



## Questions and Answers

### **Establishing a Performance Standard for Authorizing the Importation and Interstate Movement of Fruits and Vegetables (Expansion of the Current APHIS Streamlining Rule)**

#### **What is APHIS proposing to change?**

APHIS is proposing to streamline the process for approving the importation and interstate movement of fruits and vegetables by expanding the use of the notice-based process that is currently used to authorize some fruits and vegetables. APHIS is also proposing to replace the region- and commodity-specific phytosanitary import and interstate movement requirements that are codified in the U.S. Code of Federal Regulations (CFR) with general phytosanitary requirements, or performance standards, that can be applied to all fruit and vegetable commodities. Region- and commodity-specific requirements for approved fruits and vegetables will continue to be listed in the Fruits and Vegetables Import Requirements (FAVIR) database, the Fruit and Vegetable Manual, and the Hawaii and Puerto Rico Manual.

#### **Why is APHIS proposing these changes?**

Currently, import and interstate movement requirements for fruits and vegetables are codified in 7 CFR 318.13 and 7 CFR 319.56, preventing us from quickly updating them when new pest information becomes available. Even a minor change to a single condition of entry for one commodity requires rulemaking if the condition is listed in our regulations. Having specific phytosanitary import and interstate movement requirements codified in the regulations also slows down our ability to respond to new import requests if the region- or commodity-specific import requirements have to be established or adjusted each time through rulemaking. Expanding the use of the notice-based process will allow APHIS to be more responsive to evolving pest situations both in the United States and in exporting countries while decreasing the time it takes to approve fruits and vegetables that can be safely imported into the United States or moved interstate.

#### **What is a notice-based process?**

Under a notice-based process, amendments to 7 CFR 318.13 and 319.56 would no longer be needed each time APHIS approved a new fruit or vegetable or amended the requirements that apply to an already-approved fruit or vegetable. Instead, those approvals or amendments would be accomplished via the publication of notices in the Federal Register. Approved commodities and the applicable requirements would be listed in a Federal Register notice and documented in USDA's Fruit and Vegetable Manual, the Fruits and Vegetables Import Requirement (FAVIR) database, or in the Hawaii and Puerto Rico Manual, instead of the CFR.

**How do the steps of a notice-based process differ from rulemaking?**

Step		Notice-based process	Rulemaking	Description
1	Request to authorize the import or move interstate a new fruit or vegetable	x	X	APHIS receives a request to authorize the import or interstate movement of a new fruit or vegetable from a national plant protection organization or State/Territorial officials.
2	Pest risk assessment and stakeholder consultation	x	X	APHIS conducts a pest risk assessment. The assessment is posted on the APHIS website for a 30-day stakeholder consultation period.
3	Risk mitigation requirements	x	X	APHIS drafts risk mitigation documents outlining necessary measures.
4	Departmental clearance	x	X	Officials in USDA review
5	OMB review		X	Officials in OMB review a description of each proposed action and determine whether to conduct a formal review of the proposed rule.
	OMB notification	x		APHIS notifies OMB of its intent to publish an initial notice, providing an opportunity for OMB oversight.
6	Economic impact analysis		X	APHIS conducts an economic impact analysis, per the requirements of the Regulatory Flexibility Act.
7	Proposed rule		x	APHIS publishes a proposed rule in the Federal Register and solicits public comments for 60 days.

	Initial notice	x		APHIS publishes an initial notice in the Federal Register and solicits public comments for 60 days.
8	Departmental clearance	x	x	Officials in USDA review
9	OMB review		x	Officials in OMB review a description of each final action and determine whether to conduct a formal review of the final rule.
	OMB notification	x		APHIS notifies OMB of its intent to publish a final notice, providing an opportunity for OMB oversight.
10	Final rule		x	APHIS publishes a final rule in the Federal Register to address public comments and authorize the commodity import. Requirements for the commodity are codified in the U.S. Code of Federal Regulations.
	Final notice	x		APHIS publishes a final notice in the Federal Register to address public comments and authorize the commodity import. Requirements for the commodity are posted in the FAVIR database, the Fruit and Vegetable Manual, or the Hawaii and Puerto Rico Manual.

**Are Federal Register notices subject to review by the Office of Management and Budget (OMB)?**

While Executive Order 12866 does not require OMB to review Federal Register notices, OMB will continue to exercise oversight of APHIS actions under the notice-based process. Specifically, APHIS will notify OMB of all initial and final notices before they are published in the Federal

Register. This step will ensure that OMB officials have an opportunity to consider pending commodity import or interstate movement approvals before they are finalized.

**Will APHIS conduct economic analyses under the notice-based process?**

Under the Regulatory Flexibility Act, APHIS is not required to conduct an economic analysis for an action that will be authorized by the publication of a Federal Register notice. However, we will continue to analyze the economic effects of a potential pest introduction during the pest risk analysis process. Stakeholders concerned about the economic impact of a proposed action may submit comments that detail their concerns during the 60-day comment period for the initial notice.

