



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

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

January 16, 2009



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

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Subject: Azoxystrobin
Exclusive use period extension request for data protection
Heritage Fungicide; EPA Reg. No. 100-1093

Dear Ms. Schulz:

This letter responds to your request dated September 1, 2006 that data associated with the February 7, 1997 original registration of the active ingredient Azoxystrobin, receive a three-year extension of the original ten-year exclusive-use protection period, from February 7, 2007 to February 7, 2010.

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 in support of the original 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 February 7, 1997 and was the first registration for Azoxystrobin with the product name Heritage Fungicide.

Third, the data was not submitted to satisfy FIFRA section 3c(2)(B).

Data generated by IR-4 is 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 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 Syngenta's 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 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

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.

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 Heritage Fungicide: (1) globe artichoke, (2) asparagus, (3) basil, (4) broccoli, (5) cabbage, (6) dillweed, (7) juneberry, (8) lychee, and (9) mint.

As to the criteria mentioned above, Syngenta submitted information to support its claims that either: (1) there are insufficient efficacious alternatives to Azoxystrobin, or that (2) the alternatives to Azoxystrobin pose greater risks to the environment or human health. The following is our determination on each minor use crop.

Globe Artichoke

The registrant claims that there are insufficient efficacious alternatives to control *Ramularia* leaf spot (*Ramularia cynarae*) on artichoke. Most California artichoke acreage is affected by *Ramularia* leaf spot, but as of 1999, there were no adequate efficacious alternatives available to control this pest (azoxystrobin was not registered but considered as potential alternative) (Crop Profile for Artichoke, 1999). Azoxystrobin was registered for use on artichoke in 2000. In addition, OPP searched CMDS for fungicides registered to control *Ramularia* leaf spot on artichokes and azoxystrobin was the only result. According to EPA proprietary data, azoxystrobin was used to control *Ramularia* leaf spot in 2005 and 2006. Therefore, OPP agrees that there are insufficient efficacious alternatives to azoxystrobin to control *Ramularia* leaf spot on artichoke.

Asparagus

Purple spot is a major worldwide disease for asparagus. The registrant claims that azoxystrobin is a reduced risk pesticide compared to chlorothalonil, which is also registered for use on purple spot. On June 18, 2003, Azoxystrobin was categorized by OPP as a reduced risk pesticide for use on Asparagus. As of today, azoxystrobin remains a reduced risk pesticide for this use, and

compared to chlorothalonil (the only other alternative) poses less risks. Therefore, OPP agrees that the alternative poses a greater risk to the environment/human health than Azoxystrobin for the control of purple spot on asparagus.

Basil

The registrant claims that there are insufficient efficacious alternatives to control corynespora blight (*Corynespora cassiicola*), dill blight (*Cercosporidium punctum*), and phoma blight (*Passalora puncta*) on basil. OPP searched CDMS and azoxystrobin was the only fungicide listed that will control any of these three diseases. These diseases are not described as problematic in Florida basil production (Roberts, 2005). However, *Corynespora cassiicola* is described as a disease in Hawaiian basil production, and azoxystrobin is the only fungicide listed to control this disease. Therefore, OPP agrees that there are insufficient efficacious alternatives to control corynespora blight on basil in Hawaii and meets the criterion.

Broccoli

Azoxystrobin is registered for control of *Alternaria* leaf spot (*Alternaria spp.*), black leaf spot (*Alternaria spp.*), and downy mildew (*Peronospora parasitica*) on broccoli. According to information submitted by the registrant, there appear to be alternatives for control of *Alternaria* leaf spot (chlorothalonil, fludioxonil/cyprodinil, and maneb) as well as for control of downy mildew (chlorothalonil, copper hydroxide, maneb, and mfenoxam). OPP used CDMS to confirm that these alternatives are registered for these diseases.

The registrant, however, claims that azoxystrobin is less risky than chlorothalonil and maneb, the most likely alternatives. On June 18, 2003, Azoxystrobin was categorized by OPP as a reduced risk pesticide for use on broccoli. As of today, OPP has determined that azoxystrobin remains a reduced risk pesticide for this use. Therefore, OPP agrees that the alternatives pose a greater risk to the environment/human health than Azoxystrobin for the control of leaf spot and downy mildew on broccoli.

Cabbage

Azoxystrobin is registered to control *Alternaria* spp. and downy mildew (*Peronospora parasitica*) on cabbage. According to the information submitted by the registrant, there appear to be alternatives for control of *Alternaria* leaf spot and black leaf spot (chlorothalonil, copper hydroxide, maneb, and fludioxonil/cyprodinil) as well as alternatives for control of downy mildew (chlorothalonil, copper hydroxide, maneb, and mfenoxam). OPP used CDMS to confirm that these alternatives are registered for use on cabbage to control these diseases.

The registrant claims that azoxystrobin is lower risk compared to some of the alternatives (chlorothalonil, maneb, and copper hydroxide). On June 18, 2003, Azoxystrobin was categorized as a reduced risk pesticide for use on cabbage. As of today, OPP has determined that azoxystrobin remains a reduced risk pesticide for this use. Therefore, OPP agrees that the alternatives pose a greater risk to the environment/human health than Azoxystrobin for the control of leaf spot and downy mildew on cabbage.

