the shires of Bourke and Narromine within New South Wales District into the continental United States. However, in our previous notice we mistakenly did not specify that the PRA and CIED only evaluated the risk to the continental United States. In this notice we are clarifying that permits for importation of

¹ To view the notice, the PRA, CIED, and the comments we received, go to www.regulations.gov. Enter APHIS–2018–0078 in the Search field.

citrus fruit from the inland region of Queensland, the regions that compose Western Australia, and the shires of Bourke and Narromine within New South Wales District will be issued only for ports in the continental United States.

Currently, citrus fruit from the Riverina, Riverland, and Sunraysia areas of Australia is allowed importation into all ports of the United States. This action will allow importation from three additional production areas of Australia to the continental United States, but will not affect currently authorized imports of citrus fruit from Australia except that the phytosanitary certificate will no longer require an additional declaration stating that the consignment is free of light brown apple moth (*Epiphyas postvittana*, also known as LBAM).

The scope of the initial request was for specific additional production areas of the inland region of Queensland, the regions that compose Western Australia, and the shires of Bourke and Narromine within New South Wales; however, the Government of Australia stated that they consider that these production areas were intended to represent production and pest status across the broader jurisdictions and that the risk profiles associated with access granted at the broader whole-state levels of Queensland, Western Australia and New South Wales would not be appreciably greater than those associated with the specifically identified areas. As explained in greater detail below, this notice is limited to the scope of the initial request.

The regulations in 7 CFR 319.5 provide the process for submitting a request for a revision to importation requirements for plants or plant products. Based on the scope of the request submitted by the NPPO of Australia in accordance with this process, APHIS prepared the PRA that we made available with the initial notice. The areas covered by the PRA were not considered to be illustrative or representative of a broader jurisdiction but were rather the specific areas requested by the NPPO itself. Moreover, we disagree that adjacent areas within a region can be presumed to have an equivalent pest profile to the regions evaluated by the PRA; in our experience, risk profiles can vary considerably within a geographical area. For these reasons, APHIS cannot expand the scope of the areas of Australia allowed to export citrus to the United States without first revising the PRA to include the expanded area Australia proposes, and publishing a new notice

with the revised PRA in the **Federal Register** for public comment.

One commenter stated that the PRA did not assess the risk of the pink hibiscus mealybug (*Maconellicoccus hirsutus* (Green)). The commenter noted this pest is present in parts of the United States but is currently not found in Arizona. The commenter further stated that pink hibiscus mealybug is found in Australia and may be found in the regions where additional citrus imports into the United States may be approved. The commenter stated that the PRA should indicate whether the pink hibiscus mealybug is a pest of concern in the Australian regions under consideration for export and its risk of introduction evaluated.

APHIS agrees with the commenter that pink hibiscus mealybug should be included in the pest list for citrus from Australia and has revised the PRA accordingly.² The pink hibiscus mealybug has already been introduced into the United States, however, and there is no eradication or control program for it in areas of the United States in which it is established. We have determined the overall likelihood of pink hibiscus mealybug following citrus fruit imports into the continental United States to be negligible. These changes do not affect the overall conclusions of the analysis and the Administrator's determination of risk.

Phytosanitary Measures

Two commenters expressed concern that the phytosanitary measures discussed in the CIED may not adequately prevent the introduction of Oriental red mite (*Eutetranychus orientalis*), brown citrus rust mite (*Tegolophus australis*), Lebbeck mealybug (*Nipaecoccus viridis*), and Kelly's citrus thrips (*Pezothrips kellyanus*) and stated that the risk of introducing these pests is not negligible.

As we concluded in the PRA, the overall likelihood of introduction of brown citrus rust mite, Oriental red mite, Lebbeck mealybug, and Kelly's citrus thrips is negligible. Occurrence of these pests is infrequent in the export area. Furthermore, as outlined in the PRA, growers in Australia employ integrated pest management and cultural practices that further reduce the prevalence of these pests on the harvested commodity. This is also supported by the absence or low numbers of interceptions of these four pests of concern on citrus fruit from Australia at ports of entry. The control of mites is achieved by close monitoring

during spring and autumn, encouragement of natural enemies, and the use of selective miticides. Mealybug and thrips populations are closely monitored from early spring and may be controlled through the release and promotion of natural enemies. The well-timed use of oil sprays is also highly effective.

