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 OPPOSITION TO BAYER CROPSCIENCE LP AND NICHINO AMERICA, INC.'S MOTION FOR AN ACCELERATED DECISION

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ATTACHMENT AND EXHIBIT LIST

Respondent will be citing to Petitioner's Exhibit List from its Motion for Accelerated Decision where possible, and where Respondent is providing a new document will refer to that document as Respondent's Attachment with a corresponding letter.

Respondent Attachment	Description
A.	Letter from Jack Housenger (EPA Office of Pesticide Programs) to Peter Jenkins, Center for Food Safety (Mar. 28, 2016)
B.	Declaration of Susan T. Lewis
C.	EPA Decision Memorandum for Registration of Flubendiamide (Aug. 1, 2008)
D.	Emails between Clive A. Halder, Director of Regulatory Affairs, BayerCropScience; Danielle A. Larochelle, Registration Product Manager, Bayer CropScience and EPA Registration Division (July 17, 2008 thru July 31, 2008)
E.	Four Bayer letters requesting extension of time limited registrations (May 30, 2013 thru December 16, 2015)

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7.	Notices of Registration for Flubendiamide Technical (EPA Reg. No. 71711-26) and Belt SC Insecticide (EPA Reg. No. 264-1025) (Aug. 1, 2008)
8.	Letter from Lois Rossi (EPA Registration Division) re: Preliminary Assessment Letter for Flubendiamide Registrations (July 31, 2008)
10.	Letter from Richard Gebken (EPA Registration Division) re: Extension of Flubendiamide Registrations to Aug 31, 2015 (July 18, 2013)
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16. Letter from Richard Gebken (EPA Registration Division) re: Extension of Flubendiamide Registrations to January 29, 2016 (Jan 14, 2016)

17. Letter from Jack Housenger (EPA Office of Pesticide Programs) re: Request for Voluntary Cancellation of Flubendiamide Registrations (Jan. 29, 2016)

18. Letter from Dana Sargent (Bayer CropScience LP) re Refusal to Request Voluntary Cancellation of Flubendiamide Registrations (Feb. 5, 2016)

55. EPA's Conditional Opposition to CropLife America's Motion to File an Amicus Curiae Brief, Dkt. #24, *In re Reckitt Benckiser*, EPA FIFRA Docket No. 661 (May 6, 2013)

LIST OF ACRONYMS

BCS	Bayer CropScience LP
NAI	Nichino America, Inc.
EPA	United States Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
HHS	United States Department of Health and Human Services
NAS	National Academy of Sciences
NOIC	Notice of Intent to Cancel
NOR	Notice of Registration
PAL	Preliminary Acceptance Letter
RMD	Risk Mitigation Decision
SAP	Scientific Advisory Panel (EPA)
USDA	United States Department of Agriculture
USGS	United States Geological Survey
VFS	Vegetative Filter Strip

I. INTRODUCTION

Petitioners Bayer CropScience LP and Nichino America, Inc., (hereafter "Registrants," or where necessarily referred to individually, "Bayer" or "Nichino") want this tribunal to believe that the issues in this case are legally and factually complex. But in fact, this is a simple case that can and should be easily resolved.

After reviewing the initial application for registrations for flubendiamide, EPA determined there were uncertainties and risks of concern regarding flubendiamide's mobility, stability/persistence, accumulation in soils, water columns and sediments, and the toxic nature of the primary degradate known as des-iodo to aquatic invertebrates. EPA communicated these concerns to the Registrants and identified conditions of registration that would allow EPA to issue the requested registrations. As is described more fully below, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is required to make a finding that the pesticide will not cause unreasonable adverse effects on the environment taking into account its risks and benefits before it grants a registration.

Because of EPA's concerns related to the possibility that flubendiamide, a persistent chemical with significant aquatic toxicity, could get into, and remain in, the aquatic environment, the Agency identified three types of conditions that could enable it to make a no unreasonable adverse effects determination for a limited period of time: use conditions (including use of a vegetative buffer) that might help prevent flubendiamide from getting into water; data-generation conditions to resolve whether flubendiamide would get into water; and an expiration condition that would limit the registration to five years unless the aquatic-risk issue were satisfactorily resolved. EPA and the Registrants communicated throughout July 2008 concerning the wording of the conditions that would enable EPA to make the no unreasonable adverse effects finding. On

August 1, 2008, EPA granted, and Registrants thereafter accepted, the conditional registrations that led to this proceeding; after the discussions, the condition that started out as an automatic expiration after five years had changed into the condition at issue in this case: a requirement for the Registrants to request a voluntary cancellation, if after review of required new data EPA determined that continued registration would cause unreasonable adverse effects on the environment despite the mitigation measures. As discussed below, EPA believes it is clear the Registrants understood EPA's rationale for the cancellation condition, and accepted both this particular condition and all the other conditions of their registrations. Registrants have provided no evidence in their Motion to suggest that Registrants ever, until very recently, voiced any concern about these conditions.

Had Registrants: (1) refused the condition, (2) applied post-registration for an amendment to remove the conditions, or (3) applied post-registration for a new registration without the conditions, and EPA denied any of these requests, Registrants would have been entitled to a denial hearing under FIFRA section 3(c)(6). A denial hearing would have been the proper venue for what the Registrants ask for here – a full scientific hearing on whether they are entitled to registrations for flubendiamide without the voluntary cancellation condition.

But the Registrants cannot fail to comply with conditions of registration and then avoid the consequence specified in FIFRA section 6(e), which was expressly noted in the approval notices for their registrations. While the expiration date of the registrations was extended as new information was evaluated, not once in over the seven years since EPA originally granted these conditional registrations did the Registrants request new or different registrations without the condition at issue here (more than a year past the time allowed to challenge the original registration decision based on the general statute of limitations). In fact, the Registrants did not

voice any concern with these conditions until EPA sent them a letter explaining that the Agency would be invoking the conditions they had agreed to. If this Tribunal determines that the cancellation conditions were unlawful, the ramifications are great. First, because EPA's decision to issue the initial registrations depended in no small part on the conditions, including the cancellation condition, the flubendiamide registrations at issue would be invalid because EPA has never made a finding that without all of the conditions the FIFRA findings necessary to support the registrations could be made. Second, if registrants experiencing "buyer's remorse" are allowed to ignore a condition of registration that they do not like, EPA would have to reconsider whether its current practice of approving conditional registrations is adequate to prevent unreasonable adverse effects. If EPA is unable to rely on registrants' compliance with the terms and conditions of registration, EPA will become less able to make the finding that the terms and conditions of a pesticide's registration are sufficient to conclude that the pesticide will not cause unreasonable adverse effects. Such a scenario would impact many companies and applications not involved in this proceeding, and slow the introduction of promising new pesticide products into the market. The likely result would be that growers, registrants, and the environment would all suffer. *See* Respondent Attachment A at 2 (Letter from Jack Housenger (EPA Office of Pesticide Programs) to Peter Jenkins, Center for Food Safety (Mar. 28, 2016)). Therefore, the focus in this case should not be on whether the conditions were lawful, because without the conditions the initial FIFRA finding of no unreasonable adverse effects is unsupported and the registration itself should be considered invalid. Instead, the proper focus of this section 6(e) proceeding should be on whether the Registrants have complied with the conditions of registration.

