UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of:	)	
Bayer Crop Science LP and Nichino America, Inc.	)	FIFRA-HQ-2016-0001
Petitioners.	)	

RESPONDENT'S RESPONSE TO AMICUS BRIEFS FILED BY CROPLIFE AMERICA AND THIRTY-SIX GROWER GROUPS

On April 7, 2016, a coalition of thirty-six grower groups (hereafter "Growers") filed an amicus brief in support of the objections filed by Bayer CropScience LP and Nichino America, Inc., (hereafter "Registrants") to Respondent EPA's February 29, 2016 Notice of Intent to Cancel certain flubendiamide pesticide registrations pursuant to section 6(e) of the Federal Insecticide, Fungicide, and Rodenticide Act (hereafter "FIFRA"). On April 11, 2016, CropLife America (hereafter "CropLife") filed another amicus brief in support of Registrants' objections to the Notice of Intent to Cancel. On April 8, 2016, Michael B. Wright, counsel to the Tribunal, sent an email to the parties to this proceeding stating that "[t]he parties, if they wish, may choose to include any responses to amicus briefs in their primary discovery" due to be filed on April 22, 2016. While EPA has addressed most of the arguments raised by Growers and CropLife in its April 18, 2016 Respondent's Opposition to Registrants' Motion for an Accelerated Decision (hereafter "EPA Brief"), Respondent submits this additional short response to the briefs filed by CropLife and Growers.

CropLife's Brief

As with the papers filed by Registrants and Growers, CropLife's brief seeks to divert this Tribunal from the two narrow issues appropriate for consideration in this proceeding under section 6(e) – whether Registrants failed to comply with a condition of registration and whether EPA's proposed disposition of existing stocks is consistent with FIFRA. Instead, CropLife asserts that EPA may only proceed with cancellation of flubendiamide under section 6(b) of FIFRA. CropLife's position on that point is factually and legally defective.

Central to CropLife's reasoning seems to be its perception that EPA determined in 2008 that flubendiamide use "would not cause unreasonable adverse effects on the environment, and therefore granted a registration for five years to allow Registrants sufficient time to generate and submit additional data to address potential persistence." CropLife Brief at 9. In CropLife's narrative, EPA's unreasonable adverse effects determination is construed as not being time-limited in any way, such that the only purpose of the five-year time limitation in the registration was to assure the timely submission of data. But as set forth in EPA's Brief, EPA's concerns with the persistence and aquatic toxicity of flubendiamide required that measures be included in the registrations to limit the potential for harm to the aquatic environment. EPA Brief at 13, 21-27; Declaration of Susan T. Lewis, Attachment B to Respondents' Opposition to Registrants' Motion for an Accelerated Decision (hereafter "Lewis Declaration"), ¶¶ 14-19. These measures included vegetative buffer strips and other measures expected to reduce the amount of flubendiamide reaching surface waters, studies to assess the effectiveness of these mitigation measures, and, in case the mitigation measures prove insufficient, a voluntary cancellation condition to assure that the potential for environmental risk was appropriately limited. It was this voluntary cancellation condition that is challenged by Registrants, CropLife, and Growers.

But CropLife ignores even the possibility that the cancellation condition could have been an integral part of EPA's 2008 registration decision (and EPA submits it is clear that the cancellation condition was an integral part of that decision), and ignores the fact that EPA never made findings that would support flubendiamide registration for an unlimited period of time. *See* EPA Brief at 36-41.

CropLife suggests that the "streamlined process" for cancellation under section 6(e) is limited to the failure to meet conditions requiring the generation and submission of data. CropLife Brief at 6. To the contrary, the statutory text and EPA's implementing regulations make clear that non-data conditions are appropriate under section 6(e). EPA Brief at 9-10, 17-19. The court in *Woodstream Corp. v. Jackson*, 845 F.Supp, 2d 174 (D.D.C. 2012) squarely addressed this issue in circumstances similar to those presented here and upheld a condition providing for the automatic expiration on a date certain of a pesticide registration. In fact, the voluntary cancellation provision in flubendiamide was negotiated with the Registrants because they preferred that condition to an automatic expiration condition such as the one later upheld in *Woodstream*. EPA Brief at 29-30.

CropLife contends throughout its brief that EPA cannot use section 6(e) to cancel products that EPA believes cause unreasonable adverse effects on the environment, and must instead resort to proceeding under section 6(b) in any case where EPA has risk concerns. EPA agrees in part – EPA can only cancel a registration under section 6(e) if the factors set forth in that section are met, and a section 6(b) proceeding is the proper forum for adjudicating whether a pesticide causes unreasonable adverse effects. But EPA is manifestly not asking this Tribunal to cancel flubendiamide registrations on account of their causing unreasonable adverse effects on the environment. Rather, the Agency is entitled to proceed with cancellation under section 6(e)

here because Registrants failed to comply with a condition of their registrations. And as EPA pointed out in its Brief, Registrants were well aware of the cancellation conditions at their inception, they understood the importance of the cancellation conditions to EPA, and they accepted the cancellation conditions. *See* EPA Brief at 27-31; Lewis Declaration at ¶¶ 18, 21-23.

