



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

MAR 28 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Peter Jenkins, Attorney/Consultant
Center for Food Safety
660 Pennsylvania Avenue
Suite 302
Washington, D.C. 20003

Dear Mr. Jenkins:

On February 11, 2016, you sent me a letter "demanding" that the U.S. Environmental Protection Agency take four actions related to the refusal by both Bayer CropScience and Nichino America, Inc., to comply with a condition of registration to request voluntary cancellation of certain flubendiamide registrations held by those companies. In your letter, you wrote that the EPA's letter of January 29, 2016 invoked the "Special Review" process and that using that process to remove the flubendiamide registrations would take several years to complete. Instead, you demanded more expeditious action, and specifically that the EPA:

- 1) declare the flubendiamide registrations to be expired;
- 2) alternatively, declare an "imminent hazard" and suspend the registrations;
- 3) issue a Stop Sale, Use or Removal Order to promptly end the use of flubendiamide;
- 4) officially suspend the issuance of conditional registrations

I believe your letter was based in part on a misunderstanding of our January 29th letter. It was never our intention to initiate the special review procedures in 40 CFR Part 154 for flubendiamide. Instead, the January 29th letter was written to implement a condition in the conditional registrations for flubendiamide. Those registrations provided that if, after a review of data submitted by the flubendiamide registrants (and other information) EPA determined that flubendiamide caused unreasonable adverse effects on the environment, EPA could notify the registrants and direct them to request voluntary cancellation within seven days. Our letter was the formal notification triggering the condition that voluntary cancellation be requested within seven days. Regrettably, the registrants decided to disregard their original agreement and declined to comply with that condition, and on February 29th of this year EPA sent to the registrants a Notice of Intent to Cancel the registrations pursuant to Section 6(e) of FIFRA for failure to comply with that particular condition of registration. That Notice of Intent was later published in the Federal Register on March 4, 2016.

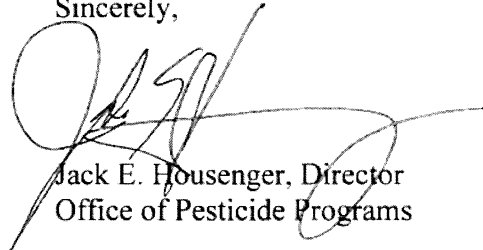
A hearing under section 6(e) of FIFRA is limited to a narrow set of issues – whether the registrants complied with the condition of registration as well as the disposition of existing stocks – and must be completed within seventy-five days of a request for hearing. We carefully considered the options available to the agency and believe this cancellation action is the appropriate way to expeditiously resolve the failure of the registrants to comply with the condition of the flubendiamide registrations. In light of this cancellation action, we do not intend

to declare the registrations expired; declare an imminent hazard; or issue Stop Sale, Use or Removal orders. Without going into detail, I would note that those options either raise unnecessary legal risks or would require significant amounts of time and agency resources when compared with the section 6(e) hearing process we are pursuing.

As to your demand that EPA cease issuing conditional registrations, my short answer is that Congress adopted the provisions of section 3(c)(7) of FIFRA in order to allow EPA to issue conditional registrations when the agency makes the findings required by that section, and we will continue to use that authority in the appropriate circumstances. Having said that, I will also note that we expect registrants to comply with conditions of registration and that such compliance is an important factor for us to continue issuing conditional registrations. We are deeply concerned that the flubendiamide registrants accepted a registration with important conditions and later elected not to comply with those conditions. We hope and expect that this refusal to comply with registration conditions is a very isolated example; if it is not, we may have to revisit the circumstances under which we issue conditional registrations.

I hope that this adequately addresses your concerns and I thank you for your interest.

Sincerely,

A handwritten signature in black ink, appearing to read 'J. Housenger', is written over the typed name and title. The signature is fluid and cursive, with a large loop at the beginning and a long horizontal stroke extending to the right.

Jack E. Housenger, Director
Office of Pesticide Programs