II. SUMMARY OF ARGUMENT

The Registrants want this Tribunal to ignore the fundamental facts of this case, and instead go beyond the statutory scope of the FIFRA section 6(e) proceeding where Registrants hope facts might be more in their favor. While the Registrants dress up their plea in terms of "powerless" registrants "forced" by EPA to accept registrations with "unlawful" conditions, the simple fact is that the Registrants now regret the best deal they were able to get in 2008 and want this tribunal to give them not merely a "do-over," but a registration on their own terms, irrespective of the requirements of FIFRA. Registrants seek to avoid the cancellations that the following undisputed facts make inevitable:

- In 2008, EPA approved – and Registrants accepted – conditional registrations issued under FIFRA section 3(c)(7).
- In 2016, Registrants failed to comply with a condition of those registrations.
- EPA issued a notice of intent to cancel pursuant to FIFRA section 6(e) based on the Registrants' failure to comply with a condition of registration.
- In this FIFRA section 6(e) proceeding the only matters for resolution are whether the conditions have been satisfied within the time provided, and whether EPA's determination with respect to the disposition of existing stocks is consistent with FIFRA.

Because these facts are beyond dispute, the Registrants, in their Motion for Accelerated Decision, choose to challenge EPA's authority to proceed under FIFRA section 6(e). The Registrants' challenges can be grouped into two basic arguments:[1]

- Registrants contend that the cancellation conditions were unlawfully included in the flubendiamide registrations and (at least implicitly) contend that they should

[1] The Registrants have also larded their Motion with claims regarding the risks and benefits of the flubendiamide products. Although EPA generally disagrees with those claims, they simply are not germane to the questions at issue in the Motion (i.e., whether the cancellation conditions are lawfully part of the flubendiamide registrations, and if so, whether the Respondents or others have a right to a FIFRA section 6(b) hearing that takes precedence over the Agency's authority to cancel pursuant to FIFRA section 6(e)) and therefore require no response.

be severed from the registrations so that failure to comply with those conditions should not be grounds for cancellation under FIFRA section 6(e).

- Registrants contend that EPA's 2016 determination that continued registration of the flubendiamide product would cause unreasonable adverse effects necessarily requires that EPA afford Registrants and other adversely affected persons a hearing in accordance with FIFRA section 6(b).

These contentions are without merit, and EPA discusses below the reasons why. The first of the two above-listed contentions is addressed in section VII.A, and the second in section VII.C. However, this detailed response to the Registrants' contentions should not distract the Tribunal from the simple facts that must inevitably dictate the outcome of the case, which are that Registrants have failed to meet conditions of their registrations, and their flubendiamide products are therefore subject to the cancellation procedures set forth in FIFRA section 6(e).

III. PROCEDURAL HISTORY

On February 29, 2016, EPA signed and sent to Registrants by both email and certified mail a Notice of Intent to Cancel (NOIC) the flubendiamide registrations under FIFRA section 6(e). This Notice was shortly thereafter published in the Federal Register. 81 Fed. Reg. 11,558 (Mar. 4, 2016). Following the publication of the NOIC in the Federal Register, on March 31, 2016, Registrants filed a request for hearing as well as their objections to the cancellation. On April 7, 2016, a group of growers filed an amicus brief in support of the Petitioners. On April 11, 2016, CropLife America, a trade association representing pesticide registrants also filed an amicus brief in support of the Petitioners. Also on April 11, 2016, Registrants filed their Motion for Accelerated Decision. On April 15, Center for Biological Diversity filed an amicus brief in support of EPA. EPA files this opposition to the Registrants' Motion for Accelerated Decision. To the extent that EPA finds that additional response to contentions of the amici is appropriate, EPA will file such response by April 22, 2015, in accordance with the Order of April 8, 2016.

A. FIFRA Statutory and Regulatory Background

EPA regulates pesticides under both FIFRA and Federal Food, Drug, and Cosmetic Act (FFDCA). FIFRA sets forth a federal licensing scheme for the sale, distribution and use of pesticides; FFDCA establishes the mechanism and standards by which EPA must set tolerances (allowable levels) for pesticide residues in food. As a general matter, as set forth in FIFRA section 3(a), a pesticide must be registered by EPA before it can be distributed or sold in the United States.

B. The Federal Insecticide, Fungicide, and Rodenticide Act

The principal purpose of FIFRA is to regulate the sale, distribution and use of pesticides (through registrations) while protecting human health and the environment from unreasonable adverse effects associated with pesticides. *See generally* FIFRA section 3. Under FIFRA, EPA registers a pesticide only after conducting an extensive scientific review of the risks, and when appropriate, the benefits of that pesticide to determine whether the use of the pesticide causes "unreasonable adverse effects on the environment."[2] "A FIFRA registration is a product-specific license describing the terms and conditions under which the product can be legally distributed, sold, and used." *Reckitt Benckiser, Inc. v. EPA*, 613 F.3d 1131, 1133 (D.C.Cir.2010).

FIFRA governs the sale, distribution and use of pesticides. The Act makes it unlawful, subject to certain exceptions, for any "person in any State [to] distribute or sell to any person any pesticide that is not registered" under the Act. FIFRA section 3(a); *see also* FIFRA section

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[2] "Unreasonable adverse effects" is defined, in part, as "(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." FIFRA section 2(bb)(1). A second prong of this definition was added in 1996 and incorporates the FFDCA safety standard. It is discussed in more detail in the FFDCA section below.

12(a)(1)(A). Thus, a registration granted by EPA under FIFRA is a license that establishes the terms and conditions under which the pesticide may be lawfully sold, distributed, and used. *See* FIFRA section 3(c)(1) (A)-(F), FIFRA section 3(d)(1); *see also Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199, 1204 (9th Cir. 2002) (observing that FIFRA sets forth a comprehensive regulatory scheme for controlling the use, sale, and labeling of pesticides).

Under FIFRA section 3(c)(5), EPA must approve the registration of a pesticide if the Agency determines that (1) the pesticide's composition warrants the claims to be made for it, (2) labeling and other materials required to be submitted comply with FIFRA's requirements, (3) the pesticide will perform its intended function without "unreasonable adverse effects on the environment," and (4) when used "in accordance with widespread and commonly recognized practice," the pesticide will not generally cause unreasonable adverse effects on the environment. The burden of demonstrating that a pesticide meets this standard is on the applicant seeking registration of that pesticide, and continues as long as the registration remains in effect. *Environmental Defense Fund v. EPA*, 548 F. 2d 998, 1004, 1012-18 (D.C. Cir. 1976, *cert. den.*, 431 U.S. 925 (1977).

