



CENTER FOR
FOOD SAFETY

Jack E. Housenger, Director
Office of Pesticide Programs
Environmental Protection Agency
Office of Chemical Safety and Pollution
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Arlington, VA 22202-4501

FEDERAL EXPRESS

Re: Flubendiamide and registered products, EPA Reg. No.s: 264-1025, 264-1026, 71711-26, 71711-31, 71711-33 – water quality condition violation – COMPLIANCE DEMAND

Dear Mr. Housenger,

This demand letter is in reference to the recent announcement by Bayer CropScience and Nichino America, Inc., (hereinafter, "Bayer") that they refuse to comply with a condition of the conditional registrations (CR) that your agency granted to those companies for Flubendiamide and the commercialized products thereof (*Belt, Synapse, Vetica, Turismo*). The key facts are reflected in the letter of Jan. 29 that you issued to Nancy Delaney of Bayer CropScience urging the company to comply with the conditions of the registrations. The key condition relates to protection of water quality and aquatic invertebrates. The Center for Food Safety (CFS), with over 750,000 members nationwide, has a strong interest in stopping the use of insecticides such as Flubendiamide that are contaminating our nation's waters and harming its aquatic life. **We demand that you use your existing legal authority to declare the above-referenced EPA-issued CRs to be expired or, alternatively, to promptly suspend them. EPA also should suspend the issuance of any CRs for any pesticides unless or until the system is reformed to provide the reliable environmental protections that Americans deserve.**

As you know, the Aug. 1, 2008 CR at issue was granted with the condition that after five years, if EPA's expressed concerns about foreseeable harms to aquatic systems were not satisfactorily resolved, then Bayer was to accept voluntary cancellation of the CR. More than seven years have passed since then and Bayer is violating the terms of the CR. Just last week, Bayer publicly announced it refuses to comply with the condition.¹ This is a direct affront to your authority. EPA's CR regulation provides that, upon lapse of the condition period, if a condition remains unsatisfied the pesticide's registration is deemed expired. 40 C.F.R. § 152.115(b)(2) provides (emphasis added):

¹ Bayer Press Statement, *Bayer Contests EPA's Decision on Valuable Insecticide for Farmers - Company seeks to stop Agency's proposed cancellation of flubendiamide, which exaggerates risk and would deny farmers a valuable tool in battling damaging insects*. Feb. 5, 2016, available at: www.prnewswire.com/news-releases/bayer-contests-epas-decision-on-valuable-insecticide-for-farmers-300215936.html.

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*The registration will **expire** upon a date established by the Agency, if the registrant fails to submit data as required by the Agency.*

Both of those circumstances are present for the Flubendiamide registrations: 1) the date for completion of the condition established by EPA has passed, and 2) the registrant has failed to meet the condition. Yet, EPA's Jan. 29 letter has invoked the Special Review process. All are aware that EPA's Special Review process typically will take several more years to complete. Invoking Special Review is an unacceptably lenient approach by EPA when it can instead declare the registration "expired" per the agency's regulation, above. Further, as EPA did with the herbicide *Imprelis* in 2010, EPA should declare that the labels of the Flubendiamide products now are inadequate to warn of non-target effects or to protect the environment and that existing Flubendiamide products on the U.S. market should be subject to a Stop Sale and Use Order.²

Reflecting back on the 2008 CR, EPA was only allowed to grant registration then if the agency concluded that approval of the CR with the condition would "not significantly increase the risk of any unreasonable adverse effect on the environment."³ EPA's condition aimed to protect the nation's waters and aquatic invertebrates from such adverse effects. Your letter of Jan. 29 indicates that, because of Bayer's failure to comply with that condition, the environment **is** being contaminated and the current situation amounts to an "unreasonable adverse effect," stating:

In fact, EPA's most recent analysis suggests that the continued use of flubendiamide is expected to have significant negative impact on invertebrates of aquatic systems, which could lead to negative impacts on other taxa as well.

Numerous native U.S. aquatic invertebrates, such as freshwater mussels, crayfish, dragonflies and many other species, are listed as threatened or endangered under the Endangered Species Act (ESA).⁴ It is unacceptable to allow continued possible jeopardy to such species, as well as to allow such impacts on non-ESA listed species. CFS notes that under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA shall suspend a pesticide registration if necessary to prevent an "imminent hazard".⁵ FIFRA defines this as: "*when the continued use of a pesticide during the time required for cancellation proceeding would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered or threatened [under the ESA]*".⁶ Those circumstances exist here and will continue during the envisioned multi-year Special Review proceeding unless EPA suspends Flubendiamide based on its "imminent hazard".

