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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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Michael A. Peplowski
Manager, Product Registrations
ISK Biosciences Corporation
7470 Auburn Rd, Suite A
Concord, Ohio 44077

Subject: **Fluazinam**
Exclusive-use period extension request for data protection
Omega 500F; EPA Reg. No. 71512-1

Dear Mr. Peplowski:

This letter responds to your request dated October 15, 2010 that data associated with the August 10, 2001 original registration for the active ingredient fluazinam, receive a three year extension of the original ten year exclusive-use protection period, from August 10, 2011 to August 10, 2014.

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 August 10, 2001 and was the first registration for fluazinam with the product name Omega 500F.

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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> (I) there are insufficient efficacious alternative registered pesticides

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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.

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 Omega 500F: (1) Blueberry, (2) Cranberry (3) Broccoli, (4) Brussels sprouts, (5) Chinese Cabbage, (6) Mustard greens, (7) Lima Beans, (8) Mung Beans, and (9) Turnip greens.

As to the criteria mentioned above, ISK Biosciences Corporation submitted information to support its claims that fluazinam plays or will play a significant part in managing pest resistance.

Summary of Findings

EPA evaluated information about characteristics of fluazinam, disease claims, and production practices for nine crop sites. The agency understands that fluazinam is a multi-site product which has activity for control of many important pathogens. It belongs to the Fungicide Resistance Action Committee (FRAC) Group 29. Group 29 chemicals are generally viewed as having a "low-risk" potential for resistance development and may serve as appropriate rotation partners for disease management activities, especially in production systems where multiple fungicide applications are necessary on a per season basis. The Omega 500F labeling contains "mode/target site of action grouping and identification symbol" graphics as well as voluntary resistance management statements recommended by PR Notice 2001-5. The label states:

"Some plant pathogens are known to develop resistance to products used repeatedly for disease control. OMEGA 500F is effective for strategic use in programs that attempt to minimize disease resistance to fungicides. OMEGA 500F has a multi-site mode of action that disrupts the energy production in the fungus. It is listed in FRAC code 29, as an uncoupler oxidative phosphorylation. Some other fungicides, which are at risk from disease resistance, exhibit a single-site mode of fungicidal action. OMEGA 500F, with its multi-site mode of action, may be used to delay or prevent the development of resistance to single-site fungicides. Consult with your Federal or State Cooperative Extension Service representatives for guidance on the proper use of OMEGA 500F in programs that seek to minimize the occurrence of disease resistance to other fungicides. No known resistance has developed to OMEGA 500F and thus it is an excellent partner for those products that specify the use of a protectant or other fungicide that has a different mode of action."

ISK is supporting its claim for extension of the exclusive-use period based on criterion III, pest resistance management benefits. In considering this claim, and other information relative to this determination, EPA reviewed nine crops. Details from the distinct crop evaluations follow. The

Registration Division (RD) of the Office of Pesticide Programs (OPP) has verified that the following nine crops are listed on the most recently stamped Omega 500F label. RD has also verified that fluazinam tolerance citations for the Crop Groups encompassing the nine minor uses are enumerated in 40 CFR 180.574.

Blueberry

The registrant claims that fluazinam plays or will play a significant part in managing pest resistance for all crops in Crop Group 13-07B including blueberry.

Diseases labeled for fluazinam are Anthracnose (ripe rot), Phomopsis twig blight and fruit rot, and Botrytis fruit rot. Fluazinam is also labeled for prevention of the secondary disease stage (fruit infection) of mummy berry on blueberry. Including fluazinam, other fungicide classes are registered and used to control these diseases. Table 1 below presents the Mode of Action group for the conventional pesticides currently labeled for use on blueberry.