We also note that Lebbeck mealybug was added to the list of pests no longer regulated at U.S. ports of entry for the continental United States and Hawaii on September 8, 2020. To re-categorize pests so they no longer require action at ports of entry, APHIS submits a proposal to the National Plant Board (NPB), an organization composed of plant regulatory officials for State departments of agriculture. In this proposal to NPB, we propose to change the regulatory status of certain insects and plant diseases and provide our rationale for why they should no longer be considered of quarantine significance. The NPB reviews each proposal and must concur with the recommendation to change the pest's regulatory status. The NPB concurred with our proposal to deregulate Lebbeck mealybug and accordingly we added it to the list of pests no longer regulated. The list of pests no longer regulated can be viewed on the APHIS website at <https://www.aphis.usda.gov/aphis/ourfocus/planthealth/plant-pest-and-disease-programs/frsmp/frsmp-non-reg-pests>. We have revised the PRA to remove this pest from the list of pests associated with citrus from Australia.

One commenter noted that APHIS proposed removing the additional declaration requirement that ensures the consignment is free of LBAM. The commenter stated that the PRA notes that LBAM population pressure is sometimes high in Australia, however, and larvae suspected to be LBAM have been intercepted from Australia on permit cargo of citrus. Despite removal of this declaration making import requirements consistent with APHIS domestic requirements for LBAM, the commenter expressed concern that removal of this declaration requirement at the international level may lead to the pest escaping detection during routine production, post-harvest, and packing practices.

As we explained in the CIED, the current host list for APHIS domestic pest management for LBAM exempts conventionally produced citrus from LBAM quarantined areas from any

² See footnote 1 for directions on how to view the updated PRA.

specific mitigations.³ The host list states that this is because LBAM survival on citrus is low compared with non-citrus hosts. The PRA also found that there was low larval survival on oranges, that oranges are a suboptimal host, that fruit fall prematurely if infested, and that damage symptoms are easily seen and culled. For these reasons we concluded that under normal population conditions and strict adherence to good harvest and packing procedures, LBAM is unlikely to follow the pathway of commercial fruit.

The combination of low field prevalence and packing procedures make it highly unlikely that a foundation LBAM population could be moved out of the registered place of production after conventional production and harvesting practices. The CIED determined that these considerations are also applicable to citrus fruit from Australia, and thus merit removal of the additional declaration requirement for LBAM. Furthermore, interception data from 1984 to 2018 shows only one interception of LBAM in citrus fruit from Australia, and 90 interceptions of Tortricidae (the next highest taxa) in citrus fruit from Australia. The most recent interceptions were in 2005. In the event of Tortricidae interceptions in citrus fruit from Australia, APHIS can require additional mitigations for LBAM. We are making no changes in response to this comment.

Pest Free Areas

One commenter stated that the option of allowing citrus fruit to originate from an area that is free of Queensland fruit fly (*Bactrocera tryoni*), Mediterranean fruit fly (*Ceratitis capitata*, also known as Medfly), and/or Lesser Queensland fruit fly (*Bactrocera neohumeralis*) may be problematic. The commenter expressed concern that this could allow fruit to enter an area evaluated in the PRA which may have been deemed a pest free area (PFA) for only one of the listed fruit flies. The commenter further stated that the approved production area should certify that all three fruit flies are not present at time of export or be subject to the most appropriate cold treatment schedule.

We agree that if an area is not a pest free area for all three species of fruit flies, citrus must be subject to phytosanitary treatment for the relevant species of fruit fly, and this is the

mitigation structure that we proposed in the CIED with regard to pest free areas.

