US Environmental Protection Agency Office of Pesticide Programs

Exclusive Use Extension Request Response Letter for Pyraclostrobin

January 11, 2012

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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JAN 1 1 2012

Subject: **Pyraclostrobin**
Exclusive-use period extension request for data protection
Original submission dated 8/2/2007 and various resubmissions
Pyraclostrobin Technical; EPA Reg. No. 7969-185; D382758

Dear Ms Sanson:

This letter responds to your request dated August 2, 2007 and subsequent resubmissions that data associated with the September 30, 2002 original registration for the active ingredient pyraclostrobin, receive a three year extension of the original ten year exclusive-use protection period, from September 30, 2012 to September 30, 2015.

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 contain 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 were submitted in support of the first registration of the new chemical.[1] The registration cited was granted on September 30, 2002 and was the first registration for pyraclostrobin with the product name Pyraclostrobin 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 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-
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> (I) there are insufficient efficacious alternative registered pesticides available for the use;

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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 reminder of the original 10-year exclusive-use period. See 49 FR 30884, 30889.

(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 Pyraclostrobin Technical: (1) Brussels sprouts, (2) Cabbage, (3) Cauliflower, (4) Chinese broccoli ('gai-lon'), (5) Chinese Cabbage (Napa; 'bok-choy'), (6) Chinese mustard cabbage ('gai-choy'), (7) Kohlrabi, (8) Broccoli, and (9) Strawberry. The end use product label (EPA Reg. No. 7969-187) is available for these sites and may be found on the PPLS label system (http://oaspub.epa.gov/apex/pesticides/f?p=102:1:700192464180981.)

As to the criteria mentioned above, BASF Corporation submitted information to support its claims that there are insufficient efficacious alternative registered pesticides and that the minor use pesticide plays or will play a significant part in an integrated pest management program for strawberries.

Summary of Findings

EPA evaluated information about characteristics of pyraclostrobin, disease claims, and production practices for nine crop sites.

Pyraclostrobin is classified as a quinone outside inhibitor (QoI) fungicide *(Group* 11 - according to the Fungicide Resistance Action Committee (FRAC)). QoI fungicides inhibit fungal respiration by binding to the "quinone outside" site of the mitochondrial cytochrome b protein. When the compound binds to the site it blocks electron transfer between cytochrome b and cytochrome c, which disrupts synthesis of ATP and ultimately inhibits cell respiration. Several QoI fungicides are currently registered. Resistance by some fungal pathogens has been documented. In spite of resistance to some pathogens, QoI products are among the most widely used fungicides due to their effectiveness in managing many diseases caused by numerous fungal pathogens. All BASF pyraclostrobin end-use product labels contain "mode/target site of action grouping and identification symbol" graphics as well as voluntary resistance management statements recommended by PR Notice 2001-5.

(1) Brussels sprouts, (2) Cabbage, (3) Cauliflower, (4) Chinese broccoli ('gai-lon'), (5) Chinese Cabbage (Napa; 'bok-choy'), (6) Chinese mustard cabbage ('gai-choy'), and (7) Kohlrabi

The registrant claims that there are insufficient efficacious alternative foliar treatments to pyraclostrobin for the management of the disease "blackleg" on the listed Brassica (cole) crops.

Blackleg is caused by a seedborne pathogen, *Phoma lingam.* The disease can also spread to growing plants through aerial spores from infected host-plants in nearby fields. In spite of management through the use of certified seed or, if established in the soil, long-term crop rotation, blackleg is potentially one of the most serious diseases of cole crops (IL, 1989; MA,

2011). Where the pathogen is present especially in warm, wet conditions extension services of New York (Cornell, 2011), several Midwest states (Midwest, 2011), and Kentucky (KY, 2010) recommend pyraclostrobin as the only foliar fungicide for managing blackleg for these crops. Some locations - California (UC, 2008), North Carolina (NCSU, 2011), Michigan (MSU, 2011), New Jersey (NJ, 2011), and Wisconsin (WI, 2011) - have no foliar chemical treatments for blackleg for these crops. New England extension services recommend potassium bicarbonate as a foliar treatment for blackleg (NE,2011). Given the few choices that growers in some locations have for the management of blackleg disease, the Agency agrees that pyraclostrobin is one of the few effective fungicide treatments available for managing blackleg. Therefore, for these seven crops, pyraclostrobin meets the requirement for Criterion I.

8) Broccoli

The registrant claims that there are insufficient efficacious alternative foliar treatments to pyraclostrobin for the management of the disease "blackleg" on broccoli.

Broccoli is moderately susceptible to blackleg, but if an infestation occurs, pyraclostrobin and iprodione are the only fungicides recommended as treatments by the Midwest extension manual (Midwest Broc, 2011), Cornell (Cornell Broc, 2011), and Kentucky (KY Broc, 2010). Iprodione is the only fungicide treatment of blackleg recommended by extension services from California (UC, 2008), North Carolina (NCSU Broc, 2011), Michigan (MSU Broc, 2011), New Jersey (NJ Broc, 2011), and Southeastern states (SE Broc, 2011). Wisconsin (WI Broc, 2011) had no recommended foliar chemical treatments for blackleg of broccoli. New England extension services recommended potassium bicarbonate as a foliar treatment for blackleg (NE Broc, 2011). Given the few choices growers have if they must manage blackleg on broccoli, the Agency agrees that pyraclostrobin meets the requirement for Criterion I.

9) Strawberry

The registrant claims that there are insufficient efficacious alternative foliar treatments to pyraclostrobin for the management of the disease "anthracnose fruit rot" on strawberries and that pyraclostrobin plays a significant part in an integrated pest management (IPM) program.

For managing anthracnose fruit rot North Carolina extension (NCSU Straw, 2011) and the 2010 Southeast Regional Strawberry Integrated Management Guide (SE Straw, 2010) recommended pyraclostrobin and concluded that it provided stronger control for anthracnose fruit rot than other QoIs.

Pyraclostrobin is the only QoI fungicide recommended for managing anthracnose fruit rot in some production areas. The use of QoI fungicides constitutes a major component of an IPM program in strawberry production and fills a need as an important and effective chemistry group. Therefore, based on the limited tools available for managing anthracnose fruit rot on strawberries, and the importance of pyraclostrobin (as the only QoI fungicide that is recommended) in an IPM program, the Agency agrees that Criteria I and IV have been met.

DETERMINATION

After reviewing your application, the Agency agrees that for at least nine minor uses, that there are few efficacious alternatives to pyraclostrobin for the management of blackleg and anthracnose fruit rot on the respective minor crops listed above, and that pyraclostrobin plays a significant role in the IPM strategies for production of strawberries. Therefore, the Agency

GRANTS your request for a three year extension of exclusive-use data protection for selected data under EPA Registration No. 7969-185. Exclusive-use protection for data, which complies with 40 C.F.R. 152.83(c), submitted in support of this registration will expire on September 30, 2015.

Lois Rossi

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