Unfortunately, Bayer's CR violation for Flubendiamide is not an isolated occurrence. More than a decade ago, EPA's imposed condition mandating a valid "pollinator field test" for the registration of the neonicotinoid clothianidin (registered to Bayer in 2003); that also remains unsatisfied now **13**

² EPA Region III, *In re E.I. du Pont de Nemours & Co.*, Stop Sale, Use, or Removal Order, Docket No. FIFRA-03-2011-0277SS (Aug. 11, 2011) ¶ 22.

³ 7 U.S.C. § 136a(c)(7)(A)(i)-(ii); see 40 C.F.R. § 152.114(d)

⁴ 16 U.S.C. § 1536(a)(2).

⁵ 7 U.S.C. § 136d(c)

⁶ 7 U.S.C. § 136(l).

years after it was imposed.⁷ The pollinator field test condition is essential to protect honey bees, bumblebees and native pollinators of all kinds, yet your agency has failed to mandate an adequate test result.

Bayer's blunt refusal to comply with the Flubendiamide condition it agreed to shows that the agrichemical company now views this as an unconditional registration. If the recipients of CRs arrogantly treat EPA's conditions as having no legal force, then the practice of issuing CRs must be suspended as they are not reliable.

As you are aware, the Government Accountability Office (GAO) issued a thorough audit in 2013 that castigated EPA's management of CRs.⁸ The audit found that due to the lack of a reliable condition tracking system "pesticides with conditional registrations could be marketed for years without EPA's receipt and review of these data." Unfortunately, the Flubendiamide situation indicates EPA has failed to fully heed the GAO audit conclusions. The environmental protections Americans deserve are suffering as a result.

This situation provides further evidence of the unreliability of EPA's approach because plainly agency officials did not have confidence that Flubendiamide was an acceptable risk in 2008, as they imposed the "exit strategy" of cancelation after five years of determining whether the risk was acceptable or not. This sort of "pre-acceptance" of uncertain risks violates the CR regulatory approach, which again can be employed "only if [EPA] determines that use of the pesticide during such period will not cause any unreasonable adverse effect on the environment" (emphasis added).⁹ In this case EPA has now determined Flubendiamide is causing unreasonable adverse effects, but more than seven years after the fact. This is unacceptable.

EPA's partner agency in Canada, the Pest Management Regulatory Agency (PMRA), recently issued an official "Notice of Intent" stating its plan to entirely cease the practice of granting CRs, effective June 1 of this year.¹⁰ The cited reasons are basically their "lack of transparency" together with the existence of scores of CRs with conditions still outstanding. As the same problems exist in the United States, in keeping with the normal harmonization between PMRA and EPA, your agency should promptly follow suit and officially suspend the practice of issuing such registrations pending further reform of the CR system to ensure its transparency and reliability.

To reiterate: The refusal of Bayer to comply with your agency's imposed conditions provides a strong demonstration that the current conditional registration system is unreliable and unable to protect Americans or the environment from unreasonable adverse effects. CFS demands that EPA promptly:

1) declare that the above-referenced Flubendiamide registrations are deemed expired;

⁷ CFS et al., Clothianidin Legal Petition (Mar. 21, 2012), available at www.centerforfoodsafety.org/wp-content/uploads/2012/10/CFS-Clothianidin-Petition-3-20-12.pdf.

⁸ U.S. GAO, *Pesticides: EPA Should Take Steps to Improve Its Oversight of Conditional Registrations* (Aug. 2013), available at <http://www.gao.gov/products/GAO-13-145>

⁹ 7 U.S.C. § 136a(c)(7)(A)-(C)

¹⁰ Health Canada, PMRA. *Notice of Intent Regarding Conditional Registrations under the Pest Control Product Regulations*, Notice NOI2016-01, 19 Jan, 2016, available at: <http://www.hc-sc.gc.ca/cps-spc/pest/part/consultations/ noi2016-01/ noi2016-01-eng.php>.

2) alternatively, suspend the registrations based on the "imminent hazard" they present;

3) issue a Stop Use and Sale order to promptly end the use of the Flubendiamide products in view of Bayer's refusal to comply with the terms of its registration, the urgent need to protect the nation's waters and aquatic life, and the lack of adequate warnings or use directions on the products' current labels; and

4) officially suspend the issuance of any more conditional registrations for pesticides unless or until the system for conditional registrations is reformed.

Please respond to this letter **within 30 days**. Please contact me at 202.547.9359; email: pjenkins@centerforfoodsafety.org, if you have any questions regarding this letter.

Sincerely,



Peter T. Jenkins, Attorney/Consultant
Center for Food Safety

CC: (via email) Carmen Rodia, Richard Gebken, Ariadne Goerke, Susan Lewis; EPA