



**UNITED STATES ENVIRONMENTAL PROTECTION
AGENCY WASHINGTON, DC 20460**

**OFFICE OF
CHEMICAL SAFETY
AND POLLUTION
PREVENTION**

April 25, 2023

Alice Wei
Senior Regulatory Project Manager
Registration and Regulatory Affairs
Valent U.S.A. LLC
4600 Norris Canyon Rd.
San Ramon, CA 94583

Subject: Product Name: Ethaboxam Technical Fungicide
 EPA Reg. No.: 59639-185
 Decision No.: 582224
 Application Date: February 25, 2022
 EPA Finding: Extend the exclusive use data protection period for ethaboxam by 3
 years from March 4, 2024 to March 4, 2027.

Dear Ms. Wei:

This letter addresses your request that certain data associated with the original registration of ethaboxam receive a three-year extension to the ten-year exclusive use protection period. Ethaboxam Technical Fungicide (EPA Reg. No. 59639-185) was first registered by the agency on March 4, 2014. Without an extension of exclusive use protection, the data protection period would expire on March 4, 2024. Though only nine registered minor crops are needed to support this request, the following twelve were cited:

Crop Group/Subgroup	Crop Data Submitted	Minor Use Represented ^b
Tuberous and corm vegetables subgroup (Crop subgroup 1C)	Potato ^a	Ginger
Root vegetables subgroup (Crop subgroup 1A)	Ginseng	Ginseng
Legume vegetables group (Crop group 6)	Soybean ^a	Lima beans
Pepper/eggplant subgroup (Crop subgroup 8-10B)	Bell pepper and non-bell pepper ^a	Bell pepper and non-bell pepper
Melon subgroup (Crop subgroup 9A)	Cantaloupe ^a	Cantaloupe

Crop Group/Subgroup	Crop Data Submitted	Minor Use Represented ^b
Squash/cucumber subgroup (Crop subgroup 9B)	Summer squash and cucumber ^a	Summer squash and cucumber
Cereal grains group (Crop group 15)	Corn and wheat ^a	Popcorn and buckwheat
Rapeseed subgroup (Crop Subgroup 20A)	Canola ^a	Rapeseed
Sunflower subgroup (Crop subgroup 20B)	Sunflower ^a	Safflower

^a The residue data submitted by registrant or IR-4 were conducted on representative crops listed in this column.

^b Minor use sites proposed by the registrant.

After review of this petition, EPA is granting the request for an exclusive use extension of three additional years to end on March 4, 2027 for EPA Registration No. 59639-185.

Valent U.S.A. LLC cited FIFRA section 3(c)(1)(F)(ii) 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)(ii) sets forth the criteria for extending the period of exclusive use protection. The period of exclusivity can be extended one year for every three qualifying minor uses registered within the first seven years of an original registration whose data retains exclusive use protection, with a maximum addition of three years to the original ten-year exclusivity period. All of the minor use crop candidates were registered within the requisite seven years period, prior to March 4, 2021, and are grown on less than 300,000 acres per year.

The first step in determining whether data qualifies for an extension of its exclusive use period is to ascertain whether there are any exclusive use data associated with a registration. FIFRA section 3(c)(1)(F)(i) and its implementing regulations specifically describe the set of data that are eligible for exclusive use protection. A study entitled to exclusive use protection is defined in 40 C.F.R. 152.83(a), and the following requirements must be met:

- (1) The study pertains to a new active ingredient (new chemical) or new combination of active ingredients (new combination) first registered after September 30, 1978;
- (2) The study was submitted in support of, or as a condition of approval of the application, resulting in the first registration of a product containing such new chemical or new combination (first registration), or an application to amend such registration to add a new use;
- (3) The study was not submitted to satisfy a data requirement imposed under FIFRA section 3(c)(2)(B); and
- (4) A study is an exclusive use study only during the 10-year period following the date of the first registration.

The following is our analysis for determining whether the data associated with the registration you have cited contains exclusive use data. First, the data associated with this registration do pertain to, or have been derived from testing on, a new active ingredient that was first registered after September 30, 1978. Second, the data were submitted in support of the first registration of

the new chemical¹. The registration cited was granted on March 4, 2014, and was the first registration for ethaboxam. Third, the data were not submitted to satisfy FIFRA section 3(c)(2)(B). Data generated by IR-4 are not entitled to exclusive use protection (see 40 CFR 152.94(b)). However, the Agency will count minor uses supported by IR-4 generated data when determining how many additional years that exclusive use protection may be extended.

Although EPA has determined that there are exclusive use protected data associated with this registration, the Agency has not made individual determinations on every study associated with the above referenced registration as to exclusive use protection. If the Agency receives a me-too application for this pesticide during the extension period citing Valent U.S.A. LLC data, it will then address which of those data have the extension of protection. Therefore, this response is a general determination that the exclusive use studies associated with this registration will receive the determined extension of exclusive use protection.

After determining that there are exclusive use data associated with this registration, EPA analyzed whether: (1) minor uses have been registered within seven years of the original registration and (2) at least one of the following required criteria were satisfied for extending the exclusive use protection pursuant to FIFRA section 3(c)(1)(F)(ii). FIFRA section 3(c)(1)(F)(ii) states, in pertinent part:

“The period of exclusive data use provided under clause (i) shall be extended 1 additional year for each 3 minor uses registered after the date of enactment of this clause, and within 7 years of the commencement of the exclusive-use period, up to a total of 3 additional years for all minor uses registered by the Administrator if the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, that -

- (i) there are insufficient efficacious alternative registered pesticides available for the use;
- (ii) the alternatives to the minor use pesticide pose greater risks to the environment or human health;
- (iii) the minor use pesticide plays or will play a significant part in managing pest resistance; or
- (iv) the minor use pesticide plays or will play a significant part in an integrated pest management program.”

