

April 30, 2010

Submitted Via Electronic Mail
Docket No. EPA-HQ-OPP-2008-0742

Office of Pesticide Programs (OPP)
Public Docket (7502P)
Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

Re: Docket No. EPA-HQ-OPP-2008-0742; Biopesticides Registration Action Document (BRAD) for Coat Protein Gene of Plum Pox Virus; Proposed Label

To whom it may concern:

These comments are submitted by the Biotechnology Industry Organization (BIO) in response to the April 1, 2010 opening of the above-referenced docket by the United States Environmental Protection Agency (EPA or the Agency) soliciting comments on the following documents: Biopesticides Registration Action Document (BRAD) for Coat Protein Gene of Plum Pox Virus; Proposed Label. 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 (USDA) 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.



EPA is providing a 30-day public comment period before making a final decision to register a pesticide product, C5 HoneySweet Plum, containing the new plant-incorporated protectant (PIP), Coat Protein Gene of Plum Pox Virus. BIO is familiar with the significant economic losses that the Plum Pox Virus causes to the stone fruit industry and the fact that this biotechnology-derived product offers a science-based, economical and beneficial defense to these losses. BIO fully supports prompt regulatory action necessary to enable the distribution of the C5 HoneySweet Plum to growers. BIO applauds the work done by the USDA-Agricultural Research Service-Appalachian Fruit Research Station to develop the C5 HoneySweet Plum, and supports action by EPA and other relevant agencies to promote additional work by government, academic and independent researchers to bring other beneficial products of agricultural biotechnology to growers.

As a threshold matter, BIO questions the scientific and public policy basis for requiring registration of the Coat Protein Gene of Plum Pox Virus under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Where a PIP derived from plant viral coat protein gene(s) poses low probability of risk and would not cause unreasonable adverse effects, BIO continues to urge EPA to follow the logic set forth in the proposed PIP rule in 1994, as further refined by the supplemental proposed exemption in 2007. 59 Fed. Reg. 60496, 60525 (Nov. 23, 1994), 72 Fed. Reg. 19590 (Apr. 18, 2007).

This docket also includes a proposed label for the PIP. The “Directions for Use” section of the proposed PIP label would require that all plant propagation materials incorporating the plum pox virus resistance gene (PPVR) have the following information securely attached: “PPVR not for use in organic agriculture.”

Under EPA’s authorizing statute, FIFRA, pesticide directions for use should be protective of human health and the environment. It is a violation of Federal law to use a pesticide in any manner inconsistent with its labeling. This ensures the safe use of pesticide products.

Organic agriculture is regulated quite differently – by a different federal agency, USDA’s Agricultural Marketing Service (AMS), under a separate statute, the Organic Foods Production Act of 1990, and for a different purpose, as a marketing standard. The regulatory scheme for organic agriculture, the National Organic Program (NOP), includes its own certification and enforcement procedures for sale of a product as organic when it does not meet the organic marketing standards. Those standards prohibit the use of most pesticides and products of agricultural biotechnology, including PIPs.

BIO member companies that produce PIPs and market PIP-containing seed prepare PIP labels in accordance with the terms and conditions of their respective registrations. Where the PIP label requires certain FIFRA-related information regarding use of seed containing the PIP (e.g., insect resistance management) to be conveyed to growers, the companies do so, typically by way of grower guides. The issue presented here regarding PPVR is that the only direction that appears on the proposed label (and that is required to be attached to all plant propagation materials) relates to a marketing standard administered by USDA and is unenforceable under FIFRA. In furtherance of the NOP,

USDA is free to ensure that information on a raw or processed agricultural product's compliance with the NOP is conveyed to downstream sellers, distributors and users through a NOP label. FIFRA, however, is not the appropriate vehicle to accomplish that objective and attempting to use the FIFRA label in this manner would be inappropriate.¹

EPA's notice offers no justification for the proposed label requirement. Such a requirement appears to be beyond the scope of EPA's jurisdiction and to usurp the appropriate certification and enforcement processes of the NOP. Without legal justification for the proposed action, this labeling requirement appears unsupported and, should EPA decide to actively regulate this product under FIFRA, BIO requests that the language be deleted from the final approved label.

BIO appreciates the opportunity to provide these comments.

Sincerely,



Sharon Bomer Lauritsen
Executive Vice President
Food and Agriculture

¹ EPA's only previous foray into the NOP recognizes the separate jurisdiction of AMS and provides guidance to pesticide registrants regarding voluntary label language that may be used to advertise that a particular pesticide has been certified as "organic" under the NOP. PESTICIDE REGISTRATION (PR) NOTICE 2003-1, Labeling of Pesticide Products under the National Organic Program, available at http://www.epa.gov/PR_Notices/pr2003-1.pdf. Importantly and appropriately, EPA has never required or suggested that pesticides, or products containing pesticides, that are *not* allowed for use in organic production should be labeled as such.