C. Registering Pesticides Conditionally under FIFRA Section 3(c)(7)

To grant any registration under FIFRA, EPA must determine, that among other things, use of the pesticide will not result in unreasonable adverse effects to human health and the environment. However, as this same standard is used throughout FIFRA for a variety of different regulatory actions,[3] it is necessarily context dependent: For example, when EPA

[3] See e.g., FIFRA section 3(a) (authority to issue rules limiting sale and distribution of unregistered pesticides); FIFRA section 3(c)(3)(B) (allowing registration where differences in labeling or formulation would not significantly increase the risk of unreasonable adverse effects); FIFRA section 3(d)(2) (authority to change the classification of a pesticide from general use to restricted use if necessary to prevent unreasonable adverse effects); FIFRA section 5(e)

recently determined that an emergency use authorization issued under FIFRA section 18 for use of a certain pesticide product to control plant-parasitic nematodes on carrots in Michigan met the no unreasonable adverse effects standard for that particular emergency use in Michigan, that determination did not constitute a determination that the pesticide product would not cause unreasonable adverse effects if used on carrots in another state, nor that the pesticide would not cause unreasonable adverse effects if used on a permanent basis within Michigan pursuant to a special local needs registration under FIFRA section 24(c),[4] nor that the pesticide would not cause unreasonable adverse effects when used nationwide under a section 3 registration:

> EPA has not made any decisions about whether fluensulfone meets FIFRA's registration requirements for use on carrots or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance decision serves as a basis for registration of fluensulfone by a State for special local needs under FIFRA section 24(c). Nor does this time-limited tolerance by itself serve as the authority for persons in any State other than Michigan to use this pesticide on the applicable crops under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. 81 Fed.Reg. 11,121, 11,122-23 (March 3, 2016)

To make the no unreasonable adverse effects determinations for nationwide registrations as requested for flubendiamide, EPA generally requires more than 100 different scientific studies and tests from applicants.[5] These tests generally evaluate whether a pesticide has the potential to

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(authority to issue an experimental use permit (by implication from the authority to revoke for unreasonable adverse effects)), FIFRA section 6(a)(2) (requiring reporting of information concerning unreasonable adverse effects); 40 C.F.R. section 162.153(c) (state special local needs registrations); 40 C.F.R. section 166.25(b) (emergency exemptions).

[4] FIFRA section 24(c) provides that, under certain conditions, states may register additional uses of federally registered pesticides formulated for distribution and use solely within that state to meet special local needs.

[5] The general data requirements applicable to obtaining pesticide registrations are set forth in 40 C.F.R. Part 158.

cause adverse effects on humans, wildlife, fish, and plants, including endangered species and non-target organisms, as well as possible contamination of surface water or ground water from leaching, runoff, and spray drift. Potential human risks range from short-term toxicity to long-term effects such as cancer and reproductive system disorders.[6]

FIFRA section 3(c)(7) authorizes EPA to conditionally register pesticides under certain well-defined circumstances.[7] Pertinent to this case is the authority to issue conditional registrations for new active ingredients under FIFRA section 3(c)(7)(C). As with all pesticide registrations, the first step in the Agency's evaluation is to determine whether a pesticide's proposed use – taking into account all terms and conditions of registration relevant to that use – meets the registration standard to ensure the protection of human health and the environment. Assessing whether a pesticide meets the "no unreasonable adverse effects" standard under FIFRA is a complicated determination of assessing risks and benefits of the pesticide as well as the consideration of any uncertainties in these assessments. Respondent Attachment B ¶¶ 4-9 (Declaration of Susan T. Lewis). The specific terms and conditions of each registration are therefore integral and inextricably linked to the registration decision.

FIFRA section 3(c)(7)(C) provides that EPA may conditionally register a pesticide containing an active ingredient not in any currently registered product "for a period reasonably sufficient for the generation and submission of required data (which are lacking because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement) on the condition that by the end of such period the Administrator

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[6] For further details see https://www.epa.gov/pesticide-registration/about-pesticide-registration.

[7] FIFRA section 3(c)(7)(A) conditional registrations are issued for pesticides that are identical or substantially similar to a currently registered pesticide. FIFRA section 3(c)(7)(B) are conditional new use registrations.

receives such data and the data do not meet or exceed risk criteria enumerated in regulations issued under this Act, *and on such other conditions as the Administrator may prescribe*." [emphasis added]. *Id.* Additionally, EPA may only grant such a registration if the Agency determines that during the period to meet the conditions set forth in the registration, the use of the pesticide "will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest." *Id.* As described more fully below, if the registrant does not comply with all the conditions, FIFRA mandates that EPA shall cancel the registration pursuant to FIFRA section 6(e).

Consistent with the FIFRA statutory provisions that authorize EPA to impose conditions beyond data, FIFRA's implementing regulations in 40 C.F.R. Part 152 subpart F further explain EPA's process. *See* 40 C.F.R. section 152.112 (a), (b), (d), and (f) – (h), 40 C.F.R. section 152.114 and 40 C.F.R. section 152.115 (stating that EPA may impose conditions beyond just data). Specifically, 40 C.F.R. section 152.115(c) states, "[t]he Agency may establish, on a case-by-case basis, other conditions applicable to registrations to be issued under FIFRA section 3(c)(7)." While 40 C.F.R. section 152.115(b)(2) explains that the appropriate statutory provision for cancelling a FIFRA section 3(c)(7)(C) registration for failing to submit data is FIFRA section 6(e), other provisions in 40 C.F.R. section 115 make clear, consistent with the statutory language in FIFRA section 3(c)(7), that failure to comply with other conditions of registration can also lead to cancellation under FIFRA section 6(e). 40 C.F.R. section 152.115(c) specifically restates the statutory provision that EPA "may establish on a case-by-case basis, other conditions applicable to registration to be issued under FIFRA sec. 3(c)(7)." The very next paragraph in 40 C.F.R. section 115(d), then makes clear that "[i]f *any condition* of the registration of the product is not satisfied, or if the Agency determines that the registrant has failed to initiate or pursue

appropriate action towards fulfillment of *any condition*, the Agency will issue a notice of intent to cancel under FIFRA section 6(e)." [emphasis added] The clear meaning of the Statute and EPA's implementing regulations is that EPA may require conditions for registrations issued under FIFRA section 3(c)(7)(C) that are not related to the generation of data, and that failure to comply with any of such conditions leads to cancellation pursuant to FIFRA section 6(e). In the case of flubendiamide, EPA appropriately determined a condition was not met and issued a notice of intent to cancel under FIFRA section 6(e).