CropLife cites *Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34 (D.D.C. 2011) for the proposition that EPA must resort to cancellation under section 6(b) in any and all circumstances where it has concerns that a pesticide might cause unreasonable adverse effects. CropLife Brief at 18-20. CropLife overstates the relevance of *Reckitt* to this proceeding. In *Reckitt*, the court was concerned that if EPA could immediately take pesticide products off the market on the basis of misbranding violations (proceeding under sections 2(q)(1)(F) and 12(a)(1)(F) of FIFRA) that would appear to apply in every circumstance where EPA could assert that a pesticide caused unreasonable adverse effects on the environment,[1] and that could be accomplished immediately without first affording any process to a registrant using the *in rem* seizure authority of FIFRA section 13, then EPA would never use its authority under the more process-laden section 6(b).[2] 762 F.Supp. at 37 and 49. The court in *Reckitt* certainly never

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[1] FIFRA section 2(q)(1)(F) provides that a pesticide is misbranded if "the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under [section 3(d) of FIFRA] are adequate to protect health and the environment.

[2] EPA never actually attempted to bring a misbranding action against the petitioners in *Reckitt*, but it had made statements identifying a misbranding action as a legal option available to the Agency in a non-binding guidance document, identified as the "RMD" in the following procedural summary by the Court of Appeals for the District of Columbia Circuit:

> On June 18, 2008, by certified mail, EPA notified the company of the RMD, described procedures for responding, and repeated the RMD's warnings that "[r]odenticide products that do not comply . . . that a registrant releases for shipment after June 4, 2011, *would be considered misbranded*" (emphasis added) and that EPA "will initiate cancellation actions against products for which it does not receive notification of the registrant's intent to comply." The company responded that it did not intend to comply with the RMD, and requested that EPA "expeditiously commence" cancellation pursuant to Section 6 for Reckitt Benckiser's products affected by the RMD. When EPA did not do so, the company filed suit on March 3, 2009, for injunctive and declaratory relief, seeking an order directing EPA to begin cancellation proceedings and enjoining EPA from beginning misbranding proceedings prior to their completion. The district court dismissed the complaint for lack of subject matter jurisdiction, concluding that the company's claims arose

considered or opined upon whether, irrespective of risk concerns, a cancellation could be effectuated under the processes set forth in sections 6(e) or 6(f) if their respective conditions for cancellation were met. Indeed, CropLife cites no authority for the proposition that, when EPA has risk concerns, a section 6(e) proceeding may not go forward when a registrant fails to comply with a condition of a conditional registration, or that a voluntary cancellation may not go forward under the process set forth in section 6(f) of FIFRA. And the decision in *Woodstream* strongly suggests otherwise.

CropLife asks this Tribunal to determine that the voluntary cancellation condition in the flubendiamide registrations, a condition that was knowingly and willfully accepted by Registrants, was unlawful at its inception. CropLife Brief at 24. Indeed, EPA submits that this is the central issue raised by CropLife. CropLife cites no case law to support the proposition that a registrant cannot knowingly make a binding commitment to accept a registration that will expire at some point in the future without regard to a hearing under section 6(b). And regulatory common-sense suggests otherwise. Indeed, as noted in the Declaration of Susan Lewis accompanying EPA's Brief, the Agency frequently negotiates with applicants for registration over which risk-mitigation measures meet the commercial needs and desires of the registrant while stilll allowing EPA to make the no unreasonable risk finding required to support a pesticide registration. Lewis Declaration, ¶¶ 10-11. There may well have been other conditions that could have been imposed on the flubendiamide registrations in 2008 that could have allowed the Agency to determine that a time-limitation was no longer needed, but the Registrants presumably had their own reasons for accepting the particular conditions in the Preliminary

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under the reregistration provisions of Section 4 and thus invoked the judicial review provisions of Section 4(m), 7 U.S.C. § 136a-1(m), which provides for initial review in the court of appeals.
Reckitt Benckiser, Inc. v. EPA, 613 F.3d 1131 at 1135-36 (D.C.Cir.2010)(footnotes omitted).

Acceptance Letter and the Notice of Registration. Perhaps the Agency could have accepted a very restricted (but not time-limited) geographical or crop limitation as a replacement for the assurance that the voluntary cancellation condition gave that production of material that posed significant risk to the aquatic environment would cease expeditiously after five years if the Agency determined that the risks could not be appropriately mitigated. A registrant might well prefer the broader, but time-limited registration. The language in FIFRA does not clearly deprive a registrant from opting for a voluntary cancellation condition instead of having to choose a much more restricted registration (or no registration at all), and EPA cannot think of a reason why such a limited reading of section 3(c)(7) would be desirable.

