



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Raymond S. Brinkmeyer, Ph.D.
Regulatory Leader – Regulatory Affairs
Dow AgroSciences
9330 Zionsville Road
Indianapolis, IN 46268-1054

Subject: Petition for Exclusive Use Data Protection for Minor Use Registrations for
Quinoxyfen (EPA Reg. 62719-375)

Dear Dr. Brinkmeyer,

This letter is in response to Dow AgroScience's petition dated July 2, 2008 and meeting with the Agency on August 4, 2009 regarding exclusive use data protection for minor use registrations for Quintec (EPA Reg. 62719-375).

In order for the Agency to make a determination on your petition, we need additional information. 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 on the Agency web site at <http://www.epa.gov/pesticides/minoruse> and may be helpful to you. The additional information that is needed is described below.

Your petition requested exclusive use data protection under FQPA section 210(b)(2)(ii) and FIFRA section 3(c)(1)(F)(vi). FQPA section 210(b) provisions are covered by FIFRA section 3(c)(1)(F)(ii) and will be identified as 3(c)(1)(F)(ii) provisions in this letter.

According to Agency records, quinoxyfen was first registered as Quinoxyfen Technical (EPA Reg. 62719-375), on September 30, 2003 and the exclusive use period for quinoxyfen will not expire until September 30, 2013. The FIFRA provision for minor use registrations whose exclusive use periods have not expired is FIFRA section 3(c)(1)(F)(ii). FIFRA section 3(c)(1)(F)(ii) sets forth the criteria to be met for extending the exclusive use period. Each minor use you request to be counted towards an extension must meet at least one of the four criteria.

The following is the text of FIFRA § 3(c)(1)(F)(ii) which includes the four criteria:

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 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.

Data that are protected by an extension of the data exclusivity period include studies that were submitted to the Agency in support of an application for registration of a new pesticide active ingredient or amendment adding a new uses(s) to this registration. The data for which Dow AgroSciences petitioned the Agency for exclusive use data protection are magnitude of residue studies for hops, grape, cherry, peppers, lettuce, strawberry, cantaloupe, plum, peach, winter squash and artichoke. Agency records indicate that these data were generated by IR-4. Data generated by IR-4 or other government entities are not eligible for data protection; however, minor use registrations supported by IR-4 data count towards an extension of the exclusive use period.

Please note that four of the minor uses in the petition, plum, peach, winter squash and artichoke, were not registered at the time you submitted your petition in 2008. To qualify for an extension, the minor uses must be registered **before** the petition is made. Also, please note that grapes are not considered a minor use under the acreage determination of a minor use in FIFRA section 2(II).

A threshold requirement to receive an extension is that the new minor use must be registered within the first 7 years of the commencement of the exclusive use period. For quinoxifen, the minor uses you request for an extension must be registered by September 30, 2010.

The information the Agency needs to determine if quinoxyfen can be granted an extension of its data exclusivity period includes:

- The registration date of the first registration of quinoxyfen.
- The number of years of extension you are seeking. (You can request up to 3 years)
- The minor crops for the extension. [Check to make sure they are minor uses, see FIFRA 2(l)]
- The dates the minor crops were **registered**. (Note, the minor uses must be registered within 7 years of the initial registration date of quinoxyfen to be eligible for an extension)
- Information to support the criterion or criteria claims for each minor use. (Refer to Q & A number 11 in the FIFRA 3(c)(1)(F)(ii) section of the Qs & As for guidance)

FIFRA section 3(c)(1)(F)(vi) provides an incentive to register minor uses for an active ingredient whose initial exclusive use period has expired. It provides for a new exclusive use period for data generated by an applicant or registrant to register a new minor use. It allows registrants to request at the time they submit their application for a new minor use (the use does not have exclusive use protected data) that the data be given exclusive use protection. The request must indicate that to the best of the registrant's knowledge, the exclusive use period has expired and that data submitted to support the minor use(s) are eligible for exclusive use protection. A threshold requirement is that a registrant or applicant **must** request exclusive use protection at the time they submit their application for a new minor use.

FIFRA section 3(c)(1)(F)(vi) does not apply to quinoxyfen because the exclusive use period for quinoxyfen has not expired. In addition, the magnitude of residue studies you requested in your petition be covered by FIFRA section 3(c)(1)(F)(vi) are IR-4 data and are not eligible for data protection because they are government-generated data.

You can submit supplemental information to your petition dated July 2, 2008 if you wish to pursue an extension of the data exclusivity period for quinoxyfen. If you prepare a supplemental information request, please put the statement "**ATTENTION: Minor Use – Exclusive Use Request. Supplemental Information**" in the subject section of your cover letter. If you have additional questions about exclusive use data protection for minor use registrations, you can contact Pat Cimino, Specialty Crop Advisor, at 703-308-9357, cimino.pat@epa.gov.

Sincerely,

Pat Cimino
Specialty Crops Advisor
Biological and Economic Analysis Division
EPA - Office of Pesticide Programs

cc: Shaja Joyner
Tamue Gibson
Nicole Williams