FRAC GROUPING	RISK OF RESISTANCE DEVELOPMENT	DISEASES TREATED/PREVENTED	NOTES
29 (Fluazinam)	LOW	Anthracnose Phomopsis Botrytis Mummy berry	No known resistance in the United States
3	MEDIUM	Anthracnose Phomopsis Mummy berry	Percent crop treated (PCT) – 50%
7	MEDIUM to HIGH	Anthracnose Phomopsis Mummy berry	PCT – 24%
9	MEDIUM	Anthracnose	
11 (QoI)	HIGH	Anthracnose Mummy berry	PCT – 10-33%
M3, M4, M5	LOW	Anthracnose	PCT – 10-47%

Table 1 – Risk of resistance development according to "FRAC Code List 2011." Disease Treated and Notes according to EPA BEAD Review.

In summary, fluazinam is one of a limited number of effective treatments for managing Anthracnose, Phomopsis blight, Botrytis, and secondary stage mummy berry. It is the only Group 29 fungicide registered in the U.S. and can reduce the reliance on limited chemical groups. Fluazinam is recommended as one of the rotation partners to fungicide chemistries that are known to have medium to high risk of pest resistance. Therefore, OPP agrees that Criterion III has been met, that is, fluazinam will likely play a significant role in resistance management for its use on blueberry.

Cranberry

The registrant claims that fluazinam plays or will play a significant part in managing pest resistance for cranberry.

Similar to blueberries, the use of fungicides such as FRAC Group 3 chemicals on cranberries has "risk of resistance if not rotated," according to the Cranberry - Pest Management Strategic Plan (PMSP) of 2002. In particular, preventing fungicide-resistance is a high priority to the cranberry

industry, which specifically attaches importance to "alternative modes of action to aid in pest resistance management" (Cranberry PMSP, 2002). Information submitted by the registrant describes fluazinam as the only FRAC Group 29 fungicide among alternative fungicides available for use on Crop Group 13-07B which **1)** has a different mode of action, **2)** is a multi-site fungicide, and **3)** has no known resistance in the United States (ISKBC, 2011). There are registered alternatives for many cranberry diseases; however, the cranberry industry considers resistance issues to be a priority and encourages the incorporation of alternate modes of action.

In summary, fluazinam is at low risk for developing resistance, can be used as a rotation partner with other fungicides at a higher risk for resistance, and has resistance management language on its label facilitating its use, thereby functionally aiding the Cranberry – PSMP. Therefore, OPP agrees that Criterion III has been met, that is, fluazinam will play an important role in resistance management for its use on cranberry.

Broccoli

The registrant claims that fluazinam plays or will play a significant part in managing pest resistance for all crops in Crop Group 5 including broccoli.

Information including the crop profile for broccoli in California submitted by ISKBC indicates that club root, the disease targeted by fluazinam, is among the top two most important soil-borne broccoli diseases. Heavy infestations in fields can result in the abandonment of all Brassica production. The chemical alternatives to control club root include fumigants and fungicides within FRAC Groups 14 and 21 (ISKBC, 2011; USDA, 1999a). Phosphorous acid is also a treatment currently available to growers, in addition to other possible tactics such as long-time rotation and raising soil pH above 7.2 (Clubroot Control, 2011). Fumigants may be effective, but are not listed as a treatment in many areas, such as Michigan (USDA, 1999b), due to high cost and application requirements that may not be available or feasible. FRAC Group 14 chemicals are known to have low to medium risk of pest resistance and resistance in some fungi has been documented (ISKBC, 2011; FRAC, 2011). The risk of resistance in FRAC Group 21 chemicals is unknown but believed to be medium to high risk of developing resistance (FRAC 2011). Information submitted in ISKBC's application suggests that club root is difficult to control, requiring multiple applications (Clubroot Factsheet, 2000). Thus, rotational treatments that do not include fluazinam could increase the likelihood of resistance development to current fungicides (FRAC, 2011). Phosphorous acid and fluazinam were recommended by Oregon State University Extension for club root control (Clubroot Control, 2011).

