August 28, 2010

APHIS Agriculture Select Agent Program
Regulatory Analysis and Development
PPD, APHIS, Station 3A-03.8
4700 River Road Unit 118
Riverdale, MD 20737-1238

Subject: Docket No. APHIS-2009-0070

To whom it may concern:

The American Phytopathological Society (APS) appreciates the opportunity to comment on the July 29, 2010, U.S. Department of Agriculture Animal Plant Health Inspection Service (APHIS) Advance Notice of Proposed Rulemaking (ANPR) request for comments on the biennial review of the USDA list of select agents and toxins. We understand that comments are requested on whether any agent or toxin should be removed from the list, whether the list should be tiered based on the relative bioterrorism risk of the agent or toxin, and corresponding changes to security requirements.

APS was founded in 1908 and is the premier educational, professional, and scientific society dedicated to the promotion of plant health and plant disease management for the global good. The Society represents nearly 5,000 scientists in the public and private sector whose work advances the understanding of the science of plant diseases and its application to plant health. The work of plant pathologists also includes the discovery, description, and diagnosis of microorganisms causing plant diseases. The APS has served as an unbiased resource on plant health for USDA and other Federal agencies for many years. The progress made in plant health programs in the United States through support of research, teaching, and extension from Federal, state and private sources has facilitated the sustainability and profitability of America's plant production industries.

The study of plant pathogenic microorganisms, including select agents, is essential for the biosecurity of the United States. In an Executive Order released July 2, 2010, President Obama recognized that research on select agents by legitimate scientists is critical to identify and develop containment and control strategies for the diseases caused by these agents. (http://www.whitehouse.gov/the-press-office/fact-sheet-executive-order-optimizing-security-biological-select-agents-and-toxins-). Legislation leading to the select agent regulations recognizes that some select agents may pose a greater threat to the public health and safety than others and specifically states that security requirements should be "commensurate with the risk of the agent and toxin, including the risk of use in terrorism." Thus, to reduce the hurdles that scientists studying select agents encounter while ensuring our Nation's defenses against the threat of biological weapons:

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APS supports a tiered list for select agents, with biosecurity requirements that are based upon the risk posed by the pathogen or toxin.

APS supports tiering select agents with biosecurity requirements commensurate with the risk that a particular plant pathogen could be misused to do significant harm. We urge reduced biosecurity requirements for agents posing lower economic or environmental risks and which are NOT known to pose a direct human or animal health risk. Reduction in the biosecurity requirements would reduce the expensive regulatory burden and allow for critical research needed to mitigate damage by these pathogens should they be introduced. Specifically, we recommend the following:

1. **Place plant pathogen select agents in a tier lower than that of human or animal pathogens**. With the exception of *Rathayibacter toxicus*, the plant pathogens on the current select agent list DO NOT pose a direct human or animal health risk. Thus, for most of the plant pathogen select agents that are listed, we recommend a tier be established to place them in a category below that of the lowest tier for human pathogens. Our sister society, the American Society for Microbiology, is recommending three tiers for human pathogens (ASM, August 19, 2010). APS proposes a fourth tier that would include agents that do not result in human or animal morbidity or mortality. These agents would require significant effort to disseminate (particularly, those that are not transmitted by insects), would not have the potential for major public health impact, would not cause public panic or social disruption or require special action for public health preparedness. Agents currently on the Select Agent list that would fall in this category are:
   Peronosclerospora philippinensis (Peronosclerospora sacchari)
   Phoma glycinicola (formerly *Pyrenochaeta glycines*)
   Ralstonia solanacearum race 3, biovar 2
   Sclerophthora rayssiae var zeae
   Synchytrium endobioticum
   Xanthomonas oryzae
   Xylella fastidiosa (citrus variegated chlorosis strain)

2. **Reduce biosecurity requirements for plant pathogen select agents. Reduce biosecurity requirements for plant pathogen select agents.** Current biosecurity requirements were designed to address significant dangers to humans, animals and the environment associated with the handling by human operators, and the potential escape or release, of human and zoonotic pathogens. These regulations, when applied without reasonable modification to the handling of plant pathogens, exceed stringency levels necessary to assure containment for these pathogens that do not pose a risk either to handlers or to humans or animals that might be exposed by inadvertent release. The level of risk to plants will depend upon the proximity of potential host plants in agronomic settings or the natural landscape, the likelihood of disease-supportive environmental conditions and the presence of suitable means of dissemination and infection. Research to identify resistance of crop plants to pathogens frequently requires inoculations of large numbers of plants in greenhouses with many isolates of a plant pathogen. The stringency

of current requirements intended to assure the structural security of laboratory and greenhouse facilities, and the extent of current requirements for tracking individual vials or cultures of plant pathogens and/or individual pathogen-inoculated plants, are burdensome and costly. The actual, real-world benefits of each policy should be weighed against resulting counterproductivity, since the significant time and cost inputs for researchers result less time and effort spent in developing mitigation strategies needed by producers to deal with the disease.

3. **Develop a timely and transparent process inclusive of expert opinion from both the public (government and academic) and private sectors to determine which plant pathogen agents should be removed or added to the list.** APS urges a systematic review panel, which would include federal and nonfederal scientists (with security clearances) be established to identify agents that should be designated select agents, and to designate the tier for each select agent. A second charge to this panel would be to recommend and review practical and effective biosafety requirements and biosecurity/personnel checks needed for the proposed lowest tier.

The APS membership realizes the complexity of issues surrounding the designation and regulation of select agents and toxins, and we appreciate the opportunity to bring our expertise into the decision process.

Sincerely,

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