

July 6, 2010

Submitted Via Electronic Mail

Docket No. EPA-HQ-OPP-2010-0281  
OPP Regulatory Public Docket (7502P)  
Environmental Protection Agency  
Rm. S-4400  
One Potomac Yard (South Bldg.)  
2777 S. Crystal Dr.  
Arlington, VA

Re: Docket No. EPA-HQ-OPP-2010-0281; Agency Information Collection Activities; Proposed Collection; Comment Request; Plant-Incorporated Protectants; CBI Substantiation and Adverse Effects Reporting; EPA ICR No. 1693.06, OMB Control No. 2070-0142

To whom it may concern:

These comments are submitted by the Biotechnology Industry Organization (BIO) in response to the May 5, 2010 notice by the United States Environmental Protection Agency (EPA or the Agency) of its plans to submit a request to renew an existing approved Information Collection Request (ICR) to the Office of Management and Budget (OMB) entitled: "Plant-Incorporated Protectants; CBI Substantiation and Adverse Effects Reporting" (the Notice). Before submitting the ICR to OMB, EPA is soliciting comments on specific aspects of the proposed information collection. 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 EPA, along with the United States Department of Agriculture 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 and fiber production in the United States and 24 other nations. This success has been grounded on the work that EPA 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 EPA has undertaken to develop and enforce a sensible, science-based approach to the regulation and development of these products.

The Notice addresses two ICRs described in regulations pertaining to plant-incorporated protectants (PIPs), codified in 40 CFR part 174 – first, substantiation for claims that certain information submitted to the Agency constitutes confidential business information (CBI), and second, adverse effect reporting. BIO's members appreciate the importance of both the protection of their own CBI and their obligation to report to EPA any adverse events that may arise relating to PIPs. BIO's members believe that the current reporting requirements, as outlined in the Notice, are necessary and appropriate and do not constitute an undue burden on the industry, including on small businesses. The current requirements provide the Agency with necessary information to allow it to meet its statutory obligations regarding CBI and adverse events. No evidence has shown that any expansion of the current reporting requirements would be warranted.

BIO appreciates the opportunity to provide comments in response to this Notice.

Sincerely,

A handwritten signature in black ink, appearing to read 'Sharon Bomer Lauritsen', with a long horizontal flourish extending to the right.

Sharon Bomer Lauritsen  
Executive Vice President  
Food and Agriculture