Treatments

Two commenters noted that the treatment evaluation document assessed the effectiveness of schedules T107-d-2 and T107-d-3 on Lesser Queensland fruit fly and concluded that they would provide sufficient control. One of the commenters stated that this conclusion was based on a small-scale, comparative study of the relative cold tolerances of eggs and early instar larvae of Queensland fruit fly, Lesser Queensland fruit fly, and Jarvis' fruit fly (*Bactrocera jarvisi*) in mandarin. The commenter stated that additional larger-scale studies on alternative citrus hosts should be conducted to provide more significant findings which could further (or diminish) support of the addition of Lesser Queensland fruit fly to T107-d-2 and T107-d-3.

The other commenter raised the same point but added that without scientific evidence confirming the referred efficacy, T107-d-2 and T107-d-3 must not be accepted as a phytosanitary treatment for Lesser Queensland fruit fly.

Jarvis' fruit fly and Lesser Queensland fruit fly both have narrow coastal distributions in Northeastern Australia. Jarvis' fruit fly is also found in the tropical area of Northern Australia. Both species only inhabit areas that are subtropical and tropical in climate. This supports the Australian research that these species are not more cold-tolerant than Queensland fruit fly. Citrus is also not the preferred host of either fruit fly.

In contrast, the mandarin fruit that the Australian scientists used to test cold tolerance for Lesser Queensland fruit fly is an optimal host and would be the preferred host to test cold tolerance of this species. The small-scale comparative study conducted by the Australian Department of Agriculture and Water Resources to determine the relative cold tolerance of Queensland fruit fly, Lesser Queensland fruit fly, and Jarvis' fruit fly supplemented the large scale studies that supported our recommendations to approve the T107-d-2 and T107-d-3 treatment schedules. We note that small-scale comparative studies of this kind compare two points or a small number of points to see if they are significantly different. In the case of the fruit fly study, they were not. We are making no changes in response to these comments.

The Government of Australia requested the addition of several treatment options for fruit flies. These treatments are already in the USDA Treatment Manual. Specifically, they

requested adding T107-a-1, T107-a-2, and T107-a-3, which are approved for use as stand-alone cold disinfestation against Medfly for citrus fruit. They also requested adding schedule T105 at a dose of 100Gy for fruit flies, as listed in table 5-2-2 in the USDA Treatment Manual.⁴

These additional treatments, which appear in the USDA Treatment Manual, may be used for citrus fruit that originates in an area where the only fruit flies present are those for which these treatments are approved. We note that the schedule T105 treatment is approved at a dose of 100Gy for Jarvis fruit fly, Lesser Queensland fruit fly, and Medfly. There is an option for a dose of 150Gy for all other fruit flies in the family *Tephritidae* not listed in table 5-2-2. Guidelines for the approval of additional treatments can be found in 7 CFR 305.3.

The Government of Australia further stated that standard commercial production practices implemented by the Australian citrus industry, such as disease management strategies used to control citrus black spot disease (CBS) in the field and packinghouses in Australia and complemented by phytosanitary inspection, would appropriately manage the risks posed by the fungus. The Government of Australia noted that over the history of inspection of citrus exports from these production areas, CBS has not been a problem, and stated that Australia considers that any additional import requirements would exceed reasonable requirements to manage the risk.

The phytosanitary measures we proposed to address the risk of CBS in citrus fruit from Australia are the same measures we require of domestic producers to ship citrus interstate within the United States. We are making no changes in response to this comment.

Therefore, in accordance with the regulations in § 319.56-4(c)(2)(ii), we are announcing our decision to authorize the importation into the continental United States of *Citrus sinensis* (L.) Osbeck (orange), *C. limonia* Osbeck (Rangpur), *C. meyeri* Yu. Tanaka (lemon), *C. aurantiifolia* (Christm.) Swingle (Key lime), *C. latifolia* (Yu. Tanaka) Tanaka (lime), *C. paradisi* Macfad. (grapefruit), *C. reticulata* Blanco (mandarin), and their hybrids from three additional areas of Australia (the inland region of Queensland, the regions that compose Western Australia, and the shires of Bourke and Narromine

³ The host list can be viewed on the APHIS website at https://www.aphis.usda.gov/plant_health/plant_pest_info/lba_moth/downloads/exempted_host_list.pdf.

