



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

**Petition for Clethodim**

**April 28, 2000**

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April 28, 2000

Ms. Michelle Knorr  
Office of General Counsel  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20004

Dear Ms. Knorr:

As you know, the FQPA attempts to assist minor crop registrations by enabling registrants to gain an additional year of exclusive use of a chemical for every three minor crop registration. Specifically, the amendment states that minor crop registrations, "Extends period for exclusive use of data for new pesticide active ingredients for one additional year for each three minor uses registered after enactment within the first seven years of the exclusive use period, up to a total of three years. For existing pesticides, it affords ten years of data compensation for addition of a minor use."

The ten year exclusive period for clethodim ends in 2002. Currently, Valent is actively pursuing many new minor crops through the Agency and IR-4 although registration was not achieved within the seven year period (1999). However, we feel there are two issues which may enable us to take advantage of this amendment.

First, the PR notice announcing this incentive for IR-4 registrations did not publish until 1996. Thus, Valent had only three years to fulfill these requirements instead of the seven years stated in the FQPA.

Second, Valent did submit these data for registration in this time frame but they were obviously not registered. We feel that even though both IR-4 and the Agency were unable to complete these registration actions in time, we still did everything in our power to fulfill these requirements.

Considering the Agency is placing an emphasis on the registration of products for use on minor crops, we feel these points should show sufficient evidence to grant additional years of exclusivity once these new uses are registered (3<sup>rd</sup> quarter, FY00)

With Best Regards,

A handwritten signature in black ink, appearing to read "E. Maurer", with a long horizontal flourish extending to the right.

Eric J. Maurer  
Federal Registration Manager  
Valent USA Corporation  
202-872-4682

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August 1, 2000

**VIA FACSIMILE**

Ms. Michele Knorr  
Office of General Counsel  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20004

**RE: EXTENSION OF EXCLUSIVE USE PERIOD FOR CLETHODIM**

Dear Ms. Knorr:

On April 28, 2000, Mr. Eric Maurer of Valent U.S.A. Corporation sent a letter to you regarding the extension of exclusive use period for clethodim. In that letter, Mr. Maurer proposed that, because clethodim has pending registrations on numerous minor crops, that Valent is entitled to additional years of data exclusivity for clethodim in accordance with the minor use crop incentive amendment to FQPA.

The extension of the exclusive use period is extremely vital to Valent's business interests because the patent on clethodim expires in less than one year and the exclusive use period ends in 2002. Therefore, we would like to do whatever we can to expedite your consideration of our proposal. To that end, I am writing this letter to provide additional information supporting our proposal.

Clethodim, the active ingredient in Select 2 EC Herbicide, was first registered in 1992. Therefore, the exclusive use period for data supporting this registration commenced in 1992. Since 1996, when FQPA was enacted, clethodim has been developed for use on three (3) minor crops and five (5) crop groupings that include minor crops. These crops or crop groups, and the status of the registration of each are listed in Table 1 (attached).

Clethodim, when used on all of these crops, meets the definition of a minor use pesticide, as defined in the FQPA amendment. That definition requires that, to qualify as a minor use pesticide, the pesticide must be used on a crop grown on less than 300,000 acres. The amendment also states that the following criteria must also be met:

- There are insufficient efficacious alternatives for the use
- The alternatives pose greater risks
- The minor use is significant in managing pest resistance; or
- The minor use plays a significant part in integrated pest management

All of the crops listed in Table 1 are grown on less than 300,000 acres. Also, the need for clethodim registrations on these products is supported by the fact that all of these crop registrations were developed by IR-4. While Valent did everything in its power to support the registration of clethodim for these uses (financial, analytical, administrative support), each of these uses had to be sponsored by a County or University extension service or a local commodity grower group in order to be accepted as an IR-4 project. These groups would not have supported registration of clethodim for these uses if other, equally effective, products were available.

The amendment to FQPA dealing with minor crop registrations states that a registration of a pesticide for a minor use "extends the period of a data submitter's exclusive use of data submitted to support the application for the original registration of a pesticide for one additional year for each three minor uses registered after the date of enactment of the new Act and within seven years of the commencement of the ten year exclusive use period..."

Valent believes that the three minor crop registrations and the five crop group registrations (which each count as three crops per the FQPA amendment) that are pending entitle Valent to an additional three (3) years of exclusive use. Although none of these registrations have been granted to date, the registration submissions were made within (or nearly within) the seven year period following the start of the exclusive use period as required by the FQPA amendment. And we believe that the following factors should be considered when deciding whether these registrations qualify under the minor use incentive amendment:

- The amendment to FQPA including the minor use incentive did not publish until 1996. This left Valent with only three years to fulfill the requirement of the amendment.
- All of the minor crop registrations were developed and most were submitted by IR-4. While Valent did everything in its power to support IR-4 in making these submissions, IR-4's schedule for submissions is not within Valent's control.
- Once submitted, Valent has done everything in its power to expedite the registration of the pending uses, but the timing of the registrations is EPA's responsibility and is also not within Valent's control.

Valent believes that, once the pending registrations are granted (currently scheduled for 1<sup>st</sup> quarter, FY2001), that the three-year extension of the exclusive use should also be granted. Valent would appreciate EPA's concurrence with this proposal. We believe that these pending registrations fulfill the spirit of the FQPA amendment, which was enacted to encourage the registration of pesticides for use on minor crops. Because of the importance of this issue to Valent's business interests and the urgency caused by the patent expiration, Valent would appreciate a decision on this matter as soon as possible. Thank you for your consideration of this proposal. If you have any questions, please feel free to call me at (925) 256-2786 or Mr. Eric Maurer in our Washington, DC office at (202) 872-4682.

Sincerely,



James Pensyl

Project Manager

Registrations & Regulatory Affairs

**Table 1**  
**Chronology of Clethodim Minor Use Registrations**

| <b>Crop/Crop Group</b> | <b>Minor Crops Included</b>  | <b>Status of Registration</b> |
|------------------------|------------------------------|-------------------------------|
| Crop Subgroup 1-D      | Sweet potato, yam, artichoke | Submitted 6/1997, pending     |
| Crop Group 8           | Peppers, eggplant            | Submitted 1/1999, pending     |
| Crop Subgroup 1-B      | Carrots, radish, turnip      | Submitted 1/2000, pending     |
| Crop Group 2           | Leaves of root vegetables    | "                             |
| Crop Subgroup 4-B      | Celery, Swiss chard          | "                             |
| Crop Subgroup 9-A      | Cantaloupe, watermelon       | "                             |
| Crop Subgroup 9-B      | Squash, cucumber, pumpkin    | "                             |
| Cranberry              | Cranberry                    | "                             |
| Strawberry             | Strawberry                   | "                             |
| Clover                 | Clover                       | "                             |