

August 10, 2009

Submitted Via Federal eRulemaking Portal

Docket No. APHIS-2007-0146
Regulatory Analysis and Development
Plant Protection Division
Animal and Plant Health Inspection Service
United States Department of Agriculture
Station 3A-03.8
4700 River Road Unit 118
Riverdale, MD 20737-1238

Re: Docket No. APHIS-2007-0146, "Update of Noxious Weed Regulations"

To whom it may concern:

These comments are submitted by the Biotechnology Industry Organization (BIO) in response to the June 10, 2009 announcement (the Notice) by the United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS or the Agency) of proposed changes to the regulations governing the importation and interstate movement of noxious weeds. 74 Fed. Reg. 27456. BIO appreciates this opportunity to provide these comments.

BIO is the world's largest biotechnology organization, providing advocacy, business development and communications services for more than 1,200 members worldwide. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology. Corporate members range from entrepreneurial companies developing their first product to Fortune 100 multinationals. We also represent state and regional biotechnology-derived associations, service providers to the industry, and academic centers.

BIO recognizes that the noxious weed regulations proposed to be updated in the Notice do not apply to plants developed through biotechnology. Such plants are, instead, regulated by APHIS under 7 C.F.R. Part 340 as "genetically engineered" (GE) plants. Nevertheless, BIO writes here to urge that APHIS take the opportunity afforded by this rulemaking to reaffirm its commitment to applying the same standard for determining what is, and is not, a noxious weed, regardless of the type of plant involved.

APHIS Statements Regarding Its Noxious Weed Determinations

As the Agency is well aware, the Plant Protection Act (PPA) provides APHIS with broad authority to protect the nation against noxious weeds. In the course of an ongoing rulemaking that would apply the PPA's noxious weed authority to GE plants, APHIS has repeatedly stated that it would impose the same standards for making noxious weed determinations in the context of GE plants

that it does for other plants. *See* 73 Fed. Reg. 60008 (Oct. 9, 2008) (Docket APHIS-2008-0023). APHIS laid out the analysis it currently undertakes in making noxious weed determinations:

The first consideration in determining if a plant is a noxious weed is identifying what direct injury or damage (physical harm) the plant causes. If direct harm or damage is established, the next consideration is to evaluate any indirect damage the plant may cause to interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment. In general, federally listed noxious weeds are plants that are likely to be aggressively invasive, have significant negative impacts, and are extremely difficult to manage or control once established.

Id. at 60012-13.

APHIS then explained the important distinction between weeds and noxious weeds, and the high standard that must be met in order to justify the classification of a plant as a noxious weed:

The distinction between a weed and a noxious weed warrants emphasis. “Weeds,” in the broadest sense of the word, could include any plant growing where and/or when it is unwanted; even plants that are desirable in some settings may be considered weeds in others. In a narrower sense, weeds are invasive, often non-native, plants which impact natural and managed ecosystems, often with significant negative consequences due to lost yields, changes in management practices, altered herbicide use, etc. Only a fraction of these problematic weeds are considered to be so invasive, so harmful, and so difficult to control that Federal regulatory intervention to prevent their introduction or dissemination is justified, and these are the focus of the regulatory controls placed on them by APHIS. However, any weed, and virtually any plant or plant product, can be evaluated by APHIS to determine whether its characteristics and potential impacts warrant its listing as a noxious weed.

Id. at 60013.

APHIS next provided examples of currently listed noxious weeds to illustrate the kinds of plants the Agency considers to be “sufficiently invasive, damaging, and difficult to control to be deemed noxious weeds.” *Id.* The impacts caused by these plants included lost productivity of crop fields due to chemicals released by plants that can damage other plants, parasitic damage to crops caused by plants that attach themselves to a host and remove nutrients from it, reduced productivity of pasture caused by encroaching plants that livestock refuse to eat, injury to humans or livestock caused by toxic plants, unchecked overgrowth that can starve productive plants of sunlight and nutrients, physical obstructions that can hamper the movement of livestock and humans, and disruption of water flow from weeds that may grow in irrigation, drainage or flood control canals.

Id.