As EPA also noted in its Brief, a registrant can elect of its own accord to bypass a section 6(b) proceeding when it requests voluntary cancellation under FIFRA section 6(f), even in circumstances where EPA has determined that a pesticide causes unreasonable adverse effects on the environment. EPA Brief at 11-12, 47-48. As discussed below in addressing the Growers' Brief, there is no question that in doing so, a registrant effectively forecloses the opportunities of growers and others to participate in a section 6(b) proceeding. A registrant can request voluntary cancellation under section 6(f) at any time after the registration of a pesticide; nothing in either section 3(c)(7) or section 6(f) suggests that a registrant cannot agree to request voluntary cancellation upon specified conditions at the inception of the registration. CropLife does not explain, and EPA can think of no reason, why Congress might have thought it appropriate to allow a registrant to use section 6(f) to foreclose the opportunities of themselves and others to participate in a section 6(b) proceeding, but not to allow that same registrant to foreclose them in exactly the same manner at the time the registration issues. The simple fact is that the registrant, and not third parties, is the license-holder, and the registrant might reasonably make a business

decision to obtain a license with particular terms and conditions that might be otherwise unavaliable to them, and in exchange to give up the opportunity for a section 6(b) proceeding (and thereby foreclose any third parties' opportunities to a section 6(b) proceeding as well).

Finally, CropLife fails to address the consequences of declaring a condition illegal when that condition was an integral part of the Agency's determination that the initial registration would not cause unreasonable adverse effects on the environment. As EPA stated in its Brief, the only appropriate remedy in such a situation would be to invalidate the regsitration in its entirety. Any registration that is not supported by the necessary agency findings required under FIFRA is unlawful and could not be defended if challenged. If a condition of registration is found unlawful, the only valid response is to vacate the registration and remand the registration decision to EPA. *See* EPA Brief at 36-41.

Growers' Brief

EPA wishes to address two issues raised by Growers in their brief. First, Growers contend that the voluntary cancellation condition deprives growers of their statutory rights to be heard. Growers' Brief at 17-21. EPA respectfully disagrees. Growers are entitled to the process provided under FIFRA for the particular cancellation path initiated under that statute. Growers do not have a right to participate in a cancellation hearing under section 6(b) unless EPA initiates a cancellation action under section 6(b). As noted above and in EPA's Brief, if Registrants had complied with the conditions of registration and submitted the appropriate requests for voluntary cancellation, Growers would have had the right to comment on the cancellation provided under section 6(f) of FIFRA, but they would not have had any rights to a section 6(b) hearing on the risks and benefits of the pesticides. *See* EPA Brief at 44-48. Because Registrants agreed to a condition and then reneged upon it, EPA has the authority to pursue cancellation under section

6(e), and Growers instead have the statutory right to participate in this proceeding to the full extent provided in section 6(e). To the extent that Growers' real complaint is with Registrants' election to accept the conditional registrations they knowingly accepted in 2008, the simple answer is that FIFRA is a licensing statute that provides licenses to particular entities, who have a much greater say in the terms and conditions of those licenses than do third parties. If Growers desired a registration without the cancellation condition, it was incumbent on them to either convince the Registrants to take the appropriate actions to attempt to acquire such a registration, to find some other company that would pursue such a registration, or to pursue such a registration themselves.

Second, Growers argue that a cancellation under section 6(e) unlawfully shields EPA's science from review. Growers' Brief at 21-23. EPA addressed this misapprehension in its Brief. EPA Brief at 32-34; *see also* Respondents' Motion to Limit Scope of Testimony (filed April 18, 2016) at 4. Registrants could at any time have sought an appropriate scientific hearing addressing whether they were entitled to flubendiamide registrations without the cancellation condition, either by refusing to accept the cancellation condition initially or by subsequently submitting applications for new and amended registrations without the offending cancellation condition. Those were the appropriate opportunities for the scientific hearing that Growers call for. For whatever reason, Registrants did not avail themselves of these opportunities, and no other entity sought a registration without the cancellation condition. Instead, Registrants accepted the cancellation condition in their registrations without raising any objection or challenge, and when they subsequently failed to comply with the condition, EPA initiated the appropriate action under section 6(e). This hearing under section 6(e), however, is bounded by

the terms of that statutory provision; it is not the appropriate proceeding for the scientific hearing sought by Growers.

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 22nd day of April, 2016, a true and correct copy of *Respondent's Response to Amicus Briefs Filed by CropLife America and Thirty-Six Grower Groups* was filed electronically using the EPA OALJ e-filing system and served in the following manner to the below addresses:

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