D. Cancellation under FIFRA Section 6(e) for Conditional Registrations

As referenced in the section above, FIFRA section 6(e)(1) provides that "The Administrator shall issue a notice of intent to cancel a registration issued under section 3(c)(7) of this Act if (A) the Administrator, at any time during the period provided for satisfaction of any condition imposed, determines that the registrant has failed to initiate and pursue appropriate action toward fulfilling any condition imposed, or (B) at the end of the period provided for satisfaction of any condition imposed, that condition has not been met."

Additionally, EPA's regulations implementing FIFRA at 40 C.F.R. section 152.115(d) state that if any condition of the registration of the product is not satisfied, or if the Agency determines that the registrant has failed to initiate or pursue appropriate action towards fulfillment of any condition, the Agency will issue a notice of intent to cancel under FIFRA section 6(e).

E. FIFRA Section 6(f) Voluntary Cancellation Process

FIFRA section 6(f) provides the process by which registrants may request EPA to cancel their registrations or amend registrations to terminate specific uses of the pesticide. This is

pertinent because, as discussed in more detail below, one of the conditions of the flubendiamide registrations was that under certain circumstances the Registrants were obligated to submit requests to voluntarily cancel in their registrations pursuant to FIFRA section 6(f). The Registrants' failure to satisfy this condition of registration is the basis for this section 6(e) cancellation proceeding. Pursuant to FIFRA section 6(f)(1)(B), before EPA can act on a request to voluntarily cancel a registration or terminate uses, the Agency must publish notice of the receipt of the request in the Federal Register and provide for a public comment period where growers and other stakeholders may submit comments on the proposed cancellation.[8] FIFRA section 6(f)(1)(C) specifically provides for an extended comment period when a cancellation or use termination involves minor agricultural uses, except that the statutory text further provides (at section 6(f)(1)(C)(ii)) that the extended comment period can be waived either on the request of the registrant or "if the Administrator determines that the continued use of the pesticide would pose an unreasonable adverse effect on the environment." Thus Congress clearly contemplated that section 6(f) could be used even when EPA determined that a pesticide caused unreasonable adverse effects on the environment. If, after review of the comments, EPA determines that the cancellation or termination of uses should be granted, the Agency would issue a cancellation order. The cancellation order would provide details on any existing stocks allowance consistent with the authority provided in FIFRA section 6(a)(1) and the Agency's existing stocks policy.[9]

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[8] The length of the comment period varies depending on the type of request, but is no less than 30 days. When a registrant requests voluntary cancellation of their registration, for whatever reason, the comment period is the only process growers have even though the statute specifically recognizes that voluntary cancellations can include pesticides that cause unreasonable adverse effects. *See* FIFRA section 6(f)(1)(C)(ii).

[9] 56 Fed. Reg. 29,362 (June 26, 1991).

IV. FLUBENDAMIDE BACKGROUND

On April 6, 2006, the Registrants jointly submitted an application for registration of a flubendiamide technical product. In addition, the Registrants submitted applications for registration of two flubendiamide end-use products. At that time, flubendiamide was a new active ingredient, not previously registered by EPA. During EPA's evaluation of the applications, the Agency found risks of concern and discussed these with the Registrants.

Because of the uncertainties of how flubendiamide and its degradate des-iodo would accumulate in the aquatic environment and potentially pose risk to freshwater benthic invertebrates, EPA determined that certain conditions were necessary in order for EPA to be able to make a no unreasonable adverse effects determination. Respondent Attachment C at 8-9 (EPA Decision Memorandum for Registration of Flubendiamide (Aug. 1, 2008)). One condition of the flubendiamide registrations, as established in the Preliminary Acceptance Letter (PAL), Petitioner Exhibit 8,[10] required that if the Agency makes a determination that further registration of the flubendiamide technical and end-use products would result in unreasonable adverse effects on the environment, within one week of this finding, the Registrants must submit a voluntary cancellation of the flubendiamide technical and all end use products. Per the Agency's Notice of Registration (NOR), the Registrants' original release for shipment of the flubendiamide products constituted acceptance of the conditions of registration expressly including those specified in the

[10] The PAL was EPA's July 31, 2008, summary of the conditions under which it was prepared to issue flubendiamide registrations, and memorialized certain conditions that had been negotiated between EPA and the Registrants. The Registrants signed the PAL concurring on the proposed conditions on July 31, 2008, and the PAL was subsequently incorporated by reference into each of the flubendiamide registrations.

PAL. Petitioner Exhibit 7 at p. 2 (Notices of Registration for Flubendiamide Technical (EPA Reg. No. 71711-26) and Belt SC Insecticide (EPA Reg. No. 264-1025) (Aug. 1, 2008)).

While EPA maintains that the Agency's assessment of the science leading to its 2008 registration decision and its 2016 decision to invoke the voluntary cancellation condition in the registrations are not at issue in this proceeding, EPA is providing some information on that assessment here solely in order that the Tribunal should understand that there is another side to the story presented in the Registrants' Motion. EPA is not presenting this summary of the factual basis for EPA's 2008 registration or EPA's 2016 invocation of the voluntary cancellation conditions to convince the Tribunal that EPA's decisions were correct, as that is not an appropriate issue in this proceeding.

At the end of three years of water monitoring, the Registrants submitted the final farm pond water monitoring reports. In its review, EPA identified several issues with this monitoring data, but recognized that the monitoring data showed clear evidence that both flubendiamide and des-iodo accumulated in the ponds monitored. The accumulation measured in the first 3 years of the pond data least impacted by the identified issues largely matched the initial 3 years of concentration predictions of EPA's aquatic exposure modeling. EPA concluded that earlier imposed vegetative buffers were not large enough to mitigate the ecological risks posed by flubendiamide applications. EPA concluded the original and subsequent ecological risk assessments performed by the Agency adequately reflected the risks posed by flubendiamide applications and therefore rejected the Registrants' argument that the label-required 15-foot VFSs were adequate to prevent risks of concern.

The Agency review, provided to the Registrants on February 20, 2015, indicated that both flubendiamide and des-iodo were accumulating in all of the farm ponds' overlying water,

sediment, and pore water; therefore, the 15-foot VFSs were ineffective at preventing flubendiamide and des-iodo from accumulating in aquatic systems downstream of the fields to which flubendiamide had been applied. A series of meetings between EPA scientists and the Registrants' scientists occurred between March 2015 and January 2016, where the Agency continued to engage in dialogue about the referenced conditional data and the environmental risk conclusions. After review of all the Registrants' data submissions and previous risk assessments, EPA's conclusions on the environmental risks posed by flubendiamide and des-iodo today are consistent with the 2008 conclusion that "Flubendiamide and the des-iodo degradate's overall stability/persistence suggests that they will accumulate in soils, water column, and sediments with each successive application." Respondent Attachment C at 7.

