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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 319

[Docket No. APHIS-2010-0036]

RIN 0579-AD27

Importation of Clementines from Spain; Amendment to Inspection Provisions

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations governing the importation of clementines from Spain by removing from the regulations the number of clementines per consignment intended for export to the United States that are required to be sampled by inspectors of the Animal and Plant Health Inspection Service (APHIS). In place of this number, we will state in the regulations that inspectors will cut and inspect a sample of clementines determined by APHIS. By removing from the regulations the number of clementines per consignment from Spain to be sampled, we will have the flexibility to respond to changing risk levels 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: Mr. Paul McGowan, Operational Director, Preclearance and Offshore Programs, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1231; (301) 851-2312.

SUPPLEMENTARY INFORMATION:

Background

The regulations in “Subpart–Fruits and Vegetables” (7 CFR 319.56-1 through 319.56-54, 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 spread of plant pests that are new to or not widely distributed within the United States.

The regulations in § 319.56-34 list specific requirements for the importation into the United States of clementines from Spain, one of which is that 200 clementines from each consignment be cut and inspected (i.e., sampled) before undergoing cold treatment. The purpose of this inspection is to detect live Mediterranean fruit flies (*Ceratitis capitata*, or Medfly) in any stage of development that may be present. If a single live Medfly is found in any stage of development, the entire consignment is rejected.

On December 29, 2010, we published in the Federal Register (75 FR 81942-81943, Docket No. APHIS-2010-0036) a proposal¹ to amend the regulations by removing the requirement in § 319.56-34(f) that 200 fruit from each consignment be sampled by cutting before treatment and replacing it with the statement that the number of fruit to be sampled before treatment will be determined by the Animal and Plant Health Inspection Service (APHIS). We explained in the proposal that this change would give us the flexibility to raise or lower the fruit sampling rate when conditions indicate a higher or lower risk of Medfly. With this change, we stated that we would be able to adjust the sampling rate and thereby detect pests that might otherwise go undetected prior to treatment. We also stated that the actual sampling rate would

¹ To view the proposed rule, the economic analysis, and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2010-0036>.

continue to be included in the workplan agreed to by APHIS and the Government of Spain, which describes in detail how the regulations are implemented operationally.

We solicited comments concerning our proposal for 60 days ending February 28, 2011. We received three comments by that date. They were from the national plant protection organization (NPPO) of Spain, a domestic citrus trade association, and a group of students. All opposed our proposal to remove the set number of 200 fruit and replace it with a statement that the number of fruit to be sampled will be determined by APHIS.

Two commenters stated that our proposal contained no objective criteria on which to base increases in the sampling rate or to evaluate the risk level of Medfly. One of these commenters, the NPPO of Spain, noted that they and APHIS had signed a bilateral workplan in October 2010, in which both parties agreed that sampling 200 fruit per consignment would provide a 95 percent confidence level of detecting a 1.5 percent infestation level. The Spanish NPPO expressed concern that the lack of specific criteria in our proposed change to the regulations could be difficult to interpret and lead to disruptions in Spanish exports.

We have subsequently held discussions with the Government of Spain regarding specific confidence and infestation levels. Changes in the sampling rate to achieve agreed-upon target levels will be based on internationally recognized sampling methodologies² and included in an annex to the bilateral workplan.

The same commenter recommended that target detection levels and sampling rates should be negotiated within the sphere of annual bilateral meetings with APHIS rather than set through rulemaking.

² International Standards for Phytosanitary Measures, ISPM No. 31: Methodologies for Sampling of Consignments (2008): https://www.ippc.int/file_uploaded/1229532867492_ISPM31_2008_E.pdf.

It was necessary for us to propose changing the regulations themselves because they require the use of a single, invariable sampling rate. With the change we are making to the regulations in this final rule, we will have the flexibility to make future adjustments to sampling rates in the context of bilateral discussions with the Government of Spain.

Another commenter noted that the current sampling rate of 200 fruit was established based on a scientific risk assessment, and that if a smaller sample is taken without conducting a similar assessment APHIS may not be able to determine the efficacy of the inspection process until Medfly are found in the channels of distribution. The commenter recommended that, for those reasons, 200 fruit per consignment be the minimum required sampling rate.

