

June 5, 2006

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VIA ELECTRONIC AND FIRST CLASS MAIL

Docket No. APHIS-2005-0103  
Regulatory Analysis and Development  
PPD  
APHIS  
Station 3A-03.8  
4700 River Road Unit 118  
Riverdale, MD 20737-0103

Re: Docket No. APHIS-2005-0103

To whom it may concern:

Arent Fox PLLC, a law firm with offices in Washington, DC and New York, counsels a broad array of clients whose products are subject to regulation under the Plant Protection Act (PPA). We appreciate the opportunity to provide comment on the proposed rule regarding special need requests under the PPA recently issued by the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS or the Agency). 71 Fed. Reg. 16711 (April 4, 2006).

Generally, the PPA's preemption provisions prohibit state regulation of the movement in interstate commerce of articles regulated under the PPA. A state seeking such a waiver must satisfy APHIS that "special needs" exist to warrant such a waiver. We understand that APHIS is proposing to amend its domestic quarantine regulations to establish a process by which a State or its political subdivision could request such a waiver. The establishment of such procedures should provide clarity, transparency and consistency to this process.

APHIS's activities in protecting U.S. agriculture and the environment from plant pests, noxious weeds, and other PPA-regulated articles are governed not only by the PPA, but also, when applicable, by the International Plant Protection Convention (IPPC), to which the U.S. is a signatory. The IPPC is the international treaty recognized by the World Trade Organization (WTO) as the standard-setting body for international plant phytosanitary issues.<sup>1</sup> APHIS action regarding plant pests or noxious weeds must be consistent not only with the PPA, but also with relevant phytosanitary standards established by the IPPC.

<sup>1</sup> The scope of the IPPC is interpreted broadly to include both direct and indirect pest risks to cultivated plants in horticulture, agriculture and managed forests, as well as to non-cultivated plants and wild flora.

Under this authority, USDA has consistently taken the position that a legitimate phytosanitary risk – a risk to plant health – must be established prior to any further consideration of quarantine measures. The PPA, as well as this proposal, define plant pests and noxious weeds by their ability to “directly or indirectly injure or cause damage to” plants. *See* 71 Fed. Reg. at 16712.

Additional clarification is required in order to incorporate this basic step in the rule’s special needs criteria. As drafted, the criteria a state must demonstrate do not include a fundamental showing that the item sought to be restricted actually meets the definitional requirements of a biological control organism, plant pest or noxious weed. Specifically, does this article actually pose a risk of death, damage or disease to plants sufficient to justify further analysis? Absent this fundamental showing of a risk to plant health by the requesting state, the criteria currently outlined in the proposed rule could be used in an attempt to improperly restrict *any* plant that is new to the state and that could, by displacing existing crops in popularity among growers or consumers, pose a perceived economic, or even cultural, threat to the status quo of a state or a political subdivision.

In undertaking its own risk assessments of potential pests and weeds at the federal level, APHIS, through its Plant Protection and Quarantine (PPQ) division, has developed extensive guidance documents under which it reviews plants for quarantine status. These guidance documents are consistent with the PPA, as well as the IPPC. The criteria set forth in this proposal appear to echo those considerations, and it is likely that APHIS will follow its own guidelines in making a special needs determination. If so, it would be helpful to a state seeking to establish special needs to understand the definitions, standards, and assumptions on which APHIS will base its decisions. Regardless of what standard is ultimately used, to comply with the requirements of federal law and international obligations, states must provide information to establish, based on sound science and an appropriate risk analysis, that the article sought to be restricted poses a legitimate threat to plant health.

Indeed, the proposal is unclear whether APHIS will apply the standards it uses in making its own risk assessment determinations, or if not, how those standards may differ. If the federal risk assessment process is to provide the standards by which state special needs requests will be judged, those standards should be referenced. If different standards are to be used, those should also be set forth. Without this information, this regulation will provide neither clarity nor consistency, and may not survive review.

For these reasons, APHIS should provide additional information as part of this rulemaking proceeding regarding the standards by which it will make special needs determination. In this context, it may be appropriate to provide additional information regarding the federal risk assessment process, and to reference the federal risk assessment guidance. At the root of any such standard, however, must be the showing that the organism sought to be restricted poses a legitimate threat to plant health.

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Thank you again for this opportunity to comment on this important regulatory proposal. Please do not hesitate to contact me with any questions that may arise regarding these comments.

Sincerely,

Handwritten signature of Stanley H. Abramson in black ink. The signature is written in a cursive style and includes the initials 'RGL' at the end.

Stanley H. Abramson