



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 11, 2016

Mr. Jan Brill
Manager, Registrations
Bayer CropScience
2 T.W. Alexander Dr.
Research Triangle Park, NC 27709

Subject: Exclusive Use Data Protection – Deltamethrin as a Wide Area Mosquito
Adulticide

Product Name: BES0668
EPA Registration Number: 432-1534
EPA Finding: Data Protection Expiration Date: September 19, 2023
Protected Studies: MRID Numbers 49114101-49114107,
49114111-49114112, and 49114119-49114120

Dear Mr. Brill,

This letter addresses your request that data [MRID Nos. 49114101-49114108 and 49114110-49114120] associated with the minor public health use registrations(s) of deltamethrin as a wide area mosquito adulticide each receive a ten-year exclusive-use protection period. EPA is granting the request for an exclusive-use data protection of ten years to protect some of the requested data from September 19, 2013 to September 19, 2023 under EPA Registration No. 432-1534.

Bayer CropScience cited FIFRA section 3(c)(1)(F)(vi) as the authority for EPA to make such a determination. The 1996 Food Quality Protection Act (FQPA) amendments to FIFRA incorporated this subsection under 3(c)(1)(F). FIFRA section 3(c)(1)(F)(vi) sets forth the criteria for establishing a new period of exclusive-use data protection. A new ten-year period of exclusivity can be established for data exclusively used to support a minor use submitted after the expiration of the exclusive use period for the active ingredient under FIFRA 3(c)(1)(F)(ii). The minor use period of exclusivity can be extended ten years from data submission providing the data support minor uses which were actually approved on the label; the data are not publicly owned (*e.g.*, the data cannot be IR-4, public literature, etc.); and the ten-year base period of exclusivity on the chemical has ended.

FIFRA Section 2(l) defines a minor use of a pesticide as one where:

(1) the total United States acreage for the crop is less than 300,000 acres ... or

- (2) *the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use and—*
- (A) *there are insufficient efficacious alternative registered pesticides available for the use;*
 - (B) *the alternatives to the pesticide use pose greater risks to the environment or human health;*
 - (C) *the minor use pesticide plays or will play a significant part in managing pest resistance; or*
 - (D) *the minor use pesticide plays or will play a significant part in an integrated pest management program.*

Under FIFRA section 2(11)(2), a use that does not provide sufficient economic incentive to seek or maintain registration but does have important value for human health or the environment qualifies as a minor use. In the application dated September 19, 2013, exclusive-use protection was requested for data submitted to support registration of deltamethrin as a wide area mosquito adulticide under FIFRA 3(c)(1)(F)(vi). You assert that the mosquito adulticide use of deltamethrin meets the first criterion for qualifying as a minor use as defined by FIFRA 2(11)(2), *i.e.*, in that the use does not provide sufficient incentive for registration. This, and at least one of four other beneficial criteria must be met for a pesticide to qualify as an economic minor use.

The following are our considerations for determining whether the data associated with the requested registration are eligible for a new ten-year period of exclusive-use protection:

- First, Deltamethrin Technical (EPA Reg No. 264-1006) was first registered March 2, 1994 and no longer retains any period of exclusive use.
- Second, this request meets the criterion that the new use can play a significant part in an integrated pest management (IPM) program (BEAD. January 20, 2016. Minor Use Determination of Deltamethrin as a Mosquito Adulticide under FIFRA 2(11)(2) (DP# 423118, DP# 427246).
- Third, whether the potential revenues from the new registration are insufficient to support the registration depends on assumptions about future sales and sales prices. However, for plausible values of sales and selling prices based on past market conditions for mosquito adulticides, the Agency estimated that the revenues are not sufficient to justify the additional registration costs for a new product (BEAD. January 20, 2016. Minor Use Determination of Deltamethrin as a Mosquito Adulticide under FIFRA 2(11)(2) (DP# 423118, DP# 427246).
- Fourth, the supporting data were not found not to be publicly owned or generated by IR-4. Data generated by IR-4 are not entitled to exclusive-use protection (see 40 CFR 152.94(b)).
- Fifth, some of the data associated with this registration [MRID Nos. 49114101-49114107, 49114111-49114112, and 49114119-49114120] do pertain solely to a registration of a minor use (BEAD. January 20, 2016. Minor Use Determination of

Deltamethrin as a Mosquito Adulticide under FIFRA 2(l)(2) (DP# 423118, DP# 427246).

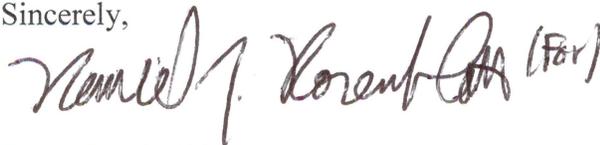
- Lastly, this minor use was approved on March 25, 2015.

DETERMINATION

The Agency concludes that the reduced risk rationale, efficacy, environmental fate, and residue data [MRID Nos. 49114101-49114107, 49114111-49114112, and 49114119-49114120] supporting the use(s) of deltamethrin as a wide area mosquito adulticide do qualify for the requested new ten-year period of exclusive-use protection. MRID Nos. 49114108, 49114110, and 49114113-49114118, however, are more generic in nature and do not pertain *solely* to the minor use of deltamethrin as a mosquito adulticide. Therefore, the Agency concludes that they do not meet the criteria for exclusive-use protection and they will not be included in the list of protected studies.

This new use pattern for deltamethrin is a minor public health use, as confirmed by the attached assessment. Therefore, the Agency **GRANTS IN PART** your request for a new 10-year exclusive-use protection of these data [MRID Nos. 49114101-49114107, 49114111-49114112, and 49114119-49114120] that will expire on September 19, 2023. The Agency is denying exclusive-use protection for the following data: MRID Nos. 49114108, 49114110, and 49114113-49114118. In addition, if the minor use registration which is supported by these data is voluntarily canceled or if such data are subsequently used to support a non-minor use, the data shall no longer be subject to the exclusive use provision of FIFRA section 3(c)(1)(F)(vi).

Sincerely,

Handwritten signature of Susan Lewis in black ink, with the initials "(For)" written to the right of the signature.

Susan Lewis, Director
Registration Division (7505P)
Office of Pesticide Programs

Attachment: BEAD. January 20, 2016. Minor Use Determination of Deltamethrin as a Mosquito Adulticide under FIFRA 2(l)(2) (DP# 423118, DP# 427246)

cc: BC, Marietta Echeverria
PM, Kable Bo Davis
Staff Reviewer, Tim Ciarlo