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 2 of 2

June 19, 2006

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

JUN 19 2006

Ms. Doina Bujor
Regulatory Manager
Registrations and Regulatory Affairs
Arysta LifeScience North America
Park West Two
1540 Weston Parkway
Suite 150
Cary, NC 27513

Dear Ms. Bujor,

I am writing in reply to your March 2, 2006, letter petitioning the U.S. Environmental Protection Agency (EPA) for an extension of exclusive use period for data that Arysta LifeScience North America (Arysta) submitted in relation to its registration of the pesticide fenhexamid. For the reason provided below, EPA denies your petition without prejudice.

Section 3(c)(1)(f)(ii) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides EPA authority, under certain circumstances, to extend the initial ten year "exclusive data use" period for up to an additional three years "if the [EPA] Administrator, in consultation with the Secretary of Agriculture, determines that, *based upon 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."

In its petition, Arysta provided EPA with no information upon which it could base a FIFRA 3(c)(1)(f)(ii) determination. As such, EPA is not able to make such a determination, and therefore, cannot, at this time, extend the exclusive use period for data that Astyra submitted in support of the registration for fenhexamid.

This petition denial does not bar Arysta from repetitioning EPA for an extension of the exclusive use period for fenhexamid data and providing in the new petition information upon which EPA could base a FIFRA 3(c)(1)(f)(ii) determination.

If you have any questions concerning EPA's denial of Aystra's exclusive data use petition, please contact Mary Waller at (703) 308-9354.

Lois A. Rossi

Lois A. Rossi
Director
Registration Division