

December 23, 2010

Mr. Cass R. Sunstein
Administrator
Office of Information and Regulatory Affairs
The Office of Management and Budget
Executive Office of the President
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Washington, DC 20503
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Dear Mr. Sunstein:

The Biotechnology Industry Organization (BIO) wishes to express in the strongest possible terms its concerns regarding unilateral actions that the U.S. Department of Agriculture (USDA or the Department) is poised to take in the name of coexistence. While we appreciate the opportunity to be included in a meeting of various stakeholders with Secretary Vilsack on December 20, the dialogue in that meeting only served to heighten our concerns.

Ostensibly USDA's actions would be taken in the context of deregulating a particular biotechnology-derived crop, glyphosate-tolerant alfalfa, under the Plant Protection Act (PPA) and assessing that deregulation action under the National Environmental Policy Act (NEPA). In reality, the implications of USDA's actions would sweep far more broadly across the face of American agriculture, undermining a twenty-five year track record of science-based technological innovation that has brought significant benefits to growers, consumers and the environment without any evidence of adverse effects to health, safety or the environment.

To be clear, BIO supports coexistence in American agriculture. Farmers should and do have the right to choose the type of farming practices and markets that best meet their individual needs. Indeed the organic farming industry has grown dramatically during the same period of time that biotechnology-derived crops have been adopted by the vast majority of corn, cotton and soybean farmers. Organic growers have achieved these impressive results under the National Organic Program, a process-based marketing program that imposes none of the rigorous health or environmental safety requirements that apply to products of agricultural biotechnology.

Based on its authority under the PPA, USDA has overseen tens of thousands of field tests of biotechnology-derived plants and deregulated over 70 of these crops. In each case, USDA has made an independent, science-based evaluation of the potential environmental impacts of its deregulation decision as required by NEPA. Recently a handful of federal



court decisions have questioned USDA's compliance with the procedural requirements of NEPA.

BIO applauds the fact that USDA has stepped up its NEPA compliance efforts in response to these court decisions and, in the case of glyphosate tolerant alfalfa, complied with the court's order to prepare an environmental impact statement (EIS). In its effort to address its procedural responsibilities under NEPA with respect to alfalfa, however, it appears that USDA is attempting to regulate coexistence under statutes that are not only ill suited, but legally incapable of so doing and, in the process, exceeding its statutory authority. Moreover, in a case such as this where no plant pest risks are identified by USDA, the PPA provides no authority for the imposition of conditions on a deregulation decision.

Indeed the Department appears to have lost sight of certain fundamental legal and scientific principles:

- NEPA is a purely procedural statute; it directs USDA to assess the potential environmental impacts of its actions but does not provide USDA with any additional authority to address those impacts.
- The scope of USDA's authority to address the impacts of agricultural biotechnology (including but not limited to coexistence) is limited to the PPA and the Coordinated Framework for Regulation of Biotechnology, both of which are science and risk-based.
- Any conditions imposed by USDA as part of a deregulation action must be based on PPA authority.
- No court has ever directed USDA to regulate coexistence or change its coexistence policy, nor has any court held that a biotechnology-derived crop has presented a risk to health, safety or the environment.

American agriculture has an impressive track record of successfully addressing the economic and market-based issues associated with coexistence, whether neighbor-to-neighbor or through state seed certifying agencies or other local, state or regional initiatives. And in the field of agricultural biotechnology, growers have worked closely with the seed industry to meet their respective stewardship obligations through contractual arrangements and other mechanisms. That is where matters of coexistence and stewardship are addressed most effectively and efficiently.

The United States has worked long and hard to successfully establish and maintain a science-based regulatory process for agricultural biotechnology and the benefits of those efforts are irrefutable. Now, as the rest of the world begins to recognize the benefits of this technology, is hardly the time to undermine the U.S. regulatory process in reliance on inapposite court decisions, market-based perceptions and false assumptions. We can ill afford to subject American agriculture and consumers to the same paralyzing effects as

those imposed on European growers and consumers through the adoption of so-called “precautionary” principles rooted in myth, falsehood and innuendo. Any change in America’s agricultural biotechnology policy along the lines implicitly suggested by USDA would totally undermine U.S. international trade interests and long-standing positions of the U.S. government in the World Trade Organization, International Plant Protection Convention and Biosafety Protocol, among others.

USDA’s failure to deregulate agricultural products derived from modern biotechnology in a science-based and timely manner is already having a detrimental effect on BIO members and risks moving high-paying jobs and research overseas. In addition, without new technologies, U.S. farmers will lose their competitiveness in the global market. Now that the EIS has been prepared for glyphosate-tolerant alfalfa, it is time for USDA to prepare its record of decision and authorize full deregulation of this important crop as soon as possible.

BIO is the world's largest biotechnology organization, providing advocacy, business development and communications services for more than 1,100 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.

Your continuing interest in these issues is very much appreciated. We have sent similar letters to United States Department of Agriculture Secretary Tom Vilsack; United States Trade Representative Ronald Kirk; Office of Science and Technology Policy Director John Holdren; National Economic Council Director Lawrence Summers; and U.S. Department of Justice, Assistant Attorney General for Environment and Natural Resources Division Ignacia Moreno. Please feel free to contact me if we can provide any additional information.

Sincerely,



Sharon Bomer Lauritsen
Executive Vice President
Food and Agriculture

cc: Ms. Margaret Malanoski