



Healthy Plants • Healthy World

October 8, 2002

Docket No. 02-082-1  
Regulatory Analysis and Development  
PPD, APHIS Station 3C71  
4700 River Road, Unit 118  
Riverdale, MD 20737-1236

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Subject line: No. 02-082-1

Re: Docket No. 02-082-1. Agricultural Bioterrorism Protection Act of 2002;  
Listing of Biological Agents and Toxins and Requirements and Procedures for  
Notification of Possession (Federal Register, August 12, 2002 (Vol. 67, No.  
155, pgs 52383-52389)

To Whom it May Concern:

The American Phytopathological Society (APS), founded in 1909, is the premiere educational, professional and scientific society dedicated to the promotion of plant health and plant disease management for the common good. The Society, representing the interest of five thousand scientists whose pivotal research advances the understanding of the science of plant pathology and its application to plant health, respectfully submits its comments regarding the proposed federal actions regarding the Agricultural Bioterrorism Protection Act of 2002; Listing of Biological Agents and Toxins and Requirements and Procedures for Notification of Possession (Docket No. 02-082-1; Federal Register, August 12, 2002 (Vol. 67, No. 155, pgs 52383-52389) with specific concerns to the listing of foreign and emerging plant pathogens in the interim rule (7CFR Part 331).

The APS was pleased to contribute to the development of the list in cooperation with APHIS and others that was published in the 12 August 2002 Federal Register. The APS was also pleased to note that APHIS removed several endemic plant pathogens of widespread research interest from the draft list. This resulted in many federal, private, state and university researchers continuing unhampered their work on various strains of those pathogens endemic in the United States to develop basic and applied information toward environmentally compatible and economically viable disease management measures. The APS realizes the need for a dynamic "list of agents and toxins identified as potentially posing a severe threat to plant health or plant products," but is concerned about the criteria used to determine those threats, the impact of regulations on monitoring and identifying the presence of those threats, and any imposition that would hinder an immediate and effective response to eradicate those threats or lessen their impact.

The APS is concerned that specific identification technology is not yet readily available for APHIS, plant pathogen diagnostic clinics and/or law enforcement agencies to distinguish many of the plant pathogens on the list from closely related organisms. The plant pathology diagnostic capabilities of the U.S. agricultural infrastructure are still oriented toward utilization of classical morphological, cultural and/or pathogenicity characteristics that require culture of the organism, and it is unclear if such activities would be considered

possession and hence in violation of the USA Patriot Act. Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) the exemption for "clinical or diagnostic laboratories and other persons who possess, use, or transfer overlap agents or toxins that are contained in specimens presented for diagnosis, verification, or proficiency testing" is noted. However, whether such an exemption applies to lengthy pathogenicity tests as, for example, are needed to distinguish the "CVC strain" of *Xylella fastidiosa* from the endemic Pierce's Disease strain (and others) widely distributed in the U.S. should be clarified. Hence, the current state of specific and accurate diagnostic technology for a given pathogen needs to be considered in identification of candidates for a list of threats.

While rapid diagnostic capabilities are available in a few specific research laboratories in the U.S., rapid detection technology for pathogens on the list is not yet validated by the appropriate expertise in federal, state, university or private diagnostic laboratories. Although the technology is being developed at a rapid pace to identify pathogens without culturing, most public sector diagnostic laboratories are not equipped and staffed to conduct such rapid diagnoses of plant pathogens. It may be premature to list pathogens until the technology is validated and distributed. The recently funded USDA Rapid Pathogen Detection Initiative should soon provide the necessary technology for some of the listed pathogens, and the Regional Plant Disease and Pest Surveillance & Detection Network should provide some infrastructure support to facilitate identification of threats. In the meantime, the APS advises that the scientifically valid rapid identification and detection capabilities in the public and private sector be inventoried, and only those pathogens for which rapid and specific detection is possible and can be economically implemented be listed.

Also uncertain at this time is how the statutes of the USA Patriot Act and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) will influence a response to the detection of a pathogen on the list in the U.S. It will likely be uncertain at first if the newly detected pathogen is a result of intentional release or due to natural emergence, as new diseases are routinely found in the U.S. Thus, will law enforcement or regulatory agencies be the designated first responders? While diagnostic laboratories may be exempt from regulations regarding possession, "investigational use" to begin a fundamental response to look at options for containment and subsequent management or elimination requires an exemption from the Secretary that may take fourteen days once an application for exemption has been filed. Timeliness will be paramount for developing mitigating measures to reduce the potential economic or production impact of discovering an agent on the list to the affected cropping system, and the expertise of a number of scientists, likely at different locations, will be needed to initiate the required work. Therefore, in identifying candidates for a list of threats, full consideration needs to be given to our ability to respond to a perceived threat. Impairing investigation to determine the most feasible management strategies and tactics to contain or eliminate a new disease could inadvertently result in significant spread and economic impact of an emerging disease, whether its emergence is by intentional release or natural occurrence.

While the pathogens on the list all represent potentially serious crop diseases, consideration must always be given to the biology of the pathogens and the nature of the diseases they cause when listing them as potential weapons against agriculture. It is clear from the legislative language of the P.L. 107-188 that the intent is to develop controls over pathogens, which have the potential to invoke economic harm to agricultural interests and the citizens of the United States. Thus, the pathogens included on the list should have certain biological and epidemiological characteristics consistent with their potential as threats within the context of P.L. 107-188. It is not clear that all of the pathogens on the current list in 7CFR part 331 fit these basic criteria. The APS notes that for the past two years it has been engaged in developing a threat assessment and pathogen threat list at the request of APHIS through an agreement signed in 1999. As a result of this process the APS is prepared to contribute, through a transparent process, an expert threat list of potential bioterrorism plant pathogens, beginning in 2003, which it is hoped would provide a basis for yearly revisions of the pathogens listed in 7CFR Part 331.

We emphasize that a listing of foreign and emerging plant pathogens in meeting the statutes of the USA Patriot Act and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 should be based on the best available science. We welcome additional opportunities to be of assistance in commenting on policy regarding biosecurity of the agriculture of the United States, both as benefactors of our agricultural production systems and as scientists.

Sincerely yours,

A handwritten signature in cursive script that reads "Jacqueline Fletcher".

Jacqueline Fletcher  
President, The American Phytopathological Society