



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

**Fenhexamid - EPA Response to the
Petition for the Extension
of the Exclusive Use Data Protection
Period Under FIFRA 3c(1)(f)(ii) -
Letter 1 of 2**

December 8, 2009



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DEC 8 2009

Cynthia Ann Smith
Vice President
Conn & Smith, Inc.
6713 Catskill Road
Lorton, VA 22079-1113

Subject: Petition for Extension of the Exclusive Use Data Protection
Period for Fenhexamid under FIFRA § 3(c)(1)(F)(ii)

Dear Ms. Smith:

This letter is in response to the petition for extension of the exclusive use data period for fenhexamid dated May 12, 2009. The petitioner is the TM-402 (KBR 2738) Fungicide Task Force (Consortium No. 69436) which is comprised of Arysta LifeScience North America, LLC (formerly Tomen Agro, Inc) and Bayer CropScience (formerly Bayer Corporation). The initial registration date for fenhexamid was May 21, 1999. The Agency **denies** the petition for extension of exclusive use data protection for reasons described below.

The 1996 Food Quality Protection Act (FQPA) amendments to FIFRA incorporated provisions under 3(c)(1)(F), the section that provides certain data protection, to provide additional data protection for minor use registrations. FIFRA section 3(c)(1)(F)(ii) sets forth criteria for extending the period of exclusive-use protection. If the Administrator determines that one of four criterion are met, the period of exclusivity can be extended one year for every three minor uses registered within the first seven years of the exclusive use period of the original registration. The maximum number of years the exclusivity period may be extended is three years.

The first step in determining whether data qualifies for an extension of its exclusive use period is to ascertain which data currently have exclusive use protection. FIFRA section 3(c)(1)(F)(i) and its implementing regulations carefully circumscribe the set of data that is eligible for exclusive-use protection. A study entitled to exclusive use protection is defined in 40 C.F.R. 152.83.

Pursuant to the 40 CFR 152.83 definition of exclusive use study, the following requirements must be met for a study to be considered an exclusive use study:

(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);

Provided that, a study is an exclusive use study only during the 10- year period following the date of the first registration.

The following describes our analysis for determining whether the data associated with fenhexamid contains exclusive use data. First, we determine whether there are data associated with this registration that pertain to, or have been derived from testing on, a new active ingredient. We have determined that there are.

Second, the data must have been submitted in support of the first registration of the new chemical.¹ The registration you cited was granted on May 21, 1999 and was the first registration for fenhexamid with the product name Fenhexamid Technical.

Please note, exclusive use protection is not available for studies that the Agency requires under FIFRA section 3(c)(2)(B) to maintain registration in effect. Any such data associated with this registration will not receive exclusive use protection under FIFRA section 3(c)(1)(F)(ii).

Now that the Agency has determined there are studies associated with this registration that are exclusive use studies², we must determine whether you have met the criteria for extending the exclusive use protection period pursuant to FIFRA section 3(c)(1)(F)(ii), and if so by how many years.

¹ Data are not protected solely because they pertain to a 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.

² This response is general in nature. For purposes of this petition, EPA did not determine which data associated with this registration have/had exclusive use data protection, only that at least some data are entitled to exclusive use data protection.

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 registration of a pesticide for a minor use on a crop grouping established by the Administrator shall be considered for purposes of this clause 1 minor use for each representative crop for which data are provided in the crop grouping. Any additional exclusive use period under this clause shall be modified as appropriate or terminated if the registrant voluntarily cancels the product or deletes from the registration the minor uses which formed the basis for the extension of the additional exclusive use period or if the Administrator determines that the registrant is not actually marketing the product for such minor uses.

The TM-402 (KBR 2738) Fungicide Task Force requested 2 years extension of exclusive use data protection, until May 21, 2011, for registration of eight crops; strawberry, almond, peach, cherry, plum, cucumber, lettuce and pepper.