We are making no changes in response to this comment. In most of our systems approaches for importing fruits and vegetables that involve sampling of fruit prior to export, we do not specify the sampling rate in the regulations; instead, fruit is sampled at a rate agreed upon by the NPPO of the exporting country and APHIS and contained in the bilateral workplan. This final rule will make our approach with respect to sampling clementines from Spain consistent with other systems approaches for fruits and vegetables set out in the regulations.

The scientific risk assessment that established the 200 fruit sample indicated that such a sample would give us a 95 percent confidence rate of detecting a 1.5 percent level of infestation. The risk assessment determined that such a detection rate would be sufficient to ensure that Medfly populations in the clementines were low enough to be mitigated by the subsequent required cold treatment. The sampling rate change we proposed was prompted by the desire to increase the number of fruit sampled and thus increase the confidence that we were detecting any shipments with an infestation rate of 1.5 percent or more. We anticipate using the greater flexibility provided by this final rule to allow for such increases, when conditions warrant.

In the other systems approaches in the regulations that include sampling of fruits and vegetables, we only lower the initial sampling rate after years of few or no pest detections have established a definitive record of low pest prevalence in the commodity. At some point, conditions may warrant sampling a lower number of clementines from Spain, thus providing a lower level of confidence that the sampling method is detecting all consignments of fruit with a 1.5 percent or more infestation level. For that reason, it is appropriate that the regulations provide the flexibility to reduce the sampling rate.

If we were to determine that lowering the sampling rate for Spanish clementines was warranted, we would share the data that led to our determination with our domestic stakeholders and State partners prior to finalizing any adjustments with the NPPO of Spain. After the sampling rate was lowered, we would continue to monitor inspection results closely; if detections were to increase, we would promptly return the number of fruit sampled to 200 per consignment or more, depending on conditions.

The NPPO of Spain expressed concern that an increase in the sampling rate would require more time for APHIS inspectors to sample the additional fruit, potentially resulting in costly treatment and shipping delays.

If the sampling rate is increased in order to detect infestations of Medfly that might otherwise go undetected, we estimate that the number of additional fruit to be sampled would not be so high as to cause significant delays in treating or shipping consignments of fruit. A consignment of clementines consists of one or more lots containing no more than a combined total of 200,000 boxes of clementines that are presented to an inspector for pre-treatment inspection. Under the current regulations, the percentage of sampled clementines ranges from 0.02 percent to 0.1 percent per consignment inspected. Even if inspection amounts were to be

increased two or three times, the sampling rate would still be well under 1 percent of the consignment.

Another commenter asked whether we intended to establish timeframes for increasing the sampling rate and, if so, how those timeframes would be determined.

We have no plans to establish timeframes in conjunction with any changes to the clementine sampling rate. They will be changed on the basis of changing risk, as discussed earlier.

Another commenter stated that any reduction in the sampling rate may result in higher pest control costs and cause inspectors to bow to budgetary pressures by reducing inspections in an arbitrary or capricious way.

We have no indications that inspectors would approach inspections in this way due to any budgetary pressures. Inspectors authorized by APHIS are required to follow a well-defined, scientifically based inspection protocol.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, without change.

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 the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. The analysis is summarized below. Copies of the full analysis are available on the Regulations.gov Web site (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

A consignment of clementines consists of one or more lots containing no more than a combined total of 200,000 boxes of clementines that are presented to an inspector for pretreatment inspection. Under the regulations that require sampling of 200 clementines, the percentage of sampled clementines ranges from 0.02 percent to 0.1 percent per consignment inspected. Even if inspection amounts are increased 2 or 3 times when there is a higher pest risk, the sampling rate will still be under 1 percent of the consignment.

While this rule will help reduce the risk of pest introduction, we are unable to quantify the economic impact of decreasing the probability of introducing Medfly into the United States. Medfly introductions can be very costly to producers and to the Federal and State Governments. The mean cost of eradicating six Medfly outbreaks in 2007 was \$13.54 million.

This rule will not have a significant economic effect on producers of clementines or other U.S. entities, regardless of their size or resources. As described, an adjustment in the number of fruit sampled will have a negligible effect on the number of clementines imported from Spain.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

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

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

List 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.

§ 319.56-34 [Amended]

2. In § 319.56-34, paragraph (f) is amended as follows:

- a. In the paragraph heading, by removing the words “; rates of inspection”.
- b. By removing the words “200 fruit” and adding in their place the words “a sample of clementines determined by APHIS”.

Done in Washington, DC, this 9th day of April 2012.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