The PAL was designed so that the conditional registrations for flubendiamide would end July 31, 2013, either through amendment or voluntary cancellation. Registrants requested, and EPA agreed to, several extensions to the conditional registration expiration date, to facilitate submission and review of the 3-year farm pond water monitoring study (submitted December 22, 2014). The final extension to January 29, 2016 allowed EPA to host a final technical discussion between its scientists and the Registrants' scientists on January 6, 2016, related to the conditional data and the EPA's conclusions related to flubendiamide. This extension also allowed additional time for EPA to review 2 newly submitted studies (an aqueous photolysis study and a spiked sediment study) and to consider the most recent label proposal submitted by the Registrants on January 8, 2016. Petitioner Exhibits 10, 12, 13, 15, and 16 (Flubendiamide Registration Extension Letters).

The agreed-upon conditions in the registration included the requirement that if EPA informed the Registrants that further registration of the flubendiamide technical and end-use

products would result in unreasonable adverse effects on the environment, the Registrants would within one week of such notification submit a request to voluntarily cancel these registrations. On January 29, 2016, EPA sent a letter to the Registrants explaining that after reviewing all the information provided by the Registrants as well as other information, and after a series of meetings between EPA and the Registrants, the Agency came to the conclusion that further registration of these pesticide products would result in unreasonable adverse effects on the environment. Petitioner Exhibit 17 (Letter from Jack Housenger (EPA Office of Pesticide Programs) re: Request for Voluntary Cancellation of Flubendiamide Registrations (Jan. 29, 2016). This letter started the one week clock for the Registrants to request voluntary cancellation under FIFRA section 6(f). On February 5, 2016, the Registrants responded to EPA's January 29th letter stating that the registrant was declining to request voluntary cancellation of its products as required by the conditions of registration. At this point, EPA issued a Notice of Intent to Cancel these pesticide products pursuant to FIFRA section 6(e), and did so on March 4, 2016. Petitioner Exhibit 18 (Letter from Dana Sargent (Bayer CropScience LP) re Refusal to Request Voluntary Cancellation of Flubendiamide Registrations (Feb. 5, 2016).

V. ARGUMENT

A. The Agreed-Upon Conditions On Petitioners' Registrations Are Lawful Under FIFRA And Its Implementing Regulations

The Registrants contend that the cancellation conditions were unlawfully included in their flubendiamide registrations and (at least implicitly) contend that they should be severed from the registrations so that failure to comply with those conditions should not be grounds for cancellation under FIFRA section 6(e). EPA maintains that the cancellation conditions are

lawful, were accepted by the Registrants, and remain material elements of the flubendiamide registrations.

In 1978, FIFRA was amended to add section 3(c)(7), which allows for registration of products under special circumstances. Subsections (A) and (C) of Section 3(c)(7) were drawn from the Senate version of the bill, S. 1678. H.R.Rep. No. 95–1560 at 34. The purpose of the amendment was to address the backlog that existed in the registration process. S.Rep. No. 95–334 at 3. One of the "serious impediment[s]" identified in the registration program at that time was "EPA's inability to issue registrations on a conditional basis." *Id.* at 4. In particular, there existed a "double standard" between producers with older registrations and those seeking new registrations. As the EPA requirements for new registrants grew more stringent, new registrants could find themselves held to higher standards than producers who held older registrations, even if their respective products were nearly identical. *Id.* The 'unforeseen and undesirable twists to the law would be eliminated' by giving the EPA 'authority to conditionally register pesticides.' *Id.* In *Woodstream Corp. v. Jackson*, 845 F.Supp, 2d 174 (D.D.C. 2012) (*Woodstream II*), the District Court for the District of Columbia upheld EPA's authority to include appropriate, non-data-related, conditions on pesticide registrations, including expiration dates. *Woodstream II* at 177.

i. Non-Data Conditions Are Lawful

The initial registrations of flubendiamide were issued pursuant to FIFRA section 3(c)(7)(C), which as noted *supra* specifically authorizes the inclusion of conditions other than data conditions. In a case involving a condition that provided for automatic termination of a registration on a specific date, a court determined that the broader conditional registration authority in Section 3(c)(7) of FIFRA, which does not include the specific language in 3(c)(7)(C)

concerning additional conditions, also authorized EPA to include in conditional registrations conditions that were not related to data generation:. "The plain language of the statute does not restrict EPA's authority as to the type of conditions that may be placed on registrations. It merely requires that, as with all registrations, the product not have 'unreasonable adverse effects on the environment.' FIFRA section 3(c)(7). While the submission of test data is the only condition mentioned explicitly, the language does not expressly bar other language." *Woodstream II* at 180. And EPA has long interpreted FIFRA as allowing it to grant registrations subject to a variety of conditions. Since 1988, EPA's regulations have made clear that EPA could impose conditions beyond just data. In particular, as noted *supra*, 40 C.F.R. section 152.115(c) states that "[t]he Agency may establish, on a case-by-case-basis, *other conditions* applicable to registrations to be issued under FIFRA sec. 3(c)(7)." 40 CFR section152.115 (c) (emphasis added). This regulation recognizes that a conditional registration may contain conditions that are not tied to the requirement to submit data, and the principle was upheld by the *Woodstream II* court: "Given EPA's history of placing conditions on registration, together with case law illustrating that placing conditions on registrations and licenses is a frequent and important adjunct to an agency's power to grant registrations and licenses at all, it is clear that EPA has the authority to impose conditions other than test data requirements when granting registrations or amendments to registrations." *Woodstream II* at 182.

The process set forth in FIFRA section 6(e) authorizes EPA to issue a notice of intent to cancel for failure to meet any condition of a conditional registration issued under FIFRA section 3(c)(7). Consistent with the statute, EPA's implementing regulations at 40 C.F.R. section 152.115(b)(2) states that the appropriate statutory provision for cancelling a FIFRA section 3(c)(7)(C) registration for failing to submit data is FIFRA section 6(e). While EPA agrees with

the Registrants that all the flubendiamide conditions based on submission of data have been met, the Registrants have failed to comply with the crucial cancellation condition. As noted supra, the regulation at 40 C.F.R. section 152.115(d) goes further than section 152.115(b)(2) and states, "[i]f *any* condition of the registration of the product is not satisfied …, the Agency will issue a notice of intent to cancel under FIFRA 6(e)." 40 C.F.R. 152.115(d) (emphasis added) As the facts here clearly fit within the statutory and regulatory framework for cancellation pursuant to FIFRA section 6(e), and consistent with the decision in *Woodstream II,* EPA lawfully issued the NOIC pursuant to FIFRA section 6(e) when Registrants failed to comply with the condition of their flubendiamide registrations.

ii. The Cancellation Condition Is Lawful

The *Woodstream II* court not only upheld EPA's authority to require non-data conditions in principle, it specifically upheld EPA's authority to require conditions that would cause the automatic cancellation of a registration, for risk-based reasons, and without a formal hearing. "The conditions imposed by EPA on Woodstream's products set forth essentially three requirements: (1) Woodstream must bring its products into line with the requirements of [a specified EPA policy decision]; (2) Woodstream must comply with [those requirements] by June 4, 2011 … (3) if Woodstream does not bring its products into line with [those requirements] by June 4, 2011, it will lose the registrations upon which the conditions are placed." *Woodstream II* at 182. The court held that EPA's decision to require the conditions requiring automatic

cancellation of the registrations, for risk-based reasons,[11] and without a formal hearing,[12] was "entitled to deference, and was not arbitrary or capricious." *Woodstream II* at 184.