⁴ The USDA Treatment Manual can be viewed on the APHIS website at https://www.aphis.usda.gov/import_export/plants/manuals/ports/downloads/treatment.pdf.

within New South Wales District), subject to the following phytosanitary measures:

- The citrus must either originate from an area within these approved production areas that is free of the fruit flies Queensland fruit fly, Medfly, and/or *Bactrocera neohumeralis* (Lesser Queensland fruit fly), or be treated with cold treatment or other approved treatment for the relevant fruit flies.
- If the area has Queensland fruit fly or Lesser Queensland fruit fly, cold treatment schedules T107-d-2 or T107-d-3 must be used.

• The citrus fruit must be accompanied by a phytosanitary certificate issued by the NPPO of Australia that attests that citrus fruit were produced in a fruit fly pest-free area or that indicates that cold treatment was applied to the consignment during transit to the continental United States, or a combination of PFAs and quarantine treatments; were inspected by the NPPO of Australia and found free of pests of concern. We are not requiring an additional declaration for light brown apple moth because the PRA considers this pest unlikely to follow the pathway on citrus fruit from these areas.

• The citrus fruit is subject to inspection at the port of entry into the United States.

• Only commercial consignments of Australian citrus fruit may be imported into the United States.

• Fruit must be washed, brushed, surface disinfected in accordance with 7 CFR part 305 and according to treatment schedules listed in the USDA Treatment Manual, treated with fungicide at labeled rates, and waxed at packinghouses.

• An operational work plan that details the requirements under which citrus will be safely imported is in place.

• The citrus fruit must be imported under permit.

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

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the burden requirements associated with this action are included 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' Paperwork Reduction Act 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 12th day of August 2021.

Mark Davidson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2021-17709 Filed 8-17-21; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B-29-2021]

Foreign-Trade Zone (FTZ) 107—Des Moines, Iowa; Authorization of Production Activity; Lely North America, Inc. (Automated Milking and Feeding Equipment); Pella, Iowa

On April 14, 2021, Lely North America, Inc. (Lely) submitted a notification of proposed production activity to the FTZ Board for its facility within Subzone 107E, in Pella, Iowa.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (86 FR 21686, April 23, 2021). On August 12, 2021, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including Section 400.14.

Dated: August 12, 2021.

Andrew McGilvray,
Executive Secretary.

[FR Doc. 2021-17691 Filed 8-17-21; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B-58-2021]

Foreign-Trade Zone (FTZ) 43—Battle Creek, Michigan; Notification of Proposed Production Activity; Pfizer, Inc. (mRNA COVID-19 Vaccine); Kalamazoo, Michigan

Pfizer, Inc. (Pfizer) submitted a notification of proposed production activity to the FTZ Board for its facilities in Kalamazoo, Michigan. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on August 6, 2021.

Pfizer already has authority to produce pharmaceutical, consumer healthcare and animal healthcare products within Subzone 43E. The current request would add a finished product and a foreign-status material/component to the scope of authority. Pursuant to 15 CFR 400.14(b), additional FTZ authority would be limited to the specific foreign-status material/component and specific finished product described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt Pfizer from customs duty payments on the foreign-status material/component used in export production. On its domestic sales, for the foreign-status material/component noted below and in the existing scope of authority, Pfizer would be able to choose the duty rate during customs entry procedures that applies to the mRNA COVID-19 vaccine (duty-free). Pfizer would be able to avoid duty on foreign-status components which become scrap/waste. Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

The proposed foreign-status material/component is mRNA bulk drug substance (duty rate—6.5%). The company currently intends to ship mRNA bulk drug substance produced at its facility in Andover, Massachusetts (Subzone 27R) to its Kalamazoo facilities for further processing.

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: ftz@trade.gov. The closing period for their receipt is September 27, 2021.

A copy of the notification will be available for public inspection in the "Reading Room" section of the Board's website, which is accessible via www.trade.gov/ftz.