



June 2, 2017

Environmental Protection Agency
Office of Pesticide Programs
Environmental Protection Agency Docket Center (EPA/ DC) (28221T)
1200 Pennsylvania Avenue NW
Washington, DC 20460-0001

Submitted Electronically via Federal eRulemaking Portal (<http://www.regulations.gov>)

Re: Docket ID No. EPA-HQ-OPP-2014-0293-0400. Public Participation for New Active
Ingredient Plant Incorporated Protectant MON 87411

Dear Sir or Madam:

The Biotechnology Innovation Organization (BIO) is pleased to submit these comments in response to the U.S. Environmental Protection Agency's (EPA) request for public input on the proposed registration decision for commercial use of corn products containing a new plant-incorporated protectant ("PIP") for corn rootworm control.¹

BIO is the world's largest trade association representing roughly 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. BIO represents many of the agricultural biotechnology product developers in North America, including companies developing "PIP" products subject to EPA oversight.

While we are pleased that EPA is planning to register a PIP product with this new mode of action to manage important agricultural pests, we are concerned that EPA continues to hold products of agricultural biotechnology to a different standard than conventional, chemical pesticides. Despite these products' long history of safety and documented environmental benefits, EPA has singled out PIP products for a disproportionate level of regulatory scrutiny, imposing more extensive registration requirements, and delaying decision-making via lengthy external reviews and discretionary comment periods. Ultimately, this double-standard runs counter to EPA's mission by unnecessarily delaying or preventing the development and marketing of environmentally beneficial products to help growers combat pests.

PIPs are also held to a different standard than conventional chemical pesticides in registration decisions through the use of time-limited conditional registrations for PIPs. Given the long history

¹ <https://www.regulations.gov/document?D=EPA-HQ-OPP-2014-0293-0400>



of safe use and environmental benefits associated with PIPs, it is more appropriate to remove any restrictions on the length of registration for this type of product.

That said, if EPA continues to implement time-limited registrations for PIPs on the basis of the potential for pest resistance to develop to a given product, EPA should follow the criteria set forth in their guidance issued in 2010 regarding registration timeframes. The guidance provides for longer registration periods products with a lower likelihood of insect resistance. In particular:

“...a product with pyramided PIP toxins (i.e., two or more toxins with distinct, non-cross reacting modes of action), that are non-high dose (the definition for a high dose product remains unchanged), with either a seed blend or external refuge, qualifies for an eight-year registration.”²

We respectfully request that EPA use its substantial history evaluating PIPs to apply a more balanced approach to regulatory evaluations and decisions which consider actual risk posed by these products rather than implementing policy based upon the “novelty” of the product or other arbitrary factors.

Please feel free to contact me directly if you have any questions about our comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Clint Nesbitt", written over a dotted horizontal line.

Clint Nesbitt
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² <https://archive.epa.gov/pesticides/biopesticides/web/pdf/2010%20cry3435ab1%20brad.pdf>