In summary, of the few effective treatments for club root, fluazinam is the only EPA registered FRAC Group 29 fungicide and is therefore a likely resistance management partner for a difficult to control soil-borne disease that may need multiple applications. OPP agrees that Criterion III has been met, that is, fluazinam will play a significant role in resistance management for its use on broccoli.

Brussels sprouts

The registrant claims that fluazinam plays or will play a significant part in managing pest resistance for all crops in Crop Group 5 including Brussels sprouts.

Similar to broccoli, Brussels sprouts are susceptible to club root infection. The chemical alternatives to control club root include fumigants and fungicides within FRAC Groups 14 and

21 (ISKBC, 2011; USDA, 1999a). FRAC Group 14 chemicals are known to have low to medium risk of pest resistance and resistance in some fungi has been documented (ISKBC, 2011; FRAC, 2011). The risk of resistance in FRAC Group 21 chemicals is unknown but believed to be medium to high risk for developing resistance (FRAC 2011). Information submitted in ISKBC's application suggests that club root is difficult to control, requiring multiple applications (Clubroot Factsheet, 2000). Thus, rotational treatments that do not include fluazinam could increase the likelihood of resistance development to current fungicides (FRAC, 2011).

In summary, of the few effective treatments for club root, fluazinam is the only EPA registered FRAC Group 29 fungicide and is therefore a likely resistance management partner for a difficult to control soil-borne disease that may need multiple applications. OPP agrees that Criterion III has been met, that is, fluazinam will play a significant role in resistance management for its use on Brussels sprouts.

Chinese cabbage (Napa)

The registrant claims that fluazinam plays or will play a significant part in managing pest resistance for all crops in Crop Group 5 including Chinese cabbage.

The few fungicide alternatives to fluazinam used in the control of club root on Chinese cabbage are similar to those used on Brussels sprouts and broccoli. The main fungicide alternatives to control club root are fungicides within FRAC Groups 14 and 21 (ISKBC, 2011; USDA, 1999a). FRAC Group 14 chemicals are known to have low to medium risk of pest resistance and resistance in some fungi has been documented (ISKBC, 2011; FRAC, 2011). The risk of resistance in FRAC Group 21 chemicals is unknown but believed to be medium to high risk for developing resistance (FRAC 2011). Therefore, ISKBC claims that fluazinam has potential for its strategic use in resistance management programs and delaying or preventing the development of resistance to Group 14 and 21 chemicals.

In summary, of the few effective treatments for club root, fluazinam is the only EPA registered FRAC Group 29 fungicide and is therefore a likely resistance management partner for a difficult to control soil-borne disease that may need multiple applications. OPP agrees that Criterion III has been met, that is, fluazinam will play a significant role in resistance management for its use on Chinese cabbage.

Mustard greens

The registrant claims that fluazinam plays or will play a significant part in managing pest resistance for all crops in Crop Group 5 including mustard greens.

The few fungicide alternatives to fluazinam used in the control of club root on mustard greens are similar to those used on other Crop Group 5 crops. The main fungicide alternatives to control club root are fungicides within FRAC Groups 14 and 21 (ISKBC, 2011; USDA, 1999a). FRAC Group 14 chemicals are known to have low to medium risk of pest resistance and resistance in some fungi has been documented (ISKBC, 2011; FRAC, 2011). The risk of resistance in FRAC Group 21 chemicals is unknown but believed to be medium to high risk for developing resistance (FRAC 2011). Therefore, ISKBC claims that fluazinam has potential for its strategic use in resistance management programs and delaying or preventing the development of resistance to Group 14 and 21 chemicals.

In summary, of the few effective treatments for club root, fluazinam is the only EPA registered FRAC Group 29 fungicide and is therefore a likely resistance management partner for a difficult to control soil-borne disease that may need multiple applications. OPP agrees that Criterion III has been met, that is, fluazinam will play a significant role in resistance management for its use on mustard greens.