APHIS also explained the limited role that economic impacts play in a noxious weed determination:

APHIS' determination that a plant is a noxious weed is based on notable physical harm or injury caused by the plant. The elements of the noxious weed definition include a number of interests that might be damaged by noxious weeds including not only plants but irrigation, navigation, the natural resources of the United States, the public health, the environment and interests of agriculture. Often APHIS quantifies the physical harm or injury in terms of economic losses. Loss in commodity value due to the presence of noxious weeds in seeds, for example, is a consequence of

the anticipated physical damage that would be caused if the seed containing a noxious weed were distributed and planted; the economic loss is never simply the result of market preference to have commodities free of certain noxious weed seeds in and of itself, in the absence of any potential physical damage or harm. APHIS does not consider significant economic effects alone that are not linked to physical damage to be sufficient to determine a plant is a noxious weed.

Id. at 60014.

In this discussion, the Agency noted its years of experience in regulating noxious weeds, and affirmed its intent to apply the same standards to GE plants: “The experience and precedents developed by the APHIS-PPQ noxious weed program provide a guide for the regulation of plants that may be noxious weeds, and we intend to apply it to the consideration of GE plants in the same way.” *Id.* at 60013.

APHIS had the opportunity to reaffirm this commitment at a public meeting held on April 29-30, 2009 at its offices in Riverdale, Maryland. At that meeting, in written materials shared with participants and later posted to the docket, APHIS repeated its obligation to apply its PPA noxious weed authority consistently. APHIS-2008-0023-5409.2. Specifically, the Agency stated: APHIS must consistently apply its PPA noxious weed authority and thus its noxious weed assessment of GE plants under the proposed regulations must be similar to and consistent with the way that APHIS has in the past and continues to evaluate the noxious weed risk of non-GE plants. It is not justifiable either from a regulatory or a scientific perspective to hold GE plants to a different standard than non-GE plants for risks regulated under the same statutory authority by the very same agency.
Id. at 2.

Comments on Proposed Updates to Noxious Weed Regulations

The updates to the Noxious Weed regulations proposed in the Notice include adding information regarding the petition process for listing noxious weeds. Proposed 7 C.F.R. § 360.500. While the information requested will be necessary to making a listing determination, certain baseline information will also be required and should also be specifically referenced in the regulation. As an initial matter, information must be provided to show that the plant in question causes injury recognized under the PPA and the International Plant Protection Convention (IPPC).¹ 73 Fed. Reg. at 60012 (“The first consideration in determining if a plant is a noxious weed is identifying what direct injury or damage (physical harm) the plant causes.”) While proposed § 360.500 requests information in a petition regarding the taxon and the potential economic and environmental impacts of spread of the plant in question, it does not explicitly require information regarding the injury the offending plant may inflict. While in many instances this information will be obvious, it is nevertheless essential to a noxious weed determination and must not be overlooked.

Similarly, the “Guide to the Listing of the Process for Federal Noxious Weeds” (the Listing Guide) referenced in the Notice outlines the listing process for federal noxious weeds, specifically describing

¹ 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 IPPC, to which the U.S. is a signatory and which Congress ratified in 1972. The IPPC is the international treaty recognized by the World Trade Organization (WTO) as the standard-setting body for international plant phytosanitary issues.

the first step as “Identify a weed that may meet the definition of “quarantine pest.”² Implicit in this definition is the fact that the weed in question must first meet the IPPC definition of a “pest” – it must cause injury. However, the Listing Guide does not specifically describe this mandatory initial determination. This omission improperly focuses the “identification” step of the listing process on the potential economic and environmental harm caused by the plant, rather than on the initial injury, and thereby misrepresents the scope of the assessment APHIS is obliged to make.

Conclusion

APHIS is obligated by the PPA and the IPPC to make noxious weed determinations according to a uniform standard of harm regardless of the type of plant involved. In all cases, APHIS must first make an initial finding of physical harm caused by the plant at issue. Only then may the Agency continue the risk assessment and risk mitigation process to determine if further regulation is appropriate.

BIO appreciates the opportunity to provide these additional comments in response to the Agency’s Notice.

Sincerely,

A handwritten signature in black ink that reads "Michael Wach". The signature is written in a cursive, flowing style.

Michael Wach
Managing Director, Science and Regulatory Affairs
Food and Agriculture

² http://www.aphis.usda.gov/plant_health/plant_pest_info/weeds/downloads/listingguide.pdf.