



**US Environmental
Protection Agency Office
of Pesticide Programs**

**Exclusive Use
Extension Request
Response Letter for
Boscalid**

November 21, 2011



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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Subject: Boscalid
Exclusive-use period extension request for data protection from July 23, 2013 to July 23, 2016
Boscalid Technical; EPA Reg. No. 7969-198

Dear Dr. Akkari:

This letter responds to your request dated August 2, 2007 with resubmission dated June 29, 2011 and a supplemental addendum dated October 11, 2011, that data associated with the July 23, 2003 original registration for the active ingredient boscalid, receive a three year extension of the original ten year exclusive-use protection period, from July 23, 2013 to July 23, 2016.

You cited FIFRA section 3(c)(1)(F)(ii) as the authority for the Agency 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.

The first step in determining whether data qualifies for an extension of its exclusive-use period is to ascertain whether there are 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(c), 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; and

(3) The study was not submitted to satisfy a data requirement imposed under FIFRA section 3(c)(2)(B); and 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.

Second, the data was submitted in support of the first registration of the new chemical.¹ The registration cited was granted on July 23, 2003 and was the first registration for boscalid with the product name Boscalid Technical.

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 BASF Corporation 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

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.

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), and if so, by how many years. 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.”

The Agency determined that the following nine minor uses were registered within seven years of the original registration of Boscalid Technical: (1) Broccoli, (2) Brussels sprouts (3) Cabbage, (4) Cauliflower, (5) Collards, (6) Kale, (7) Edible pod (snow) pea, (8) Succulent shelled (English) pea, and (9) Jerusalem artichoke.

As to the criteria mentioned above, BASF submitted information to support its claims that there are insufficient efficacious alternative registered pesticides to boscalid available for the uses (criterion I); that the alternatives to boscalid pose greater risks to the environment or human health (criterion II); and that boscalid plays or will play a significant part in an integrated pest management plan (criterion IV).

Summary of Findings

EPA evaluated information about characteristics of boscalid, disease claims, and production practices for nine crop sites. EPA evaluated boscalid information from the registrant, extension information, fungicide efficacy trials, crop profiles, Pest Management Strategic Plans (PMSPs), the Crop Data Management Systems (CDMS), the EPA Office of Pesticide Programs Information Network (OPPIN), and the Fungicide Resistance Action Committee (FRAC). The FRAC has designed a group classification system based on a fungicide's mode of action (FRAC, 2011). Boscalid is a pyridine-carboxamide fungicide, which is classified according to its mode of action as a succinate dehydrogenase inhibitor (SDHI) (*Group 7*) fungicide. SDHI fungicides

adversely affect pathogen respiration through inhibition of the mitochondrial respiratory chain of reactions. Boscalid is the only Group 7 fungicide registered for foliar use on many minor crops. Boscalid, therefore, serves as a unique mode of action for disease management and pest resistance management where a rotation of effective fungicides with different modes of action is recommended.

BASF submitted information to support its claim for extension of the exclusive-use period based on criterion I, II and IV. In considering these claims, and other information relative to this determination, EPA reviewed nine crops. Details from the distinct crop evaluations follow. The Agency determined that nine minor crops meet criteria I. The Registration Division (RD) of the Office of Pesticide Programs (OPP) has verified via the Pesticide Product Label System (PPLS) that the nine subject commodities are included on the most recently stamped boscalid end-use products. RD has also verified that boscalid tolerance citations for the Crop Groups encompassing the nine minor uses are enumerated in 40 CFR 180.589.

Broccoli, Brussels Sprouts, Cabbage and Cauliflower

The registrant claims that boscalid meets at least one of the criteria as it is one of the few, or only, treatments for Sclerotinia white mold, a soil-borne disease of broccoli, Brussels sprouts, cabbage, and cauliflower. Recommended management strategies to reduce the incidence and severity of white mold are crop rotation and annual soil incorporation of *Coniothyrium minitans* (a mycoparasite formulated as Contans®, which can be used as an ongoing soil amendment to reduce the population of the Sclerotinia pathogen. For some areas, boscalid is the only chemical treatment recommended for managing white mold of broccoli, Brussels sprouts, cabbage and cauliflower (Cornell, 2011; Midwest, 2011; NJ, 2011; NCSU, 2011). Kentucky recommended either boscalid or PCNB (KY, 2010). Given the limited choices growers might have if they must include fungicides to manage white mold, the Agency concludes that boscalid meets the requirement for Criterion I.

Collards and Kale

The registrant claims that boscalid meets the requirement for at least one criterion as it is one of the few, or only, treatments for Sclerotinia white mold and Rhizoctonia bottom rot-important soil-borne diseases of kale and collard crops. The recommended management strategies where Sclerotinia white mold is a problem are crop rotation and annual soil incorporation of the mycoparasite *Coniothyrium minitans* (Contans®) that can be used as an ongoing soil treatment for reducing the population of the Sclerotinia pathogen. Boscalid was the only fungicide recommended for white mold for kale and collard greens (Midwest Greens, 2011; NCSU Greens, 2011; NJ Greens, 2011). Kentucky extension recommended rotating boscalid with pyraclostrobin for resistance management (KY Greens, 2010). Boscalid was the only fungicide recommended for managing Rhizoctonia bottom rot (SE Greens, 2011; Midwest Greens, 2011; NCSU Greens, 2011). Given the limited choices growers might have to manage white mold or Rhizoctonia bottom rot, the Agency concludes that boscalid meets the requirement for Criterion I.

Edible Pod Pea (Snow Pea) and Succulent Shelled Pea (English Pea)

Ascochyta blight can be a severe disease of peas. Ascochyta is managed with boscalid (SE Pea, 2011) or boscalid alternated with azoxystrobin or pyraclostrobin (Cornell Pea, 2011; NJ Pea, 2011; Midwest Pea, 2011; OSU Pea, 2011) or azoxystrobin or pyraclostrobin alternated with boscalid or copper or sulfur (KY Pea, 2010). Quinone outside inhibitor fungicides, such as pyraclostrobin and azoxystrobin, are highly subject to resistance by several pathogens, therefore, boscalid is an important rotation partner. The Agency has reviewed extension recommendations for managing Ascochyta blight and determined that boscalid is one of the few effective treatments for managing the disease and for resistance management, therefore, it meets the requirements for Criteria I.

Jerusalem Artichokes

The primary disease of Jerusalem artichokes is Sclerotinia rot, which can cause early wilt, stalk rot, and degradation of tubers (Cosgrove et al., 1991). Boscalid is the only recommended fungicide treatment for managing Sclerotinia basal stalk rot (SE Artichoke, 2011; NCSU Artichoke, 2011). Rotation with non-host grains or corn is recommended as well as avoidance of Jerusalem artichoke production near pathogen hosts such as beans, sunflower, and soybean (Cosgrove et al., 1991). Because boscalid is the only effective fungicide recommended to manage Sclerotinia basal stalk rot, the Agency concludes that the conditions for Criterion I have been met.

DETERMINATION

After reviewing your petition, the Agency concludes that for at least nine minor uses that there are insufficient efficacious alternative registered pesticides to boscalid available and that boscalid plays or will play a significant part in managing pest resistance. Therefore, the Agency **GRANTS** your request for a three year extension of exclusive-use data protection for selected data under EPA Registration No. 7969-198. Exclusive-use protection for data, which complies with 40 C.F.R. 152.83(c), submitted in support of this registration will expire on July 23, 2016.



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cc: Cynthia Giles-Parker
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