

June 28, 2010

Submitted Via Electronic Mail

Docket No. APHIS-2010-0047  
Regulatory Analysis and Development, PPD  
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-2010-0047; Notice of Intent to Prepare an Environmental  
Impact Statement and Proposed Scope of Study

To whom it may concern:

These comments are submitted by the Biotechnology Industry Organization (BIO) in response to the May 28, 2010 notice by the United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS or the Agency) of its plans to prepare an environmental impact statement (EIS) in connection with a court-mandated evaluation of the potential impacts on the human environment associated with the Agency's determination of nonregulated status for a Monsanto/KWS SAAT AG glyphosate-tolerant sugarbeet line, designated as event H7-1. 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.

For over twenty years, BIO's member companies engaged in the development of biotechnology-derived commodity crops and other plants and organisms have acted under the regulatory oversight of APHIS, along with the Environmental Protection Agency (EPA) and the Food and Drug Administration. During that time, products of agricultural biotechnology have yielded significant economic and environmental benefits, lowering both the costs and environmental impact of food, feed, fuel and fiber production in the United States and 24 other nations. This success has been grounded on the work that USDA and the other federal agencies overseeing this technology have conducted to ensure the safety of these products for the environment, as well as for the consuming public. BIO supports the work that USDA has undertaken to develop and enforce a sensible, science-based approach to the regulation and development of these products.



BIO applauds APHIS's decision to request that EPA serve as a cooperating agency in preparing this EIS, and to utilize as appropriate the environmental analysis provided by EPA and other data or analysis prepared by other agencies. This approach is consistent with the 1986 Coordinated Framework for Regulation of Biotechnology, under which products of biotechnology are regulated in the United States, and with regulations implementing the National Environmental Policy Act (NEPA).

BIO strongly encourages APHIS to also utilize EPA's human health risk assessments of glyphosate to be used on the glyphosate-tolerant sugarbeet. Where pesticides may be used on food or feed crops, as glyphosate is used on sugarbeet, EPA sets tolerances (maximum pesticide residue levels) for the amount of the pesticide that can legally remain in or on foods. EPA undertakes this analysis under the authority of the Federal Food, Drug, and Cosmetic Act (FFDCA). Under the FFDCA, EPA must find that such tolerances will be safe, meaning that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue. This finding must be made and the appropriate tolerance established before a pesticide can be registered for use on the particular food or feed crop in question. APHIS should utilize EPA's expertise in this area, as well as its expertise in the environmental assessment of glyphosate.

The alternatives that the EIS will consider are appropriate and reasonable and represent the full scope of APHIS's regulatory alternatives available under these circumstances. BIO has reviewed the list of issues APHIS proposes to address in the EIS, and supports APHIS's inclusion of these issues. An analysis of these issues should fully inform the Agency and the public as to the nature of any environmental impacts that might result from APHIS's determination regarding the regulatory status of Event H7-1 in sugarbeet.

Finally, BIO urges the Agency to include in the EIS the facts, recently recognized in the report from the National Research Council, "The Impact of Genetically Engineered Crops on Farm Sustainability in the United States," that many U.S. farmers who grow crops developed through biotechnology are realizing substantial economic and environmental benefits – such as lower production costs, fewer pest problems, reduced use of pesticides, and better yields – compared with conventional crops. These benefits should be taken into account when evaluating the potential impacts of deregulation of glyphosate-tolerant sugarbeet or any genetically engineered crop for NEPA purposes. *See* 40 C.F.R. § 1508.27(b)(1).

BIO appreciates the opportunity to provide comments in response to the Agency's scoping notice.

Sincerely,



Sharon Bomer Lauritsen  
Executive Vice President  
Food and Agriculture