

allow imports where he or she can conclude that the restrictions imposed will prevent the introduction of a pest. In deciding whether to allow imports, the Secretary weighs a variety of factors that could include whether the pest attacks a single commodity or multiple commodities, reliability of the data on which the risk of establishment projections are based, and the feasibility of proposed mitigation measures.

The lack of a specific standard for an acceptable risk level will not lead to a regulatory process that will be less transparent or establish a system that is easily changed by outside parties as one commenter indicated. Removing the "without risk" criterion will not affect the rulemaking process. Any changes to the regulations will continue to be made using notice and comment rulemaking, which helps to ensure transparency. Further, the lack of a specific standard for an acceptable level of risk will not lead to a system that is easily changed by outside parties as we will continue to base our decisions on sound science.

One commenter linked the failure to address the standard of phytosanitary security to additional costs (*i.e.*, above those indicated in the proposed rule) associated with a Mediterranean fruit fly (*Ceratitis capitata*) (Medfly) outbreak. As stated in the proposed rule, we are removing the "without risk" criterion because it is impossible to satisfy. Therefore, no additional costs due to a Medfly outbreak would be associated with this change in the regulations.

Another commenter stated that we should establish acceptable levels of risk based on the outcome of a case concerning the importation of citrus from Argentina, *Harlan Land Company, et al. vs. United States Department of Agriculture, et al.*, Case #CV-F-00-6106-REC/LJO (D. Ariz. Sept. 27, 2001). APHIS believes that the court's decision applies strictly to the rule at issue in that case and does not apply to this rule.

One commenter stated that the "without risk" criterion protects the environment in that if a foreign pest outbreak occurred and the pest became established in the United States, the environment would be compromised due to pesticide spraying and other pest control methods. Although eradication of quarantine pests may require the use of pesticides and other control methods, removing the "without risk" criterion does not have the potential to harm the environment. The "without risk" criterion is impractical, and its removal will not have any impact on the environment. In the event of an outbreak, APHIS would continue to prepare any necessary environmental documentation under the National

Environmental Policy Act and the Endangered Species Act in advance of any pesticide use and other pest control methods.

Two commenters voiced concern that we were proposing to replace the "without risk" criterion with the IPPC standard pertaining to pest-free areas, but this was not our intent. As stated in the proposed rule, we are removing the "without risk" criterion from § 319.56-2(e)(3) and (e)(4) because it is impossible to satisfy that requirement. We are not replacing the criterion with either a definition of acceptable risk or with the IPPC standard for pest-free areas. We proposed to adopt ISPM No. 4, "Requirements for the establishment of pest free areas," as a replacement for the specific criteria for area freedom in § 319.56-2(f). While ISPM No. 4 specifies that one of the considerations in establishing a pest-free area is the "level of phytosanitary security required as related to the assessed level of risk, according to the pest risk analysis conducted," this is not a deviation from our current practice of conducting a pest risk analysis for commodities not previously approved for importation.

#### *Incorporation by Reference of Standard for Establishment of Pest-free Areas*

We proposed to replace the specific criteria in § 319.56-2(f) for pest-free areas with the ISPM No. 4, "Requirements for the establishment of pest-free areas," which would be incorporated by reference into the regulations.

One commenter claimed our statement that "[w]e believe that incorporating this standard by reference into our regulations would prevent the introduction of quarantine pests into the United States and provide requirements that are consistent with the IPPC" is unrealistic because the standard could not completely eliminate the risk of introducing pests. The commenter is correct that our adoption of the standard by itself would not eliminate the risk of introducing pests. The standard describes requirements for the establishment and use of pest free areas as a risk management option for phytosanitary certification, and our intent was to communicate our belief that using the standard to determine the pest-free status of an area would provide us with an effective risk management tool that, more so than our existing criteria for the establishment of pest-free areas that have been found in § 319.56-2(f), is consistent with internationally recognized standards.

One commenter opposed the use of the IPPC standard because it appears that APHIS is proposing to supercede

the Federal government's rulemaking authority with blanket approval for the IPPC to determine U.S. sanitary and phytosanitary standards. According to the commenter, this change could result in deferring the establishment of risk criteria to an international body, which could be arbitrary and capricious and lack transparency and accountability, as well as be an abuse of discretion. Another commenter who disagreed with using the IPPC standard objected on the grounds that we would be abdicating our responsibilities to an international group that would not always be controlled by the best science.

In making this amendment to the regulations, we are not abdicating our rulemaking authority or responsibilities to the IPPC, nor are we deferring our establishment of risk criteria to that body. Any decision made regarding the pest-free status of an area in the context of our import requirements will continue to be made by APHIS, just as has been the case under the provisions of § 319.56-2(f) that ISPM No. 4 will replace. It is important to note that incorporating ISPM No. 4 by reference has the effect of making that standard, in its current form (*i.e.*, the February 1996 version made available for review with the proposed rule), part of our own regulations. Because of that, we would have to initiate rulemaking to update the incorporation by reference—thus giving the public an opportunity to review and comment upon any changes that had been made to the standard—before any future changes that might be made by the IPPC to that 1996 version of ISPM No. 4 could become part of our regulations.

With respect to the issue of transparency raised by one of the commenters, we believe that our incorporation by reference of ISPM No. 4 will make our regulations more, and not less, transparent. The criteria in § 319.56-2(f) that we have used for recognizing pest-free areas make reference to surveys performed in accordance with requirements approved by the Administrator and phytosanitary requirements deemed by the Administrator to be at least equivalent to our own, but do not provide specific details regarding those survey and phytosanitary requirements. ISPM No. 4, on the other hand, provides both general and specific requirements for determination of pest-free areas, establishment and maintenance of pest-free areas, systems to establish freedom, phytosanitary measures to maintain freedom, checks to verify freedom has been maintained, and documentation and review.