SUMMARY OF FINDINGS

EPA evaluated information about characteristics of ethaboxam, disease management claims, and production practices for the minor crops submitted. The Fungicide Resistance Action Committee

¹ Data are not protected solely because they pertain to the new chemical, but because they are submitted in support of a particular product registration of a new chemical. Thus, data submitted to support an application for the second (and later) registrations, by whatever applicant, of a product containing the same new chemical acquire no exclusive use protection. Additionally, data submitted in support of subsequent amendments to add new uses to the first registration of a product containing the new chemical gain exclusive use protection, but the protection is limited to data that pertain solely to the new use. Thus, for example, if the new use is approved after eight years of registration, the data supporting that use would gain exclusive use protection for only two years, or the remainder of the original 10-year exclusive use period. See 49 FR 30884, 30889.

(FRAC) has designed a group classification system based on a fungicide's mode of action. Ethaboxam is classified in FRAC Group 22. Its mode of action is interfering with beta-tubulin assembly in mitosis.

Valent U.S.A. LLC identified twelve qualifying minor crops and submitted information to substantiate that each crop met at least one of the four criteria above. The Agency determined that all twelve minor uses met criterion III. The Agency also determined that all twelve minor uses were registered within seven years of the original registration of Ethaboxam Technical Fungicide, EPA Registration No. 59639-185.

Further, the Agency verified there are ethaboxam tolerance citations for ginger, ginseng, bell pepper, non-bell pepper, summer squash, cucumber and cantaloupe. EPA determined that the seed treatment uses on lima beans, buckwheat, popcorn, rapeseed and safflower are nonfood uses and no tolerances are needed based on the radio-tracer data submitted to support these seed treatment uses. Additionally, each of the end-use labels contains a resistance management section and FRAC code and resistance management information.

The following is a summary of how each crop meets criterion III and thus counts towards extending the exclusive use period. This summary was based upon the information provided by the registrant and reviewed by EPA. This decision is supported by the document "A Review of Valent's Petition for Extension of the Exclusive Use Period for Ethaboxam" dated September 16, 2022. This document contains a more detailed explanation of how each crop meets the standard for extending the exclusive use period.

Applicability of Criterion III to ethaboxam:

Ginger and ginseng: Ethaboxam is the only fungicide in FRAC group 22 registered for soilborne oomycete disease control (e.g., *Pythium* spp. diseases). The FRAC indicates that resistance risk for the alternative registered conventional pesticides is high or medium to high and that the resistance risk for ethaboxam is low to medium. Because *Pythium* spp. are prone to developing fungicide resistance, it is important for growers to have access to multiple efficacious fungicides to implement a fungicide rotation program for resistance management. Given its unique mode of action and a generally lower risk of resistance than alternatives, ethaboxam satisfies criterion III and plays or will play a role in managing fungicide resistance in *Pythium* spp. diseases for ginger and ginseng.

Lima beans, buckwheat, popcorn, rapeseed and safflower: Ethaboxam is the only fungicide in FRAC group 22 registered for seed treatment for soilborne oomycete disease control (e.g., damping-off caused by *Pythium* spp.). Alternative registered conventional chemicals for soilborne oomycete diseases in these use sites include pesticides in FRAC groups 4 and 11. Because *Pythium* spp. are prone to developing fungicide resistance and have already developed resistance to FRAC groups 4 and 11, it is important for growers to have access to multiple efficacious fungicides to implement a fungicide rotation program for resistance management. Given its unique mode of action and a generally lower risk of resistance than alternatives, ethaboxam satisfies criterion III and plays or will play a role in managing fungicide resistance in *Pythium* spp. seedling diseases in lima beans, buckwheat, popcorn, rapeseed and safflower.

Bell peppers, non-bell peppers, summer squash, cucumber and cantaloupe: Ethaboxam is the only fungicide in FRAC group 22 registered for control of the soilborne disease Phytophthora blight (*Phytophthora capsici*). The FRAC indicates that resistance risk for most of the alternative registered conventional pesticides is high or medium to high and that the resistance risk for ethaboxam is low to medium. Because *Phytophthora capsici* is prone to developing fungicide resistance, it is important for growers to have access to multiple efficacious fungicides to implement a fungicide rotation program for resistance management. Given its unique mode of action and a lower risk of resistance than most single-site alternatives, ethaboxam satisfies criterion III and plays or will play a role in managing fungicide resistance in *Phytophthora capsici* in bell peppers, non-bell peppers, summer squash, cucumbers and cantaloupe.

DETERMINATION

The Agency concludes that you have provided sufficient evidence to support extension of exclusive use of data under FIFRA Section 3(c)(1)(F)(ii) for at least nine minor use sites required to attain three additional years of data exclusivity under criterion III and these uses were registered within seven years of the original ethaboxam registration. The minor use registrations which support this overall finding are ginger, ginseng, lima beans, bell pepper, non-bell pepper, summer squash, cucumber, cantaloupe, buckwheat, popcorn, rapeseed and safflower. Therefore, the Agency **GRANTS** your request for a three-year extension of the original exclusive-use data protection period for data submitted to support EPA Registration No. 59639-185. Exclusive-use protection for data, which complies with 40 C.F.R. 152.83(a), submitted in support of this registration **will expire on March 4, 2027**. A copy of our review is enclosed.

Sincerely,

**CHARLES
SMITH**

Charles Smith,
Director, Registration Division (RD)
Office of Pesticide Programs (OPP)

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Enclosure: A Review of Valent's Petition for Extension of the Exclusive Use Period for Ethaboxam.