Consistent with *Woodstream II*, EPA initially proposed that the flubendiamide registrations automatically expire in July 2013 unless EPA, at its sole discretion, extended the registration. Respondent Attachment D (Emails between Clive A. Halder, Director of Regulatory Affairs, BayerCropScience; Danielle A. Larochelle, Registration Product Manager, Bayer CropScience and EPA Registration Division (July 17, 2008 thru July 31, 2008)). Through the ensuing negotiations between EPA and the Registrants, this transformed into the final PAL, where automatic expiration was replaced by provisions whereby EPA would first have to communicate to the Registrants an affirmative finding that continued registration of the products would result in unreasonable adverse effects, and Respondents would within one week submit voluntary requests for cancellation. Respondent Attachment B at ¶ 20. This final PAL condition allowed the Registrants to distribute and sell flubendiamide longer than they would have with the automatic cancellation upheld in *Woodstream II*, which would have unquestionably been a lawful condition of registration. Inasmuch as the Registrants succeeded in negotiating for terms

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[11] The court noted that EPA approved the Woodstream registrations subject to the following unmistakably risk-based condition:

> "This registration is not consistent with the Agency's May 28, 2008, 'Risk Mitigation Decision for Ten Rodenticides.' EPA anticipates cancellation of those existing products that are not consistent with the Risk Mitigation Decision to occur no later than June 4, 2011. In the meantime, EPA is approving new registrations and amendments to existing registrations of rodenticide bait products, on a time limited basis, so long as the registrations do not present greater risks of unreasonable adverse effects than existing products. Accordingly, this registration is approved only subject to the condition that the registration shall expire on June 4, 2011." *Woodstream II* at 178.

[12] "At issue in this case is the right to impose an expiration date itself, and whether EPA may terminate a registration through the imposition of an expiration date condition." *Woodstream II* at 179.

more favorable to them than the automatic cancellation upheld in *Woodstream II*, they should not be allowed to now argue that the condition is unlawful.

iii. Conditions Serve Important Public Purposes

Insecticides are an important element of modern agriculture, and EPA recognized from the start that flubendiamide could offer many advantages over other registered pesticides: Good efficacy against a major group of crop pests, low toxicity to humans and other vertebrates, low toxicity to beneficial insects (both predatory insects and pollinators), and, by being the first of a new class of chemistry (phthalic acid diamides), a new tool against pests developing resistance to other insecticides. On account of these advantages, EPA readily understood that flubendiamide could be an attractive supplement to, or even replacement for, older, more toxic insecticide products.

However, EPA had significant concerns when considering the flubendiamide application – stability and persistence of flubendiamide residues in the environment as well as the toxicity to aquatic organisms of the chemical and its degradate. Toxic chemicals that do not readily break down into other relatively low-toxicity chemicals can remain in the environment where they continue to have toxic effects, can accumulate in increasing concentrations in certain species or environmental media, can disperse far beyond the place they were originally applied, and can manifest unanticipated adverse effects long after their initial application due to their persistence. Because removing widely-dispersed, persistent toxic chemicals from the environment can be extremely costly, difficult, and time-consuming, it is consistent with and reasonable under FIFRA for EPA, when considering risks, benefits, and uncertainties, to exercise particular caution when considering allowing the introduction of such chemicals into the environment. In order to mitigate ecological risks in other situations involving persistent and toxic insecticides,

EPA has limited similar insecticide products to greenhouses, perimeter structural treatments, or indoor uses, while prohibiting field crop uses.[13] Respondent's Attachment C at 9 (EPA Decision Memorandum for Registration of Flubendiamide (Aug. 1, 2008)). In response to another registrant's opposition to EPA's authority to require cancellation conditions, the District Court for the District of Columbia noted that conditional registrations provide significant societal benefits and EPA's decision on the appropriateness of conditions is entitled to deference:

> Pursuant to its statutory mandate, EPA balanced the potential for unreasonable adverse effects on the environment with the impact of refusing registration and/or amendments to registrations for a number of rodenticides, which could impact consumer pest control needs. Had EPA not granted the conditional registrations and amended registrations on Woodstream's products, its only other option would have been to deny those registrations outright. ... EPA's condition allowed Woodstream three unrestricted years in a market it would not have been able to enter otherwise, while Woodstream could also use that time to come into compliance with the RMD. EPA's decision is entitled to deference, and was not arbitrary or capricious.. *Woodstream II* at 184 (citing *United States v. Mead Corp.*, 533 U.S. 218 (2001)).

The information available at the time of flubendiamide's initial registration indicated reasons for concern about the stability and persistence of flubendiamide and its "des-iodo" degradate in aquatic environments. Respondent Attachment B at ¶¶ 12-16. With some chemicals, similar concerns have been adequately managed with utilization of a vegetative "buffer strip" between treated crops and waterbodies,[14] but the effectiveness of such buffers in capturing and neutralizing flubendiamide was unproven.[15] EPA determined that several further

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[13] For example, EPA has limited registrations for pesticide products containing fipronil to only above-ground spray applications (mostly granular), pet products, termiticide use, structural perimeter use, and fire ant uses. This type of mitigation was not an option for flubendiamide.

[14] For example, EPA has required vegetative buffer of up to 500 feet between areas treated with the pesticide terbufos and surface waters. See https://archive.epa.gov/pesticides/reregistration/web/html/terbufos_ired_fs.html.

[15] Each pesticide has a different chemical structure which affects how the pesticide will move on a buffer strip. Pesticides that are more soluble in water will tend to move wherever rainwater

studies would be needed before EPA could authorize an open-ended registration for flubendiamide:

- A run-off study to determine the amount of the flubendiamide retained in buffer strips of various widths
- Monitoring flubendiamide concentrations in receiving waters in watersheds where flubendiamide would be used
- A study of the chemical hydrolysis of the des-iodo degradate
- An aerobic aquatic metabolism study of des-iodo in water and sediments.

