

December 7, 2001

Docket No.95-095-2  
Regulatory Analysis and Development  
PPD, APHIS, Suite 3C03  
4700 River Road, Unit 118  
Riverdale, MD 20737-1238

Dear Sirs/Madam:

The American Phytopathological Society (APS) is pleased to comment on the Proposed Rule under 7 CFR Part 330, Docket No. 95-095-2, entitled Plant Pest Regulations; Update of Current Provisions, F.R. 66:51340-51358, 2001. The APS, founded in 1908, is the premier organization advancing modern concepts in plant health management in agricultural, urban, and forest settings. Members represent a broad cross section of the scientific community including research scientists, teachers, extension professionals, students, sales representatives, private consultants, administrators, technicians, agricultural field representatives, and pest management personnel.

In general, APS is highly supportive of a revision of regulations regarding the movement of plant pests (pathogens) that adds risk-based criteria for determining plant pest status of organisms, and establishes a notification process as an alternative to the current permitting system. We have expressed our concern for over 30 years that risk-based criteria needed to be used in regulation of movement of plant pathogens. We have expressed this concern in many comments to APHIS and Congressional Hearings. In one case, we encouraged a Colloquy on the floor of the Senate during the debate on the FY2000 Agriculture, Rural Development, and Related Agencies Appropriations Bill that specifically addressed the intent of APHIS Plant Protection activities relative to research and educational activities with plant pests. Thus, we particularly applaud a risk-based approach; establishment of categories of organisms that require expedited permits.

We agree that the bacteria listed at § 330.202 and the virus TMV would not impose additional plant pest risks. We concur that they are distributed throughout the continental United States and are known to commonly accompany plants or plant products moved in interstate commerce. We are pleased that APHIS does not consider the list comprehensive, as we question why only one virus and no fungi are on the list. APS welcomes the opportunity to examine what appears to be a large area of omission. For example, in the listing of viruses in states developed and maintained through an APHIS/APS activity, 20 viruses are reported to be in 24 to 42 states. Three viruses, cucumber mosaic, alfalfa mosaic, and tomato spotted wilt, are reported in more states than is TMV. These and the other top viruses (BYDV, MDMV, WMV, PVY, ToMV, BCMV, ZYMV, TRSV, PRSV, PVX, INSV, SqMV, SMV, WSMV, TmRSV, TEV, PNRSV) are known to be infective forms in many plants and plant produce imported and distributed widely. We would hope that candidates for addition to the list not requiring permits would be examined in less than the time frame mentioned and at least some could be included before the Final Rule is promulgated.

We also applaud the effort to assemble a list of organisms eligible for movement through pre-movement notification, and suggest that APS could assist in this activity as it has in assembling state lists of pathogens.

Moreover, according to many of our members who obtain permits to import or move plant pathogens for research purposes, the most frequent reasons our members have for requesting these microorganisms and others not listed are for research in contained environments. The lifting of what is viewed as an unnecessary burden will be more in keeping with regulations of microorganisms used in biomedical research, in which only the most harmful require permits. This restructuring of interstate movement is also consistent with the recent stakeholder report, 'Safeguarding American Plant Resources,' which analyzed APHIS's operations, procedures, rules and regulations, with concomitant specific recommendations, including some pertaining to permitting for interstate movement. This change may also increase the use of these pathogens in high school and college biology classes, in contained environments, to illustrate principles of disease causation without putting students at risk, while also exposing students to plant sciences.

APS also looks forward to the new compliance agreements, and desire that they further science by aiding necessary and expedient exchange of microorganisms within the scientific community.

Again, virtually all microorganism exchanges are for use in contained environments. Many of our members are likely to enter into compliance agreements to facilitate their ability to obtain necessary organisms. We concur that performance standards are appropriate and that the terms should be prepared with the participation of all parties involved. We urge that the conditions of the agreement be signed for a particular organism type, and that generic guidelines could be developed for handling certain types of microorganisms that are based on practical experience.

For example, the standard seems to emphasize having “operational and procedural safeguards in place to prevent the escape of the regulated organisms and to prevent the entry of other organisms and unauthorized visitors.” We contend that in a strict interpretation of these standards, there are no facilities, particularly in university facilities used by most of our members, that would be in compliance and eligible to enter into an agreement. However, these facilities have a history of successful and safe use on a routine basis without release of detectable, and biologically significant, levels of microbial pathogens. We certainly hope it is not the intent of APHIS for all plant pathogen facilities to be equivalent of high containment facilities, and suggest clarification of language to assure this.

There are issues (p.51347, p. 51355), which may not be applicable to most plant pathogens, whether in compliance agreements or notifications, namely the total number of regulated organisms received. For example, for bacteria, a vial or slant would likely contain more than 10x8 organisms to be considered likely to be in a viable and usable condition. Such numbers could not be readily determined nor would they have relevance to plant pest risk under contained conditions. Similarly, only in a few cases might it be useful to know the life stage of regulated organisms. In most cases, this would have no relevance for plant pathogens, particularly for viruses. Thus, we suggest the qualifier, ‘if applicable’ be included in the information that would have to be included in notification. Or, if the meaning is the total number of cultures, i.e. independent microorganisms, the statement is correct, but could be clarified.

We believe the environmental release of regulated organisms is well done and will enable the scientific community to carry on essential field trials with minimal risk to U.S. flora and the environment. We note, however, it emphasized experiments for the biocontrol of weeds. An additional section with focus toward experimental release of plant pathogens for the purpose of selecting resistant crop varieties and pathogen ecology should be explored. Such experiments have long been conducted by the scientific community with endemic organisms and perhaps could be carried out under the proposed Art. 330.203(a)(2).

We suggest that the language describing the safeguards and conditions for such releases is vague, and that information described as needed to obtain permits is much more extensive than has typically been needed, nor is available for many plant pathogens. Such an application may be considered under the proposed Art. 330.203(b)(1)(ii) for a permit for environmental release of pure cultures of either native or established organisms. There it is suggested that the applicant consult APHIS prior to preparing a permit application. However, it is not clear how this consultation would differ from simply filing the application and the types of information that would or would not be needed.

We appreciate the difficulty of the task to enable scientific enquiry to be as expeditious as possible while safeguarding the environment. As indicated, we believe a reasonable balance in this critical area has largely been achieved, but that further improvements could be made. APS is willing to assist in these endeavors.

Sincerely,



Noel Keen  
APS President