



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

**EPA Response to Petition for
Clethodim**

September 27, 2000



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

SEP 27 2000

OFFICE OF
GENERAL COUNSEL

Eric Mauer
Valent USA Corporation
Federal Registration Manager
2033 K Street, N.W. Suite 850
Washington, D.C. 20005

Dear Mr. Mauer:

This is in response to your April 28, 2000 letter in which you requested that the exclusive use period on Clethodim be extended by three years. The response also takes into consideration Jim Pensyl's August, 2000 facsimile.

Your request referred to section 3(c)(1)(F)(ii) of FIFRA which states, in pertinent part, "[t]he 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,"

You stated the following facts. First, the ten year exclusive use period for Clethodim ends in 2002 and Valent is pursuing new minor crops, but registration has not been granted. Second, section 3(c)(1)(F)(ii) of FIFRA was an amendment through FQPA and therefore, Valent had three years to fulfill the requirements set forth in that section, instead of the seven years stated in the statute. Third, you argue that although Valent did not receive its registrations in the seven year period, it did submit the application with supporting data. Lastly, you state that Valent should receive an additional three years of exclusive use, because it did everything in its power to fulfill the requirements, but the Agency could not complete the registration action in time.

The language in Section 3(c)(1)(F)(ii) of FIFRA is clear. Congress expressly stated that a registration must be granted within the seven years of the commencement of the relevant exclusive use period in order to extend that exclusive use period. Congress did not state that the submission of data in support of registration would give rise to an extension of the exclusive use period.

Throughout section 3(c)(1)(F) of FIFRA, Congress specified whether data rights attach at registration or at submission of data. In section 3(c)(1)(F)(ii), it is clear that Congress made the determination that the pesticide must be registered in order to take advantage of this clause. I understand your argument as to the time it has taken the Agency to review the data submitted by Valent, but in this case, EPA believes it is acting reasonably in reviewing this registration taking into account the many other priority actions before the Agency.

Please feel free to contact me for further information at 202-564-5631.

Sincerely,

A handwritten signature in black ink, appearing to read "Michele L. Knorr". The signature is fluid and cursive, with the first name "Michele" being the most prominent part.

Michele L. Knorr
Attorney
Pesticides and Toxic
Substances Law Office

cc: Jim Pensyl