EPA could reasonably have denied the applications for flubendiamide registration in the absence of these studies, in which case Registrants would have had no registrations and a right to a hearing under FIFRA section 3(c)(6). Respondent Attachment B at ¶ 15. However, in light of the Agency's successful use of buffer strips in similar situations and the potential benefits of flubendiamide, EPA determined that with the addition of label directions requiring a 15-foot vegetative buffer and the voluntary cancellation condition, the flubendiamide products would not cause unreasonable adverse effects on the environment during a period of time reasonably sufficient to allow the Registrants to generate the necessary studies, and for EPA to determine with reasonable confidence whether flubendiamide would get into water in amounts that could cause unreasonable adverse effects. Accordingly, EPA offered Registrants a time-limited conditional registrations pursuant to FIFRA section 3(c)(7)(C), requiring generation and submission of the studies described above, plus a variety of other conditions including the vegetative buffer. The conditions of these registrations enabled EPA to strike what appeared to

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moves. Pesticides that attach to soil particles tend to move less. To the extent that a pesticide is susceptible to degradation (via sunlight, oxidization, reaction with other chemicals in the environment, etc.) or metabolized by organisms in the soil, it may produce degradates or metabolites whose mobilities differ from the parent chemical.

be the optimal balance (based on the state of scientific knowledge in 2008) between making a promising new pesticide available to agriculture and minimizing the likelihood of unreasonable adverse effects on the environment.

EPA determined that the 15-foot vegetative buffer would be sufficient to prevent unreasonable adverse effects at least in the near term, and while EPA was optimistic that the 15-foot vegetative buffer would be sufficient to prevent unreasonable adverse effects on a permanent basis, EPA acknowledged in 2008 that the effectiveness of such buffers with respect to flubendiamide was unproven and that the Registrants had not yet cited or submitted studies sufficient to support a conclusion that long-term use would not cause unreasonable adverse effects on the environment given the expected persistence of flubendiamide and its des-iodo degradate. Accordingly, each of the flubendiamide registrations also included a condition providing for the expeditious and uncontested cancellation of the registrations in five years, unless EPA were to determine that studies submitted during the interim would support either a permanent registration or another path towards registration. This cancellation condition was necessary in light of the fact that the studies cited in support of the registrations in 2008 were not sufficient to support a permanent registration of flubendiamide products. Since the information available in 2008 was only found sufficient to support the conclusion that the flubendiamide products would not cause unreasonable adverse effects on the environment during a limited period of time reasonably sufficient to allow generation, submission and review of additional studies that *might* prove sufficient to support broader registrations, EPA appropriately included a condition to assure that the flubendiamide registrations with their many conditions would not extend beyond five years if the Agency's concerns and uncertainties were not resolved by then. Respondent Attachment B at ¶ 16.

EPA had substantial concerns with flubendiamide in 2008, and although it cannot be stated with any definitiveness eight years later what would have happened had Registrants declined to accept the registrations with the included conditions, it is clear eight years later that EPA did not determine in 2008 that flubendiamide registrations without time limits would not cause unreasonable adverse effects. Respondent Attachment B at ¶ 20. All EPA determined was that Registrants had submitted evidence sufficient to support a conclusion that conditional flubendiamide registrations would not cause unreasonable adverse effects over the period of time – roughly five years – needed to allow additional studies that might support unconditional registration. Accordingly, EPA proposed to issue conditional registrations that provided that, in the event that the new studies were still insufficient to support a conclusion that unconditional flubendiamide registrations would not cause unreasonable adverse effects over the long term, the registrations could be quickly terminated through an automatic expiration date, thereby minimizing the long-term risks or damage to the aquatic environment. EPA made its concerns and its proposed solutions known to the Registrants, and over a couple of weeks the parties worked together to finalize the conditions of registration memorialized in the PAL. These conditions enabled EPA to keep open the possibility that flubendiamide could eventually be granted a registration of unlimited duration, while also assuring that further adverse effects to aquatic environments could quickly be limited if it turned out that the vegetative buffers were insufficient to resolve environmental risk concerns. While neither side might call the PAL ideal, it clearly represents a mutually agreed-upon process for EPA to decide by September 1, 2013, whether the Registrants had submitted information sufficient to support continued registration, and if not, to trigger a request for voluntary cancellation. Petitioner Exhibit 8.

iv. The Cancellation Condition was Material to EPA's Decision to Grant the Registration

Under FIFRA, the burden of demonstrating that a pesticide satisfies the statutory standard for registration rests at all times on the registrant, applicant, or other proponent of initial or continued registration. *Environmental Defense Fund* at 1004, 1012-18. EPA never determined in 2008 or thereafter that the studies cited by the Registrants in support of their flubendiamide registrations were sufficient to support a conclusion that long-term use of flubendiamide would not cause unreasonable adverse effects on the environment; nor did EPA determine that it had sufficient information to resolve the uncertainties about whether flubendiamide would get into water in amounts that could cause harm to the aquatic environment. Respondent Attachment B at ¶ 16. However, the studies cited by the Registrants were deemed sufficient to support a conclusion that use for five years would not cause adverse effects on the environment that were unreasonable in comparison to the potential benefits of flubendiamide use.

To address the substantial concerns EPA had with respect to flubendiamide, and in particular with respect to long-term use of flubendiamide in light of the uncertainties remaining in EPA's review in 2008, condition number 1 in the PAL specified that "The subject products will be conditionally registered for a period of five (5) years from the date of the 'Notice of Registration.'" Conditions 5 and 7 represent the Registrants' understanding and acknowledgment that the registrations are limited in duration and would be cancelled in five years if EPA determines that continued use would result in unreasonable adverse effects on the environment. Conditions 6 and 8 generally deal with the timing of steps towards either cancellation or a different registration scheme. The remaining conditions of the PAL concern the development and submission of data. Inasmuch as five of the eight conditions in the PAL (and an even higher proportion of the paragraphs in the PAL) concern the quick termination of the

registrations if EPA's concerns remained unresolved, it is impossible to argue that EPA determined in 2008 that long-term use of flubendiamide would not cause unreasonable adverse effects on the environment. *See also* Respondent Attachment B at ¶ 25.

That the ability to quickly cancel the registration was an important factor in EPA's decision to grant the registration is reflected in the Registration Division's 2008 memorandum recommending that the Director of the Office of Pesticide Programs approve the FIFRA section 3(c)(7) registrations: "If there are risk concerns [after review of data, consideration of uncertainties, and mitigation measures] that result in the Agency being unable to determine that there are no unreasonable adverse effects to the environment, the registrants have agreed that the pesticide will be voluntarily cancelled." Respondent Attachment C at 9. This clearly shows that EPA relied upon the mutually agreed-upon conditions in the registration in order to grant the registration. Further evidence of the negotiations that took place concerning the agreed upon conditions can be found in Section v. below.

v. Registrants Knowingly and Willingly Accepted the Voluntary Cancellation Condition

There can be no question that the registrations at issue in this proceeding are conditional registrations, nor can there be any questions as to the terms of those conditions.[16] On Thursday,

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[16] The Registrants agree that the registrations are conditional: "EPA registered flubendiamide in 2008 under FIFRA § 3(c)(7)(C) (conditional registration of a new active ingredient)..." Motion at 20. The Registrants also acknowledge that EPA "granted FIFRA registration for five years to allow the registrants to generate and submit additional data to address potential persistence..." *Id.* The Registrants further describe the PAL conditions, including PAL paragraphs 6(c)(3), 6(d), 8(c)(3) and 8(d), at pages 21-22 of their Motion.

