Plant Protection and Quarantine

October 2008

## **APHIS' Quarantine 56 Revision**

In accordance with the Plant Protection Act (7 U.S. Code 7701 *et seq.*), the Secretary of Agriculture has the authority to establish regulations and take measures to prevent the spread of plant pests and disease into or through the United States. Under this authority, the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) regulates the importation of fruits and vegetables into the United States.

Effective August 16, 2007, APHIS implemented revised regulations pertaining to the importation of fruits and vegetables. Collectively, these regulations are commonly referred to as Quarantine 56 or the Q56 regulations. Overall, the Q56 revisions, which are now in effect, simplify and expedite APHIS' process for approving new imports and pest-free areas while continuing to allow for public participation in agency decisionmaking. Specifically, these changes include:

- Establishing an approval process that allows APHIS to authorize certain imports without rulemaking;
- Eliminating the listing of specific commodities that may be imported subject to certain types of riskmanagement measures; and
- Establishing a process for APHIS to approve new pest-free areas without rulemaking.

The Q56 revisions do not change which fruits and vegetables are approved for importation or alter how the risks associated with those commodities are evaluated or mitigated. The revisions make the approval process more efficient for those fruits and vegetables that are safe for importation under approved conditions.

In addition to these substantive changes, APHIS also revised the regulations to consolidate into one place the requirements of general applicability and eliminated redundant and outdated requirements from the previous regulations. The revisions also updated regulatory terms, consolidated the requirements for importing fruits and vegetables into U.S. territories, and incorporated various other nonsubstantive changes.

## **Substantive Changes**

Prior to 1987, APHIS authorized the importation of a fruit or vegetable by simply issuing a permit once the agency was satisfied that the relevant criteria in the

regulations had been met. These permits were issued without prior public notice, without rulemaking, and without specifically listing the approved commodities in the regulations. In 1987, in an effort to make the process more transparent, APHIS began approving new imports of fruits and vegetables through rulemaking.

The rulemaking process for approving fruit and vegetable imports requires that APHIS conduct a pest-risk analysis for each import request. The risk analysis serves as the primary basis for a proposed rule, which is published in the *Federal Register* for public comment. The public comments are considered, and if appropriate, a final rule to authorize the imports is prepared.

APHIS estimates that it takes a minimum of 18 months to evaluate and approve new import requests under the rulemaking-based system. In reality, the process typically takes 2 to 3 years and longer in some cases.

With international trade in fruits and vegetables increasing steadily, APHIS determined that it could not keep pace with the volume of import requests by using solely a rulemaking-based review and approval process. Therefore, under the Q56 revisions, APHIS established criteria that allows for faster, more efficient approval of certain fruits and vegetables for importation into the United States, while providing the same level of protection against foreign pests and diseases and the same level of public participation in the decisionmaking process.

APHIS established a new "notice-based process" that still requires a pest risk analysis to be conducted for new fruits or vegetables, just as in the rulemaking-based process. However, if the risk analysis shows that the commodity's risk can be sufficiently mitigated by one or more of five designated phytosanitary measures, the commodity becomes eligible for a more streamlined approval process.

Under the streamlined process, a notice announcing the availability of the pest-risk analysis is published in the *Federal Register* to allow for public comment for 60 days. Barring substantive comments that disprove the findings of the pest-risk analysis, a notice is then published in the *Federal Register* to announce that APHIS will begin issuing import permits for the commodity. If a commodity's pest risk cannot be sufficiently mitigated by one or more of the five designated phytosanitary measures, the commodity must undergo the full rulemaking process.

Commodities approved under the notice-based process will no longer be listed individually in the regulations. Additionally, commodities previously

approved for importation and which meet the noticebased criteria will no longer be listed. However, APHIS will specifically list in the Code of Federal Regulations (CFR) any commodities that are eligible for import under more stringent mitigation measures.

Lastly, under the Q56 revisions, APHIS also established a framework for a notice-based process for approving pest-free areas in exporting countries. This process, which is similar to the commodity approval process described above, allows the agency to be more responsive in recognizing changes in the pest-free status of foreign areas. In the past, APHIS recognized changes in the pest-free status of countries via rulemaking. The new and more efficient notice-based process will enable APHIS' oversight of imports to better reflect the actual pest status of areas in foreign countries.

Using the notice-based process, APHIS will publish a notice in the *Federal Register* announcing that an exporting country has provided information that meets or exceeds the pest-free criteria listed in 7 CFR 319.56-5, and that APHIS officials have completed an evaluation of the request. The notice will be available for public comment for 60 days. At the time the notice is published, APHIS will also make copies of the supporting information available. Once all comments have been considered, APHIS will, if still warranted, publish a notice in the *Federal Register* stating that the agency is recognizing the areas as free of specified pests.

## **Nonsubstantive Changes**

Many of the revisions to the Q56 regulations were made to make them easier to understand. The following are examples of the nonsubstantive changes APHIS made:

- Consolidate Requirements of General Applicability—APHIS consolidated all requirements of general applicability into one section. For example, instructions concerning required permits, ports-of-entry that can be used, charges for APHIS services, and other general requirements for importing fruits and vegetables are now located at the beginning of the Q56 regulations.
- Remove Redundant and Outdated Requirements—APHIS removed sections of the Q56 regulations that were redundant with other regulations. For example, APHIS removed Q56 text concerning treatment schedules for imported fruits and vegetables because this and other related information are already available elsewhere in the CFR. This revision and other similar changes improved the clarity of the Q56 import regulations.

- Update Terms—APHIS removed outdated terms and added several new definitions to the Q56 regulations. For example, APHIS removed the definition for Deputy Administrator because references to that official were changed to refer to the Administrator under this rule. As a result, the definition for Administrator was added to Q56.
- Update Regulations to the Territories—The Q56 regulations generally apply to fruits and vegetables imported into the United States, as well as U.S. territories and possessions. In some instances, the regulations provide different conditions for the importation of fruits and vegetables into territories and possessions than the conditions required for imports to U.S. States. With the Q56 revisions, APHIS consolidated all of the import requirements for U.S. territories and possessions into one section.

## For More Information

For additional information on the Q56 regulations, please visit <a href="http://www.aphis.usda.gov/import\_export/">http://www.aphis.usda.gov/import\_export/</a> plants/plant\_imports/quarantine\_56/favir.shtml>. For information on APHIS permits, please visit, <a href="http://www.aphis.usda.gov/permits">http://www.aphis.usda.gov/permits</a>. On October 29, 2008, APHIS launched a new, searchable database, known as the fruits and vegetable import requirement—or FAVIR—database. The database allows customers to search for authorized fruits and vegetable, by commodity or country, and quickly determine the general requirements for importation into the United States. To access the system, please visit <a href="http://www.aphis.usda.gov/favir/info.shtml">http://www.aphis.usda.gov/favir/info.shtml</a>.>

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