April 28, 2009

Issue Paper 2: Incorporation of the Plant Protection Act Noxious Weed Provisions

I. Objective of the Proposal

The goal of incorporating the noxious weed authority of the Plant Protection Act of 2000 (PPA) into the proposed revisions to the 340 regulations is to recognize and utilize both the plant pest and the noxious weed authorities provided by the Statute. The PPA grants the Secretary of Agriculture authority to develop regulations in order to detect, control, eradicate, suppress, prevent, or retard the spread of plant pests or noxious weeds. The PPA combines the authorities of several previous related acts, including the Plant Quarantine Act of 1912 (PQA), the Federal Plant Pest Act of 1957 (FPPA), and the Noxious Weed Act of 1974 (NWA).

APHIS' current Part 340 biotechnology regulations were first promulgated in 1987 using the FPPA and PQA, which provided USDA authority to regulate the importation and interstate movement of articles that are likely to result in the introduction or dissemination of *plant pests*. APHIS is proposing to revise the Part 340 regulations to also include its PPA noxious weed authority to regulate certain GE organisms. The proposal seeks to:

- Prevent potential gaps in APHIS' Part 340 regulatory oversight, namely for GE organisms which are unlikely to pose a plant pest risk but could pose a noxious weed risk.

- Have the regulatory authority to consider a broader range of potential harm from GE plants i.e., not just their potential for being a plant pest, but also their potential to be a noxious weed.

- Improve clarity of risk assessments, by evaluating GE plants that could be considered potential noxious weeds, in addition to evaluating their potential to be plant pests.

- Be able to regulate non-living material derived from a GE plant, if APHIS concludes that such material is likely to pose a noxious weed risk (e.g., create a noxious weed harm as enumerated in the PPA by injuring the interests of agriculture, the environment, or public health).

II. Description of Significant Comments Received to date.

Commenters focused on both the issue of incorporating the noxious weed authority into the scope of the rule as well as the issue of exactly *how* the noxious weed authority would be utilized or applied.

Many commenters focused on the very broad range of significantly harmful impacts encompassed in the noxious weed definition in the PPA. In general, industry and trade groups raised concerns that APHIS should narrowly limit its interpretation of the noxious weed definition, so that it was clear, for example, that economic or aesthetic impacts alone in the

absence of any significant physical damage did not make any plant a noxious weed. On the other hand, several public interest groups and numerous individuals wanted APHIS to interpret the definition as inclusively as possible, especially with regard to impacts on the environment, public health, and marketing or product quality impacts such as indirect impacts on organic agriculture.

Some commenters felt that the proposed rule "set the bar too low" for GE plants. If the impacts of GE plants are compared against impacts of "real" noxious weeds, as proposed, then few GE plants could ever rise to that level of harm and most GE plants might be quickly evaluated by APHIS to not be under its PPA jurisdiction and thus not subject to the Part 340 regulations. That is, only those plants that are noxious weeds (or are likely to be noxious weeds) to begin with would actually be within the scope of the Part 340 regulations.

III. APHIS Current Thinking

APHIS considers that it is preferable to revise its regulations to incorporate the noxious weed authority of the PPA. Doing so would allow regulatory oversight of GE organisms that do not fall within the jurisdiction of the current regulation's plant pest authority. APHIS also considers that the proposed revisions could also improve the clarity and transparency of APHIS' biotech risk assessments and enable APHIS to consider a broader range of factors (e.g., interests of agriculture, public health, the environment) that could potentially be injured by the GE plant if it were determined to be a noxious weed. The specifics of *how* APHIS will evaluate the noxious weed risk of GE plants may require some additional development and clarification. 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. However, APHIS will need to develop clear criteria and decision-making standards in order to better inform the public of how it intends to apply its PPA noxious weed authority to GE plants. Those criteria and standards will likely need to be incorporated into the regulation.

IV. Issues for Further Discussion

Comments related to incorporation of the PPA noxious weed authority into the proposed regulations raised a number of issues that APHIS will have to carefully consider:

- How can APHIS apply its PPA noxious weed authority to GE plants in a way that is consistent with and similar to its past and current noxious weed regulation of non-GE plants?

- What criteria or standards for evaluating GE plants as noxious weeds could APHIS develop that are consistent with the PPA definition of noxious weeds and APHIS application of its noxious weed authority to non-GE plants?

- How can APHIS develop noxious weed criteria applicable to GE plants and relate those criteria to the various impacts included in the PPA noxious weed definition—such as impacts on “other interests of agriculture” and “public health”— that are consistent with its past and current non-GE noxious weed assessments?