

Docket No.: APHIS-2012-0090

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

April 29, 2013

COMMENTS TO APHIS ON PETITION FOR DETERMINATION OF NONREGULATED STATUS OF SOYBEAN GENETICALLY ENGINEERED FOR RESISTANCE TO HPPD INHIBITOR HERBICIDES, EVENT SYHTOH2

Thank you for the opportunity to provide input on the petition for deregulation of Syngenta's event SYTHTOH2 soybean, genetically engineered for resistance to herbicides of the HPPD inhibitor class.

The deregulation and widespread use of herbicide-resistant crop systems has substantially altered agricultural production practices in the last 15 years. HR crop systems lead to sharply increased use of the associated herbicide(s), increased reliance on such herbicide(s), and a substantial shift in use to (much) later in the season. These substantial changes in usage patterns lead to greater incidence of crop-damaging herbicide drift; a higher likelihood and more rapid evolution of weeds resistant to the herbicide(s); increased tillage and associated soil erosion; and environmental and human health costs associated with greater pesticide use. In assessing this petition for deregulation of SYHTOH2, APHIS must consider all potential significant environmental impacts, including all reasonably foreseeable impacts.

APHIS's past assessments of herbicide-resistant crop systems have been deficient for various reasons. CFS urges APHIS to redress these deficiencies and conduct sound assessments in line with the following guidelines:

- Assess SYHTOH2 together with associated herbicide use as an herbicideresistant (HR) crop system—APHIS must consider the use and any changes in use patterns of HPPD inhibitor herbicides on SYHTOH2.
- Assess the HR crop in light of experience gained with past HR crop systems.

- Assess both the short and longer-term consequences of the HR crop system, which experience shows can be very different.
- Assess the cumulative impacts of growing multiple HR crops.

As APHIS is well aware, the transgene confers resistance to the herbicide(s), and in conjunction with the insertion site and genetic background of the host plant, determines how much herbicide can be applied and when during the season without injuring the crop. Thus the pattern of biological resistance to the herbicide(s) is event-specific and should be described by the applicant in the Petition, and the implications explored by APHIS in the EA and/or EIS, and in the PPRA. Because herbicides can impact the physiology of the HR crop and affect its performance in the field, all compositional tests and field trials to assesse agronomic properties should be conducted on SYHTOH2 that is treated with full rates of the associated herbicides.

Biological constraints are important limits on how growers use herbicides in the field. Non-engineered crops can be injured by labeled herbicides in some conditions, so growers take extra care in applying these herbicides. If an engineered crop is immune to injury even at rates higher than allowed by label or at later times in development, experience has shown that growers will push or exceed the label limits in situations where there is weed pressure. APHIS needs to explore the implications of removing biological constraints to herbicide use in their assessments.

APHIS should examine both short-term and long-term impacts of the proposed herbicide resistant crop system in the light of what has been learned from real-world experiences with previously approved herbicide resistant crop systems. What are the likely similarities and differences in terms of environmental, health and economic concerns?

Further, we are very concerned about cumulative impacts of approving this suite of crops: stacking of different resistance traits in the same crops, growing crops with different resistance traits in the vicinity of each other within a given year, and using the same resistance traits in rotation crops, for example.

In order to properly assess the impacts of herbicide resistant crop systems, APHIS must critically analyze information from a variety of sources. Whenever possible, APHIS should consult high-quality independent peer-reviewed research, up-to-date reports in the farm press and extension bulletins, government studies, and other sources of relevant information. APHIS has too often in the past referenced misinformation from industry or industry-funded sources in its assessments of issues such as how HR crops influence pesticide use, tillage regimes, evolution of resistant weeds, and similar issues.

APHIS should also require the applicants to supply information necessary for meaningful risk assessments that is not in their petitions. If the petitioner cannot supply the pertinent information, APHIS should undertake or commission appropriate research to fill in the gaps. For example, the following information should be available for review by APHIS and the public:

- Proposed herbicide application regime: how much herbicide, how often, window of application.
- Degree of resistance conferred by the transgene in different plant parts and stages of development.
- Expression of the transgene in pollen, nectar; levels of herbicide residues and metabolites in pollen, nectar.
- Herbicide residues and metabolites in plant tissues from the time of application through post-harvest.

APHIS needs to analyze the following areas:

- Agricultural production impacts, including and not limited to burden on organic and non-transgenic agricultural production and potential harms to non-target crops from the adoption of the HR crop system.
- Environmental impacts, including but not limited to:
 - o Herbicide use and changes in herbicide use patterns;
 - Gene flow from SYHTOH2 to compatible varieties and the resulting increased weediness;
 - o Agricultural practices, including herbicide use, effects on tillage; and
 - Weed resistance and volunteers.
- Socioeconomic impacts, such as:
 - o Transgenic contamination and their effects on both domestic and export markets, as well as, consumers and farmers' right of choice
 - o Changes in seed industry market concentration and their impacts.
 - Effects on the methods and costs of weed control
- Human health impacts, such as:
 - o Herbicide use, including impacts on farm workers; and
 - Safety of food products
- Livestock health, such as:
 - o Herbicide use; and
 - Safety of animal feed.
- Threatened and endangered species, such as:
 - o Herbicide use; and
 - Ouality of crop tissues as food sources.

• Disease and pest impacts stemming from both the HR crop and the associated herbicide use.

We look forward to commenting on the EA, PPRA and supporting documents produced by APHIS after APHIS analyzes the Petitions for Deregulation for these new herbicide resistance events.

Bill Freese, Science Policy Analyst Center for Food Safety