**On what factors will APHIS base its decision to authorize the import or interstate movement of a commodity?**

We base those decisions on an analysis of pest risk. This is true whether we make this decision through rulemaking or through a notice-based process.

**Will the notice-based process change the way APHIS assesses pest risks?**

All fruit and vegetable authorization requests would continue to undergo the same science-based approval process that is conducted under the current rulemaking process. When APHIS receives a request from a national plant protection organization or State/Territorial official to allow importation or interstate movement of a specific commodity, we will conduct a pest risk assessment, just as we do currently under the rulemaking process. The pest risk assessment will determine if quarantine pests are associated with the commodity in the region of origin. It will also evaluate whether the risk posed by each quarantine pest can be mitigated by one or more designated measures. If we determine that the risk posed by each quarantine pest can be mitigated by one or more of the designated measures, we will publish in the Federal Register, for a minimum 60-day public comment period, a notice announcing the availability of the pest risk analyses.

**Would rulemaking still be an option for authorizing commodities?**

Traditional rulemaking is not an option under this proposed rule.

**What will APHIS do if they receive information during the pest risk assessment or initial notice comment period that indicates the risks associated with the commodity cannot be mitigated?**

If, during either the stakeholder consultation period for the pest risk assessment or the comment period for the initial notice, APHIS receives or discovers information that the pest

risks cannot be adequately mitigated with one or more designated measures, we would have the option of withdrawing the pest risk assessment or notice in order to develop additional phytosanitary approaches. We would also have the option of canceling the action.

**When the notice-based process goes into effect, would an action to approve a commodity that had been proposed as a rule be finalized through rulemaking or via the notice-based process?**

At the point at which the notice-based process goes into effect, an action that had been proposed as a rule would be finalized via notice. As described in the table above, APHIS would respond to comments collected during the proposed rule public comment period, prepare the final action, and submit it for Departmental clearance. Once cleared, APHIS would notify OMB, giving them the opportunity to consider the action before it is finalized. When ready, APHIS would then publish the final action as a notice in the Federal Register.

**How will the proposed changes improve the approval process?**

The proposed changes could decrease the amount of time it takes APHIS to approve the importation or interstate movement of fruits and vegetables (steps 4 through 10 in the table above).

**What is the difference between this proposed rule and the 2007 and 2009 final rules that authorized the import and interstate movement of fruit and vegetable commodities using a notice-based process?**

The proposed rule would allow us to use the notice-based process for all market access requests. The current rules only allow us to use the notice-based process to authorize the import of certain fruit and vegetable commodities that do not have phytosanitary requirements codified in the U.S. Code of Federal Regulations and can meet one or more designated conditions of entry. They also allow us to authorize the movement of fruits and vegetables from Hawaii and U.S. Territories to the U.S. mainland using the notice-based process.

The proposed rule would expand the designated conditions of entry for new commodities to include a broader range of phytosanitary measures that can effectively reduce pest risk. This would allow commodities that require more complex pest mitigation measures or those that are produced under a systems approach to be authorized through the notice-based process.

**Will there still be a public comment period? Will public comments be formally addressed?**

Yes. Under the notice-based process, APHIS will publish an initial notice and a final notice for each import request. Similar to a proposed rule, the public would have 60 days to provide comments once the initial notice is published in the Federal Register. APHIS would respond to

comments on the initial notice in the same manner it responds to comments on a proposed rule. All substantive comments would be addressed in the final notice, which would be published prior to issuing any permits for that commodity. In addition, stakeholders will continue to have 30 days to consult on draft pest risk assessments before APHIS initiates the notice-based process.

**Will this proposed rule change the import approval process for plants for planting?**

No. The proposed rule would expand the use of the notice-based process to all fruit and vegetable imports. It would not apply to plants for planting.

**Will the proposed rule alter the commodity clearance process at ports of entry?**

No, this proposed rule would not alter the commodity clearance process at ports of entry.

**When will the proposed changes take effect?**

The proposed changes would take effect no sooner than 30 days after the final rule is published.

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*Additional questions and answers from the December 17, 2014 stakeholder webinar:*

**Would it be possible for complicated market access requests to continue to be considered under the rulemaking process where stakeholders have more opportunity to provide comments or share expertise?**

Traditional rulemaking would not be an option under this proposed rule. All market access requests would be considered under the notice-based process and would undergo the same rigorous, science-based, pest risk evaluation that is conducted under the current rulemaking process. In addition, the public would continue to have 30 days to review and comment on the draft pest risk assessment and 60 days to comment on the initial notice which will include the risk assessment and the risk management strategy. All substantive comments would be addressed in the final notice which would be published prior to us issuing any permits for the commodity.

**At what point during the notice-based process will the risk management documents be available for public view and comment?**

The draft pest risk assessment will be available for public comment for 30 days before APHIS initiates the notice-based process. The final pest risk assessment and the risk management

document will be available for public comment for 60 days once the initial notice is published in the Federal Register.

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December 4, 2014

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