Lima beans

The registrant claims that fluazinam plays or will play a significant part in managing pest resistance for all crops in Crop Group 6B including lima beans.

Diseases labeled for fluazinam include white mold and/or gray mold. Information submitted by ISKBC indicates that many fungicides with high risk of resistance development, such as FRAC Group 1, 7, and 11, are the primary chemicals used to control these diseases. Information submitted by the registrant states that target pathogens have not developed resistance to fluazinam in the United States (ISKBC, 2011). In addition, ISKBC states that the end-use product label emphasizes the capacity of fluazinam as a rotation partner for resistance management when used on legumes-vegetables (ISKBC, 2011). BEAD has found data that corroborates this claim.

In summary, fluazinam is one of a limited number of effective treatments for managing white mold and/or gray in lima beans. Fluazinam is the only EPA registered FRAC Group 29 fungicide and can reduce the reliance on limited chemical groups. Fluazinam is recommended as one of the rotation partners to fungicide chemistries that are known to have high risk of pest resistance. Therefore, OPP agrees that Criterion III has been met, that is, fluazinam will likely play a significant role in resistance management for its use on lima beans.

Mung beans

The registrant claims that fluazinam plays or will play a significant part in managing pest resistance for all crops in Crop Group 6C including mung beans.

Diseases labeled for fluazinam include white mold and/or gray mold. Information submitted by ISKBC indicates that many fungicides with high risk of resistance development, such as FRAC Group 1, 7, and 11, are the primary chemicals used to control these diseases. Information submitted by the registrant states that target pathogens have not developed resistance to fluazinam in the United States (ISKBC, 2011). In addition, ISKBC states that the end-use product label emphasizes the capacity of fluazinam as a rotation partner for resistance management when used on legumes-vegetables (ISKBC, 2011). BEAD has found data that corroborates this claim.

In summary, fluazinam is one of a limited number of effective treatments for managing white mold and/or gray in mung beans. Fluazinam is the only EPA registered FRAC Group 29 fungicide and can reduce the reliance on limited chemical groups. Fluazinam is recommended as one of the rotation partners to fungicide chemistries that are known to have high risk of pest resistance. Therefore, OPP agrees that Criterion III has been met, that is, fluazinam will likely play a significant role in resistance management for its use on mung beans.

Turnip greens

The registrant claims that fluazinam plays or will play a significant part in managing pest resistance in the production of turnip greens

North Carolina is among the top three states in U.S. production of turnip greens. North Carolina extension advises to use fungicides for control of club root on turnip greens (USDA, 2003). The few fungicide alternatives to fluazinam used in the control of club root on turnip greens are similar to those used on Crop Group 5 crops such as broccoli and Brussels sprouts. The main fungicide alternative to control club root is within FRAC Group 21 (ISKBC, 2011; USDA, 1999a). The risk of resistance in FRAC Group 21 chemicals is unknown but believed to be medium to high risk for developing resistance (FRAC 2011). Therefore, ISKBC claims that fluazinam has potential for its strategic use in resistance management programs and delaying or preventing the development of resistance to Group 21 chemicals.

In summary, of the few effective treatments for club root, fluazinam is the only EPA registered FRAC Group 29 fungicide and is therefore a likely resistance management partner for a difficult to control soil-borne disease that may need multiple applications. OPP agrees that Criterion III has been met, that is, fluazinam will play a significant role in resistance management for its use on turnip greens.

DETERMINATION

After reviewing your application, the Agency agrees that for at least nine minor uses, that fluazinam 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. 71512-1. Exclusive-use protection for data, which complies with 40 C.F.R. 152.83(c), submitted in support of this registration will expire on August 10, 2014.

Lois Rossi

Lois Rossi, Director
Registration Division
Office of Pesticide Programs

cc: Cynthia Giles-Parker
Tony Kish
Michele Knorr
Arnet Jones
Carl Chen