The Agency determined that the initial registration of fenhexamid occurred on May 21, 1999 and included strawberries. On March 31, 2000 FIFRA Section 3 registrations were granted for almonds, peaches and cherries and on October 24, 2003, FIFRA Section 3 registrations were granted for plums, cucumbers, lettuce and peppers. As required by statute, the aforementioned uses were all registered within the requisite seven-year period.

Seven of the eight crops in the petition were determined to be minor uses and include: strawberry, peach, cherry, plum, cucumber, lettuce and pepper. The Agency determined that almonds do not meet the acreage definition of a minor crop, i.e., the total United States acreage for the crop is less than 300,000 acres. See *The United States Environmental Protection Agency Report on Minor Uses of Pesticides*, found at <http://www.epa.gov/pesticides/minoruse> for more information about minor and major crops.

Next, EPA analyzed whether the seven minor uses met any of the statutory criteria for extending exclusive use protection. The petition claims that the strawberry, peach, cherry and plum minor uses meet criterion (II) “the alternatives to the minor use pesticide pose greater risks to the environment or human health” and the cucumber, lettuce and pepper minor uses meet criterion (IV) “the minor use pesticide plays or will play a significant part in an integrated pest management program.”

The reason provided in the petition for support of criterion (II) for strawberry is that fenhexamid received reduced risk status for strawberries on September 10, 1997. Similarly, the reason provided for support of criterion (II) for peach, cherry and plum is that fenhexamid received reduced risk status for peach, cherry and plum on March 18, 1999. Although it is possible that a reduced risk minor use will meet criterion II, the TM-402 (KBR 2738) Fungicide Task Force would have needed to provide sufficient information for the Agency to make this determination. The Task Force did not provide sufficient information to determine if the strawberry, peach, cherry or plum minor uses met criterion (II) and therefore uses for strawberry, peach, cherry and plum do not support the extension of exclusive use protection.

The Agency posted a set of questions and answers (Qs & As) on its web site that provide guidance for petitioning the Agency for exclusive use data protection for minor use registrations. The Qs & As are available at <http://www.epa.gov/pesticides/minoruse>. There is a Q & A that addresses the use of reduced-risk classifications to meet criterion II which includes the type of information needed by the Agency to make a determination. The Q & A follows and the type of information the Agency needs is highlighted in bold typeface in the answer:

Question: If a minor use registration that is eligible for extension has been determined to be a reduced-risk use by the Agency, will it automatically qualify for extension under criterion (II) “the alternatives to the minor use pesticide pose greater risks to the environment or human health;” of FIFRA § 3(c)(1)(F)(ii)?

Answer: Although it is possible that a reduced-risk minor use will meet criterion II, the registrant needs to provide sufficient information to the Agency to determine that the reduced risk use meets the criterion. This information should include references to the reduced risk submission, including MRID numbers if available, as well as any new information necessary to satisfy criterion II. The applicant needs to indicate in the petition if there have been changes in the human health and ecological toxicity end points since the reduced risk status determination was made. Once the information is

provided, the Agency will determine if the risk assessment for the individual chemical has changed.

The Agency will base its decision regarding the alternatives to the minor use pesticide on the information that was provided in the original reduced risk request through December 31, 2010. Starting on January 1, 2011, the Agency will base its decision regarding the alternatives to the minor use pesticide on the conditions existing at the time the petition for extension of exclusive use is made. Please note that EPA determines reduced risk classification by specific crop or site. Information about reduced risk pesticides and be found on the EPA web site at (<http://www.epa.gov/opprd001/workplan/reducedrisk.html>).

Regarding the criteria determination for the three remaining minor uses, the petition claims that the cucumber, lettuce and pepper minor uses meet criterion (IV) “the minor use pesticide plays or will play a significant part in an integrated pest management program (IPM).” The Agency determined that there was not enough information in the petition to determine if the cucumber and lettuce minor uses of fenhexamid meet criterion (IV).

