

December 6, 2010

Submitted Via Federal eRulemaking Portal

Docket No. APHIS-2010-0047  
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: APHIS-2010-0047: Availability of an Environmental Assessment for Supplemental Request for Partial Deregulation of Sugar Beets Genetically Engineered to Be Tolerant to the Herbicide Glyphosate

To whom it may concern:

These comments are submitted by the Biotechnology Industry Organization (BIO) in response to the November 4, 2010 announcement (the Notice) by the United States Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS or the Agency) of APHIS's preparation of a draft environmental assessment (EA) as part of its decisionmaking process to address a supplemental request for partial deregulation of sugar beets genetically engineered (GE) for tolerance to the herbicide glyphosate, or for similar administrative action to authorize the continued cultivation of the GE sugar beets subject to carefully tailored interim measures proposed by APHIS.<sup>1</sup> BIO appreciates the opportunity to provide these comments.

### **Background**

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's member companies engaged in the development of GE commodity crops and other plants and organisms have acted under the regulatory oversight of APHIS, along with the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA), since well before the first products were commercialized over ten years ago. Since that time, these products have

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<sup>1</sup> 75 Fed. Reg. 67945 (Nov. 4, 2010).



yielded significant economic and environmental benefits, lowering both the costs and environmental impact of food, feed and fiber production in the United States and 21 other nations. This success has been grounded on the work that APHIS 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 applauds the work that APHIS has undertaken in past years to develop and enforce a robust, science-based approach to the regulation and development of these products.

As APHIS has repeatedly stated, much has been learned regarding safety and risk in over twenty years of field testing and commercialization of GE plants and other organisms. Much has also been learned about the proven environmental and economic benefits of biotechnology-derived crops already on the market, and about the promise shown by GE plants and plant products still in development. BIO and its members are proud of this record of safety and of benefit to growers and the environment.

Like dozens of other GE crops, glyphosate-tolerant sugar beets were deregulated by APHIS following years of testing by product developers and careful analysis by the Agency. Deregulation under 7 C.F.R. § 340.6 allows for these sugar beets to be planted, grown and harvested in the same way as traditionally bred crops, with no additional APHIS oversight. These sugar beets were quickly adopted by the grower community and within a couple of growing seasons, constituted over 95% of planted sugar beet acreage. No harm to human or animal health, or to the environment, has been documented as a result of this sugar beet production.

Nevertheless, approximately three years following deregulation, a group of environmental groups sued APHIS, alleging that the Agency did not, *inter alia*, adequately examine the potential economic detriment caused to farmers and consumers of conventional and organic varieties of closely related crops, such as chard and table beets, by deregulation of GE sugar beets. A federal judge in the US District Court for the Northern District of California agreed with the plaintiffs, vacated APHIS's deregulation decision, and ordered APHIS to prepare an Environmental Impact Statement (EIS) for any decision in the future on whether or not to grant nonregulated status to these GE sugar beets. The court denied plaintiffs' request for a permanent injunction against the planting of the GE sugar beets pending completion of the court-ordered EIS, and remanded to the Agency to determine regulatory actions that should be imposed upon the GE sugar beets pending completion of an EIS and a final deregulation decision. The court did not, however, re-regulate sugar beets planted before August 13, 2010. These root production sugar beets may remain in the ground, be harvested, transported, processed and sold as sugar. Seed production sugar beets planted before August 13, 2010 may continue until the seeds or seed stocklings are harvested, transported and stored, or be allowed to flower and set seed, depending on how the plants are managed.

In light of the court order regarding the treatment of these sugar beets pending completion of the EIS and a final APHIS decision on deregulation, the product developers have requested from APHIS a "partial deregulation" or similar administrative action to authorize the continued cultivation of GE sugar beet. (APHIS-2010-0047-0075). As explained in detail in petitioners' request and a subsequent letter to APHIS from the petitioners (APHIS-2010-0047-0204), the GE

sugar beet would be subject to the conditions proposed by APHIS in response to the lawsuit challenging its determination of non-regulated status for the GE sugar beet, to be implemented by seed companies, grower cooperatives and growers, and enforced through the seed companies and grower cooperatives, respectively, under the direct oversight of APHIS. It should also be remembered that any action that APHIS may take in response to the request for “partial deregulation” would be an interim action, which is limited in scope and duration pending completion of the court-ordered EIS.

APHIS’s regulatory authority to act on a petition for deregulated status explicitly states that the Agency may either deny the petition or approve it “in whole *or in part*.” 7 C.F.R. § 340.6(d)(3). Moreover, the United States Supreme Court has recently affirmed APHIS’s authority to deregulate in part, under circumstances very similar to those here. In *Monsanto Co. v. Geertson Seed Farms*, the Court specifically recognized that APHIS can implement a “partial deregulation, noting that such a regulatory determination might take the form of a limited or conditional deregulation.” 130 S. Ct. 2743, 2757 n. 4 (2010). In *Monsanto Co.*, the Supreme Court was considering regulatory action APHIS might take under very similar circumstances – pending completion of an EIS for full deregulation of GE alfalfa (which, like the GE sugar beet here, had been deregulated and successfully marketed and grown before a lawsuit halted that activity). In that discussion, the Supreme Court outlined a number of scenarios under which APHIS might partially deregulate crops, such as restricting crops to a limited geographic area or mandating isolation distances. *Id.* at 2760.

The permit conditions APHIS has designed, implemented and enforced over the past decades are typically designed for crops with traits and characteristics about which relatively little may be known, and so the scope of those permit requirements for all phases of product development, growth, transportation and harvest is appropriate. Under all of the circumstances presented by RRSB, including an earlier APHIS risk assessment that has identified no plant pest risk and the crop’s previous widespread commercial use, the “partial deregulation” alternative would appear to be the most appropriate choice pending the further analysis that will accompany a decision on full deregulation. Moreover, the issuance and administration of permits covering an anticipated 1.1 million acres of sugar beet root crop production under these circumstances would also place a significant and unnecessary burden on the Agency. BIO and its member companies recognize and support APHIS’s authority to move forward with a “partial deregulation” for RRSB until the decision to fully deregulate the product has been made.

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

Sincerely,



Sharon Bomer Lauritsen  
Executive Vice President  
Food and Agriculture