UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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SEP 25 2014

Subject: **Technical Cyazofamid Fungicide**
Exclusive-use period extension request for data protection
EPA Reg. No. 71512-2; Decision 482864

Dear Mr. Peplowski:

This letter responds to your request dated September 6, 2013 that data associated with the March 30, 2001 original registration for the active ingredient Cyazofamid, receive a three-year extension of the original ten-year exclusive-use protection period, from November 9, 2014 to November 9, 2017.

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 that was first registered after September 30, 1978.

Second, the data were submitted in support of the first registration of the new chemical.[1] The registration cited was granted on November 9, 2004 and was the first registration for cyazofamid with the product name Technical Cyazofamid Fungicide.

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 ISK Biosciences 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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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.

(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."

ISK submitted information on 48 minor use crops even though only nine are needed to qualify for the three-year extension. The Agency looked at a subset of uses and determined that all the following eighteen minor uses in the Crop Group 5 (Brassica Leafy Vegetables) were registered within seven years of the original registration of Technical Cyazofamid Fungicide:

Broccoli; Chinese broccoli; raab broccoli; Brussels sprouts; cabbage; Chinese cabbage (bok choy); Chinese cabbage (nappa); Chinese mustard cabbage; cauliflower; cavalo broccoli; collard; kale; kohlrabi; mizuna; mustard greens; mustard spinach; rape greens and turnip greens.

As to the four criteria mentioned above, ISK Biosciences Corporation submitted information to support its claims that Cyazofamid plays or will play a significant part in managing pest resistance in each of these minor use crops.

Summary of Findings

All 18 minor crops in Crop Group 5 are susceptible (Pscheidt, and Ocamb, 2013;) to clubroot disease caused by *Plasmodiophora brassicae.* This fungal pest can remain viable in soils for 18 years or more (Pscheidt and Ocamb, 2013). It can spread through any type of soil by wind and water, footwear, farm equipment, and infected transplants. This disease is difficult to control and therefore disease management using cultural methods (eg. disease free transplants, long rotations of 6 years or more, soil pH manipulations using lime) are recommended in addition to fungicides (Pscheidt and Ocamb, 2013; Cubeta, 2003; Percich, 2001; Anonymous, 1999).

There are two other fungicides (fluazinam and PCNB) registered for the management of this pest. Fluazinam belongs to FRAC group 29 and has been classified as low risk of developing resistance in fungal pests. PCNB belongs to FRAC group 14 and has been classified as low-to-medium risk of developing resistance in fungal pests. The fluazinam label states, "this product may delay the start of harvest by up to 8 days, cause some plant stunting, and shorten the harvest period, without adverse effects on final yield." Cyazofamid label does not state that there are any expected adverse effects from the use of it on treated plants. Cyazofamid has been reported to be equal or more effective than fluazinam in controlling clubroot disease (Ivey *et al.,* 2004; Miller *et al.,* 2006). The other alternative, PCNB, does not control clubroot completely, but reduces the number of clubs and secondary rot (Pscheidt and Ocamb, 2013).

The Agency concludes: 1) there are insufficient efficacious alternative registered pesticides available for the use on these crops to control clubroot disease, 2) cyazofamid will play a significant role in pest resistance management (its mode of action against fungi is different than the two other registered alternatives, and PCNB efficacy has been documented to be inadequate in controlling the disease), and 3) cyazofamid is expected to play a significant role in integrated pest management because this pest is difficult to manage using registered alternatives (fluazinam has some phytotoxic effects on plants and PCNB alone is inadequate in controlling the disease), and integrated disease management has been recommended (Pscheidt, and Ocamb, 2013; Cubeta, 2003; Percich, 2001; Anonymous, 1999; Toit, 2007) for the control of this disease.

DETERMINATION

After reviewing your application, the Agency agrees that for at least nine minor uses in Crop Group 5, cyazofamid meets one or more of the four criteria mentioned above. Therefore, the Agency **GRANTS** your request for a three-year extension of exclusive-use data protection for selected data under EPA Registration No. 71512-2. Exclusive-use protection for data, which complies with 40 C.F.R. 152.83(c), submitted in support of this registration will expire on November 9, 2017. A copy of our review is enclosed.

Lois Rossi, Director

Lois Rossi

Registration Division
Office of Pesticide Programs

Enclosed – BEAD review dated 5/9/2014