The petitioner provided the following support for criterion (IV) for cucumber and lettuce: “The University of Connecticut has recommended fenhexamid for use in pest management with reference to the control of *Botrytis* and suppression of powder(y) mildew on cucumber and leafy greens.” The petition also included the web site for the University of Connecticut recommendations for IPM for greenhouse grown plants. While the University of Connecticut pest control recommendations for greenhouse grown bedding plants list fenhexamid for control of *Botrytis* on cucumber and leafy greens, no explanation of how fenhexamid plays or will play a part in an IPM program was provided. A narrative description of how fenhexamid plays or will play a significant part in an IPM program for cucumbers and lettuce was necessary for EPA to determine whether this criterion was met.

Regarding peppers, the following information was provided to support criterion (IV): “Fenhexamid is included in, *A Pest Management Strategic Plan for Pepper Production in California* which was jointly prepared by the California Pepper Commission and The California Minor Crops Council. Please see page 13 of the publication.” The web site address of the pepper strategic plan was also provided. The pepper strategic plan was done December, 2004 and on page 13 recommends registering Elevate®/fenhexamid for *Botrytis* control for use during the planting/transplanting through thinning stage of pepper production. The strategic plan indicates that “(the disease caused by *Botrytis*) is brought in on transplants... there is no effective control at this time but efficacy tests have demonstrated that fenhexamid is effective, and that “Elevate®/fenhexamid is currently in the process of being registered.” The strategic plan goes on to say on page 16 that “There are no effective materials (during the thinning to flowering stage of pepper production) registered for this disease (*Botrytis*) although Endura®/boscalid and Elevate®/fenhexamid are waiting for registrations.” The information on page 13 of the strategic plan supports the claim that fenhexamid will play a significant part in an IPM program. The Agency determined that criterion (IV) has been met for peppers. For future petitions, the Agency prefers that the narrative portions of USDA’s Pest Management Strategic Plans or Crop Profiles that describe how the minor use pesticide meets criterion (IV) be cited in the petition.

Lastly, the Agency determines if the registrant is actually marketing products for qualified minor uses and if not, the Agency shall modify or terminate any extension to exclusive use protection. The Agency reviewed its files to determine if fenhexamid is being marketed for the minor uses requested in the petition. Current labels for Arysta LifeScience products containing fenhexamid, Elevate® 50WDG and CaptEvate® 68WDG, do not include cucumber, lettuce or peppers on their labels. Bayer CropScience's fenhexamid product, Fenhexamid 50WDG, had cucumber, lettuce and bell pepper (all three for transplant and greenhouse production only) on the label approved by the Agency on December 5, 2005, but that product or any other containing fenhexamid is not currently being offered for sale by Bayer. The Agency determined that fenhexamid is not currently being marketed on cucumber, lettuce or pepper. Therefore, the Agency finds that extension of exclusive use protection would not be appropriate, even if a criterion was met.

Of the seven minor uses eligible for consideration towards extension of the exclusive use period for fenhexamid, none met the requirements set forth in FIFRA § 3(c)(1)(F)(ii). The Agency determined that the petitioner did not provide enough information to support criterion (II) for strawberry, peach, cherry or plum or to support criterion (IV) for cucumber or lettuce. Criterion (IV) was supported for pepper; however, the Agency determined that fenhexamid was not being marketed for this use and therefore cannot be counted towards extension of the exclusive use period for fenhexamid. The Agency **denies** your request for an extension of the exclusive use period for fenhexamid. The exclusive use period for fenhexamid expired on May 21, 2009 and the Agency will not accept further requests for extension of its exclusive use period.

Sincerely,



Lois Rossi, Director
Registration Division
Office of Pesticide Programs

cc: Cynthia Giles-Parker
Shaja Brothers-Joyner
Nicole Williams
Michele Knorr
Pat Cimino

REFERENCES

Crop Data Management System (CDMS) search. Web address:
<http://premier.cdms.net/webapls>

Pest Management Strategic Plan for Pepper Production in California. December, 2004. Web address: www.ipmcenters.org/pmsp/pdf/CAPepper.pdf

University of Connecticut. Pest Management for Vegetable Bedding Plants. June 2009. Web address: www.hort.uconn.edu/ipm/greenhs/htms/ipmvpbtable1.html