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INDUSTRY ORGANIZATION

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Re: Docket No. APHIS–2010–0047 - Draft Environmental Impact Statement: Glyphosate-Tolerant H7-1 Sugar Beets: Request for Nonregulated Status – October 14, 2011

Dear Dr. Stankiewicz Gabel:

These comments are submitted by the Biotechnology Industry Organization (BIO) in response to the United States Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS or the Agency) *Draft Environmental Impact Statement-October 2011, Glyphosate Tolerant H7-1 Sugar Beets Request for Nonregulated Status*. This draft environmental impact statement (EIS) was prepared in response to a mandate from the U.S. District Court in Northern California for APHIS to evaluate the potential impacts to the human environment of the deregulation of Monsanto/KWS SAAT AG glyphosate-tolerant sugar beet, designated as event H7-1. BIO appreciates the 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 associations, service providers to the industry, and academic centers.

For over twenty years, BIO's member companies have developed biotechnology-derived crops under the regulatory oversight of APHIS, the U.S. Environmental Protection Agency (EPA) and the Food and Drug Administration. As detailed in a recent report by the Agency's Economic Research Service[i], crops improved through biotechnology have provided significant benefits to U.S. farmers and consumers by substantially increasing the productivity of food, feed and fiber, while simultaneously decreasing the environmental impact of agriculture. As such, these crops are a key tool for enhancing the sustainability of agriculture; strengthening rural economies; providing a safe,

nutritious and abundant food supply; and helping to meet the challenge of energy security.

In addition, crops improved through biotechnology have an excellent safety record. During 30 years of research on genetically engineered crops and 15 years of their wide-scale production, not a single instance of actual harm to human health, animals or the environment has ever been confirmed. BIO and its members are proud of this record of health and environmental safety and of the many benefits these crops provide to growers, consumers and the environment.BIO has always advocated for a science-based approach to the regulation of genetically engineered crops. As such, BIO supports APHIS's "Preferred Alternative" (Alternative 2) to fully deregulate H7-1 sugar beets. Deregulation of event H7-1 sugar beet varieties, which the Agency thoroughly reviewed in both its initial Environmental Assessment (Docket # 04-075-2, March 2005) and this draft EIS, is the appropriate regulatory decision.

In spite of repeated legal challenges, the Agency's commitment to rational, science-based regulation, as evidenced by the thorough, rigorous analysis described in the draft EIS for glyphosate-tolerant sugar beets, has been constant. Through this and similar actions the Agency has displayed global leadership by developing and implementing regulations grounded in scientific assessments of risks, while withstanding political pressure to abandon robust science. BIO applauds APHIS's continued commitment to science-based regulation in the face of these challenges.

Support for science-based assessment of risk to human health and the environment is also the basis for BIO's opinion that a full EIS will rarely be necessary for decisions to deregulate crops derived from modern biotechnology. As mentioned above, biotech crops have an unblemished safety record. In addition, scientific evidence from molecular biology has shown that, as expected, genetic engineering causes less disruption to the plant genome than traditional breeding. The increased precision of genetic engineering leads to fewer unexpected consequences and thus greater predictability, together with a concomitant reduction in the potential for unintended environmental impacts. Therefore, a thorough Environmental Assessment (EA) typically provides sufficient information for the Agency to accurately assess the impacts of a decision to deregulate, as was true for the initial EA for the deregulation of H7-1 sugar beets. The expensive and extensive analysis in the draft EIS simply reaffirms the findings in the original EA that led to the 2005 decision to deregulate.

While some completely novel trait/crop combinations may introduce questions that warrant an EIS, BIO supports the Agency's well-established practice of completing an EA for decisions to deregulate familiar crops and phenotypic traits with predictable impacts. The EIS process adds years to the review process and withholds beneficial products from U.S. farmers. Requiring an EIS for each product would also send the false message that APHIS believes that genetically engineered crops, as a category, are likely to have significant environmental impacts. In addition to being misleading and inconsistent with the demonstrated history of safe use of genetically engineered crops, this message would undermine the competitiveness of U.S. growers in the global

marketplace, and undercut positions consistently taken by the U.S. State Department, U.S. Agency for International Development, U.S. Trade Representative, Office of Science and Technology Policy, and, most importantly, USDA itself.

We appreciate the opportunity to provide these comments.

Sincerely,

Cathleen Enright, Ph.D.
Executive Vice President
Food and Agriculture

[i] USDA-ERS. The Changing Organization of U.S. Farming. Economic Information Bulletin No. 88. December 2011. (Available at: http://www.ers.usda.gov/publications/eib88/)