Dillweed

Azoxystrobin is used to control corynespora blight (*Corynespora cassiicola*), dill blight (*Cercosporidium punctum*), and phoma blight (*Passalora puncta*) on dillweed. The registrant claims that there are insufficient efficacious alternatives for dillweed.

OPP searched CDMS for alternatives for these diseases for use on dill. Azoxystrobin was the only fungicide listed that will control corynespora blight and dill blight. Therefore, OPP agrees that there are insufficient efficacious alternatives to control corynespora blight and dill blight on dillweed.

Juneberry

Azoxystrobin is used to control Botryosphaeria canker (*Botryosphaeria spp.*), powdery mildew (*Sphaerotheca spp.*), Septoria blight (*Septoria spp.*), mummyberry (*Vaccinium spp.*), Alternaria fruit rot (*Alternaria spp.*), Phomopsis stem canker (*Phomopsis vaccinii*), and Anthracnose fruit rot (*Colletotrichum gloeosporoides*) on Juneberry. The registrant claims that there are insufficient efficacious alternatives for disease control in Juneberry. Although Cyprodinil/fludioxonil is registered to control some of these diseases (mummyberry, Alternaria fruit rot, and Anthracnose fruit rot) as well as Phomopsis vaccinii (as stated on the label), OPP's search of CDMS shows that not all diseases for which azoxystrobin is used on Juneberries have efficacious alternatives. For example, azoxystrobin was the only fungicide registered for control of powdery mildew and Botryosphaeria. Powdery mildew occasionally affects Juneberry (*Rhodus*). Therefore, OPP agrees that there are insufficient efficacious alternatives to control certain diseases of Juneberry.

Lychee

The registrant claims that there are insufficient efficacious alternatives for use on lychee. Azoxystrobin is registered for control of Cercospora leaf spot (*Cercospora spp.*), anthracnose (*Colletotrichum spp.*), powdery mildew (*Erysiphe spp.*), rust (*Puccinia spp.*), and the soilborne diseases seedling root rot and basal stem rot (*Rhizoctonia solani*) on lychee. The registrant states that fludioxonil/cyprodinil and copper hydroxide are registered for use on Anthracnose, but that there are no other effective registered alternatives for the other diseases. Anthracnose is a disease of concern for lychee (Crop Profile for Lychee and Longan, 2001; Tropical Fruit PMSP, 2003). *Rhizoctonia spp.* also appears to be problematic in lychee production (Crop Profile for Lychee and Longan, 2001).

OPP searched CDMS and found that neem oil is registered for use on rust and powdery mildew, but it does not provide adequate control of diseases (Crop Profile for Lychee and Longan, 2001).

There appear to be no alternatives to control *Cercospora spp.* or *Rhizoctonia solani*. Therefore, OPP agrees that there are insufficient efficacious alternatives to control these diseases of lychee.

Mint (Peppermint and Spearmint)

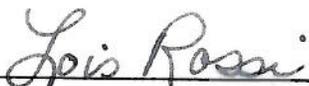
The registrant claims that there are insufficient efficacious alternatives for use on mint. Azoxystrobin is registered for control of powdery mildew (*Erysiphe spp.*), rust (*Puccinia menthae*), and the soilborne diseases seedling root rot and basal stem rot (*Rhizoctonia solani*) on mint. The registrant states that propiconazole and chlorothalonil are registered for rust, and trifloxystrobin is registered for powdery mildew.

OPP searched CDMS and there appear to be alternatives for these diseases. For powdery mildew, sulfur, pyraclostrobin, potassium bicarbonate, myclobutanil, and *Bacillus pumilus* strain QST 2808 are registered. For rust, alternatives such as chlorothalonil, propiconazole, pyraclostrobin, sulfur, and myclobutanil are registered. In one study, the efficacy of azoxystrobin, azoxystrobin + propiconazole, and pyraclostrobin against rust and powdery mildew was evaluated. Pyraclostrobin was as efficacious as the other fungicides against these diseases (McReynolds and Koskela, 2003). Although OPP realizes that these may not all be effective, the registrant did not address these alternatives in the petition.

OPP also searched CDMS for *Rhizoctonia solani* alternatives. There appear to be inadequate alternatives for this disease. According to the PMSP, *Rhizoctonia solani* causes stolon canker for which there are no alternatives (PMSP for PNW Mint, 2002). The PMSP describes azoxystrobin as providing excellent control of powdery mildew and rust. However, for stolon canker, azoxystrobin is described as not being used, and its efficacy is unknown (PMSP for PNW Mint, 2002). Later publications describe azoxystrobin as the only chemical control available for control of stem and stolon canker (*Rhizoctonia solani*) (Ocamb, 2006; Schwartz and Gent, 2005). This disease is a problem in mint production because it can cause stand losses (Schwartz and Gent, 2005).

Therefore, OPP agrees that insufficient efficacious alternatives are available for mint for control of *Rhizoctonia solani*.

After consulting with USDA, the Agency agrees that for at least nine minor uses, either (1) there are insufficient efficacious alternatives to Azoxystrobin, or (2) the alternatives to Azoxystrobin pose greater risks to the environment or human health. Therefore, after consulting with USDA, the Agency GRANTS your request for a three-year extension of exclusive-use data protection for selected data under EPA Registration No. 100-1093. Exclusive-use protection for data, which complies with 40 C.F.R. 152.83(c), submitted in support of this registration will expire on February 7, 2010.

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cc: Cynthia Giles-Parker
Shaja B. Joyner