

DEPARTMENT OF AGRICULTURE**Animal and Plant Health Inspection Service**

[Docket No. 99-079-1]

Commodity Pest Risk Analysis Process**AGENCY:** Animal and Plant Health Inspection Service, USDA.**ACTION:** Notice of public meeting and request for comments.

SUMMARY: We are seeking comments on several issues related to commodity pest risk analysis process used by the Agency's Plant Protection and Quarantine's program, including several recommendations made in a report on Plant Protection and Quarantine safeguarding system. We will use the information gathered through this notice as we consider options to improve public involvement in the process and public access to information about new and pending pest risk analyses.

DATES: We invite you to comment on this docket. We will consider all comments that we receive by December 7, 1999. We will also consider comments made at a public meeting that will be held in Washington, DC, on November 10, 1999.

ADDRESSES: Please send your comment and three copies to: Docket No. 99-079-1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Please state that your comment refers to Docket No. 99-079-1.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690-2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS rules, are available on the Internet at <http://www.aphis.usda.gov/ppd/rad/webrepor.html>.

The public meeting will be held at the Washington Court Hotel, Sagamore Hill Room, 525 New Jersey Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. Michael A. Lidsky, Assistant Director, Regulatory Coordination, PPD, APHIS,

4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 734-5371.

SUPPLEMENTARY INFORMATION:**Safeguarding System Review**

In October 1998, the Plant Protection and Quarantine (PPQ) program of the Animal and Plant Health Inspection Service (APHIS) asked the National Plant Board to review its efforts to safeguard American agriculture and plant resources. The National Plant Board assembled a group of 43 stakeholders from States, industry, academia, and environmental groups. The Safeguarding Review Group, through extensive research, interviews, site visits, and other interactions with APHIS and its stakeholders, prepared a thorough analysis of the challenges facing the safeguarding system in four major areas: Pest exclusion, international information, pest permits, and pest detection and response. The Safeguarding Review Group identified a number of opportunities to enhance the safeguarding system, which are outlined in the group's final report, "Safeguarding American Plant Resources: A Stakeholder Review of the APHIS-PPQ Safeguarding System," which was submitted to PPQ on July 1, 1999. (The report may be viewed in its entirety on APHIS' Internet website, located at www.aphis.usda.gov.) PPQ is now working with its employees and stakeholders to address the report's more than 300 recommendations on how the current safeguarding system can be improved.

One subject that was examined in the safeguarding review was the use of risk analysis, which is composed of risk assessment, risk mitigation, and risk communication, within PPQ programs. While the final report did discuss the role of risk analysis in managing resources—e.g., as a basis for adjusting staffing levels at a particular port of entry—considerably more attention was paid to PPQ's pest risk analysis activities relating to international trade and our obligations under international agreements, with a particular focus on the role of pest risk analysis in supporting decisions and justifying quarantine actions regarding the importation of plants and plant parts for propagation or consumption. While the role of pest risk analysis in PPQ's biotechnology and organism permitting program areas was noted in the report, there was no detailed discussion of those aspects of PPQ's risk analysis activities. The higher visibility accorded to PPQ's commodity pest risk analysis process can be attributed to the important role that pest risk analyses

play in supporting the regulatory changes that are necessary before a new commodity from a particular foreign region may be imported into the United States. Indeed, many of the issues raised in the safeguarding report are similar to issues raised in comments submitted pursuant to specific proposed regulatory changes and in other correspondence directed to PPQ.

Response to Report

PPQ has already taken steps to begin to address the risk-analysis-related concerns raised in the report by asking the APHIS Business Practices Team to commence a PPQ-wide review of the program's risk analysis processes. This has resulted in the formation of three working groups that are responsible for addressing the following areas:

- Benchmarking (i.e., how do the risk analysis processes in PPQ compare to one another and to those of other APHIS program areas, as well as to those of other government agencies and nongovernmental entities?);
- Obtaining customer and stakeholder feedback on ways to improve PPQ's risk analysis processes (e.g., risk assessment methodologies, risk communication strategies, etc.); and
- Documenting PPQ's risk analysis processes in order to identify any redundant or unnecessary activities and to provide a starting point for the design and implementation of subsequent process improvements.

In addition to this business practices review initiative, we are also forming a group to evaluate all of the safeguarding report's specific recommendations that relate to pest risk analysis. This group will work closely with the Business Practices Team.

With regard to the benchmarking aspect of our review activities, we are considering convening a symposium to review and discuss the existing international standards for pest risk analysis and the current "state of the art" relative to conducting pest risk analyses. We envision that this symposium would also include a report by APHIS on the comments received in response to this notice and an update on any improvements being made to our risk analysis processes resulting from the review by the Business Practices Team. We are currently planning to convene the pest risk analysis symposium during the first quarter of calendar year 2000. Once more specific information becomes available, we will publish a notice in the **Federal Register** concerning the dates and location, as well as a draft agenda, for the symposium.

