

March 23, 2010

Submitted Via Electronic Mail and First Class Mail

Desk Officer for Agriculture
Office of Information and Regulatory Affairs
Office of Management and Budget (OMB)
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Departmental Clearance Office
United States Department of Agriculture
Office of the Chief Information Officer
Mail Stop 7602
Washington, DC 20250-7602

Dear Sir or Madam:

Re: Submission for OMB Review: Comment Request; Title 7 CFR 340,
“Introduction of Organisms and Products Altered or Produced Through
Genetic Engineering;” OMB Control Number: 0579-0085.

To whom it may concern:

These comments are submitted by the Biotechnology Industry Organization (BIO) in response to the February 23, 2010 announcement (the Notice) that the United States Department of Agriculture had submitted the above-referenced information collection requirement to the Office of Management and Budget (OMB) for review and clearance. 75 Fed. Reg. 8031. 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.

BIO's members represent the majority of those entities subject to the information collection requests (ICR) that are the subject of this notice. BIO's member companies engaged in the development of biotechnology-derived (also known as “genetically engineered” or “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) for over twenty years. Since that time,



these products have yielded significant economic and environmental benefits, lowering both the costs and environmental impact of food, feed and fiber production in the United States and 24 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 to develop and enforce a sensible, 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. Many early concerns regarding this technology have proven to be unfounded. BIO and its members are proud of this record of safety and of benefit to growers and the environment.

As the Agency is well aware, APHIS has proposed major amendments to Part 340, including major increases in ICRs and recordkeeping requirements. *See* APHIS Docket No. APHIS-2008-0023. BIO has expressed its own views on the proposed amendments (including paperwork burdens) in letters of November 24, 2008 and June 29, 2009, which have been entered into that docket.

With regards to the existing Part 340's ICR burden, BIO's members do not consider the current ICRs to be unduly burdensome, and recognize that the information collected assists APHIS in confirming the safety of products being developed for the marketplace. As referenced in BIO's comments regarding the proposed amendments to Part 340, we hope that APHIS will continue to impose data requirements necessary to ensure safety without imposing undue burdens that can hamper innovation and product development, particularly for small companies and academic researchers. BIO looks forward to the opportunity to provide any additional information on this topic that APHIS may request.

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