Improving Transparency and Participation

In considering PPQ's commodity pest risk analysis process as it relates to rulemaking, the safeguarding review team concluded that the process is hampered by inadequate risk communication on the part of APHIS, which leads to conflicting interpretations about the nature and significance of risks. The final report recommended that PPQ incorporate stakeholder collaboration and scientific consultation into its pest risk analysis process. By increasing the transparency of the process and providing an opportunity for interested parties to participate prior to rulemaking, this collaboration and consultation would likely increase the amount and quality of information available to the risk assessors.

As a first step in our initiative to obtain customer and stakeholder feedback on ways to improve PPQ's commodity pest risk analysis process, we are soliciting public comment on these subjects. With regard to the preparation of commodity pest risk assessments, we are particularly interested in comments in the following areas:

- *Qualitative versus quantitative risk assessments.* The qualitative and quantitative pest risk assessments prepared by PPQ are similar in most respects. Both types of assessment identify quarantine pests and utilize qualitative ratings in their assessments of the consequences of introduction. Where they differ is in assessing the likelihood of introduction: Qualitative assessments utilize qualitative ratings for the likelihood of introduction, while quantitative assessments estimate the likelihood of introduction using scenario analysis and Monte Carlo simulation to arrive at a numerically expressed distribution of estimates (e.g., mean, mode, median, 95th percentile) for the likelihood of pest introduction. The safeguarding report notes that PPQ currently uses the less complex qualitative pest risk assessments for routine commodity import decisions and quantitative pest risk assessments for more complex commodity import decisions. However, in the absence of specific criteria for differentiating between routine and complex commodity import decisions, PPQ managers must rely on their judgment in determining what type of pest risk assessment should be used. With that in mind, what specific criteria could be used for determining which type of risk assessment is appropriate in a given situation?

- *Preparation of assessments.* The safeguarding report recommended allowing exporters or exporting countries to conduct pest risk assessments under APHIS guidance as a means of expediting the handling of requests for commodities to be allowed entry into the United States. Would this be acceptable, or would the perception that there is an inherent conflict of interest be too great? Would strict adherence by the preparer to the risk assessment guidelines of the United Nations Food and Agriculture Organization and subsequent APHIS review and approval be enough to overcome that perception?

With regard to the issue of transparency and public participation, we are particularly interested in comments in the following areas:

- *Notification of the initiation of a pest risk analysis.* It has been suggested that APHIS publish a notice in the **Federal Register** to notify the public whenever PPQ initiates a pest risk analysis pursuant to a request for a commodity to be allowed entry into the United States. Would such a notification mechanism be useful? Should notice be given of all requests received, *i.e.*, those involving both routine and nonroutine decisions, or should such **Federal Register** notices be reserved for the more complex nonroutine decisions? Could this notification be satisfactorily provided through means other than the **Federal Register**?

- *Web-based tracking system.* PPQ's plant pest and biotechnology permitting staffs currently administer Internet-accessible tracking systems that allow the public to check on the status of permit applications submitted to those staffs. (The tracking systems of the plant pest and biotechnology permitting staffs may be found on APHIS' Internet home page at www.aphis.usda.gov/ppq/bats/permits/query-permits.html and www.aphis.usda.gov/bbep/bp/status.html, respectively.) We believe that a similar web-based tracking system could be used to enhance the transparency of, and facilitate participation in, the commodity pest risk analysis development process. Such a system would provide the public with timely information about the receipt of import petitions, the status of those petitions, and the status of their associated pest risk analyses, and could provide a mechanism for the public to offer information and feedback regarding those petitions and pest risk analyses. Would such a tracking system be useful? Would the existence of a web-based tracking system preclude the need for APHIS to publish notices in the

Federal Register as discussed in the previous item?

You may submit your written comments to the address provided at the beginning of this notice under the heading **ADDRESSES**. In addition, we will be hosting a public meeting to provide interested persons a full opportunity to orally present any data, views, suggestions, and questions. The public meeting will be held on November 10, 1999, at the Washington Court Hotel, Sagamore Hill Room, 525 New Jersey Avenue, NW., Washington, DC.

A representative of APHIS will preside at the public meeting. Any interested person may appear and be heard in person, by attorney, or by other representative. Written statements may be submitted and will be made part of the meeting record. Persons who wish to speak at the meeting will be asked to provide their name and organization. We ask that anyone who reads a statement or submits a written statement provide two copies to the presiding officer at the meeting.

Registration for the public meeting will take place from 9:30 to 10:00 a.m. at the meeting room. The public meeting will begin at 10 a.m. and is scheduled to end at 5 p.m., local time. However, the meeting may be terminated at any time after it begins if all persons desiring to speak have been heard. If the number of speakers at the meeting warrants it, the presiding officer may limit the time for presentations so that everyone wishing to speak has the opportunity.

We welcome all comments on the issues discussed above and encourage the submission of ideas on any associated topics or other suggestions for the evaluation of risk and the improvement of our risk analysis processes. We will consider all comments and recommendations we receive in response to this notice as part of our Business Practices Team review initiative and the related safeguarding report implementation efforts.

Done in Washington, DC, this 4th day of October, 1999.

Bobby R. Acord,

Acting Administrator, Animal and Plant Health Inspection Service.

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DEPARTMENT OF AGRICULTURE

Forest Service

East Slate Project; Idaho Panhandle National Forests, Shoshone County, ID

AGENCY: Forest Service, USDA.