Respondents' acknowledgement of these conditions is somewhat inconsistent, and at some points Respondents' wish that PAL paragraphs 6(c)(3), 6(d), 8(c)(3) and 8(d) were not part of their registrations appears to become so desperate that they have become blind to them: "In this case, EPA has repeatedly confirmed that Bayer and Nichino have satisfied the substantive conditions

July 31, 2008, EPA sent the Registrants a preliminary acceptance letter ("PAL"), wherein EPA formally stated the conditions under which it was prepared to issue a FIFRA section 3(c)(7) conditional registration. The opening sentence of the PAL states unambiguously the conditional nature of EPA's offer: "The products referred to above will be acceptable for registration under section 3(c)(7)(C) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, provided that Bayer CropScience LP (Bayer), as authorized agent for Nichino America, Inc. (Nichino), agree/concur with the following conditions of registration ..." Petitioner Exhibit 8. The bulk of the four-page letter then states the conditions. The final sentence of the PAL – immediately above the signature block for the Registrants' concurring signature – again reaffirms the conditional nature of the registrations that could proceed from concurrence on the PAL: "[The Registrant] hereby concurs with the time-limited conditional registration of the new insecticide flubendiamide under section 3(c)(7)(C) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as outlined in this preliminary acceptance letter, dated July 31, 2008." The Registrants then concurred on the proposed conditions on July 31, 2008.

The PAL included the condition that if, after EPA review of the referenced conditional data, EPA were to make a determination that continued registration of flubendiamide products will result in unreasonable adverse effects on the environment, EPA would notify the Registrants, and within one week of notification of this finding, the Registrants would submit a request for voluntary cancellation of all the flubendiamide registrations. This condition was

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EPA imposed on the flubendiamide registrations." Petitioner Motion at 47. EPA disagrees, and maintains that paragraphs 6(c)(3), 6(d), 8(c)(3) and 8(d) of the PAL establish substantive conditions of registration and it is undisputed that the Registrants have not satisfied those conditions.

neither unexpected nor overlooked by the Registrants: The terms of the PAL were negotiated by EPA and the Registrants, and the Registrants negotiated to get this voluntary cancellation provision in instead of an automatic expiration date. Over a couple of weeks' time, EPA and the registrant worked out the wording of the conditions to be included on the final registration.

EPA's July 17, 2008 draft PAL proposed that the registration automatically expire in July 2013 unless EPA, at its sole discretion, extended the registration. Respondent Attachment D at 1-6. This condition would have been equivalent to the expiration date conditions upheld in *Woodstream II*. The Registrants' counterproposal objected to the language concerning automatic cancellation, but appears to have still presumed a registration that would end on September 1, 2013 unless EPA approved an unconditional registration or the parties agree to another path forward. Respondent Attachment D at 7-10.

Subsequent discussions shifted EPA away from its initial plan for the registrations to just expire on a date certain to a scheme where, if after review of the new studies and discussions with the Registrants, EPA concluded that the products still did not meet the registration criteria for an unconditional registration, the Registrants would be required to submit a request for voluntary cancellation within one week of EPA informing them of a finding of unreasonable adverse effects. The Registrants proposed using the FIFRA section 6(f) voluntary cancellation process which would allow for both an opportunity for public comment and an additional opportunity to influence EPA's decision making.

The Registrants' comments on a July 29, 2008 draft of the PAL illustrate both the Registrants' engagement in the negotiations regarding the process for cancellation and their acquiescence to the process ultimately specified in the PAL:

In an email exchange between EPA and Bayer concerning the negotiations on the conditions for the registration the Bayer representative, Clive Halder, described the status of the negotiations two days before EPA issued the first flubendiamide registration:

> Basically, there is only one remaining 'sore point', ... it appears to allow EPA to demand cancellation without any due process from us. My take is that the Agency would like to avoid having to go through Section 6 cancellation proceedings. We understand this, so have little problem with fitting in the 'fast death' approach, i.e., voluntary cancellation within a week of the decision. From our side, we expect that a fair cancellation demand can only occur after the conditions of part 5(b) and 7(b) have been met, specifically, that all the submitted data have been reviewed [by EPA] alongside all voluntary data submitted by Bayer, plus following a measured dialogue between the scientists. Respondent Attachment D at 16-18.

Mr. Halder's email goes on to propose alternative language that is almost identical to the final language incorporated in the final PAL as paragraphs 6(d) and 8(d).[17] His rewrite of the paragraphs, which he stated "hopefully addressed our collective needs...", offered the following language for EPA's consideration:

> 5(c) If after review of the data, as set forth in 5(b) above, the Agency makes a determination that further registration of the flubendiamide technical product will result in unreasonable adverse effects on the environment, within one (1) week of this finding, Nichino will submit a request for voluntary cancellation of the registration of the flubendiamide technical product. That request shall include a statement that Nichino recognizes and agrees that the cancellation request is irrevocable.
>
> 7(c) If after review of the data, as set forth in 7(b) above, the Agency makes a determination that further registration of the flubendiamide end-use products will result in unreasonable adverse effects on the environment, within one (1) week of this finding, Bayer will submit a request for voluntary cancellation of the registration of the flubendiamide end-use products. That request shall include a statement that Bayer recognizes and agrees that the cancellation request is irrevocable.

[17] The final 6(d) and 8(d) differ from Registrants' 7/30/2008 proposal in only two respects: The insertion of another Registrant-requested clause providing that any voluntary cancellation "be effective no earlier than September 1, 2013," and changes related to paragraph renumbering.

Taken together, the discussions between Registrants and EPA demonstrate that the Registrants were well aware of the cancellation provisions, were materially engaged in shaping those provisions, and ultimately acceded to the cancellation provisions included in the PAL. This exchange not only shows the registrant's involvement in the discussions, it also demonstrates their willing acceptance of the conditions, and negates their notion that they were coerced or threatened into acceptance. Indeed, EPA is not aware of any objection Registrants may have had to the cancellation conditions until late in 2015, when it appeared likely that EPA would invoke the voluntary cancellation condition. Respondent Attachment B at ¶ 24.

However, the primary importance of the PAL in this proceeding arises from the incorporation of its conditions into the terms and conditions of registration established by the Notices of Registration (NOR). The NORs each expressly state that the product is conditionally registered in accordance with FIFRA section 3(c)(7)(C), and incorporate by reference the conditions of registration set forth in the PAL. The NORs state that "release for shipment of these products constitutes acceptance of the conditions of registration as outlined in the preliminary acceptance letter for flubendiamide, dated July 31, 2008. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA." Petitioner Exhibit 7. The Registrants subsequently released each of these products for shipment, thereby accepting the specified conditions of registration.

Thus the Registrants, in both their July 31, 2008 PAL concurrence and in their post-NOR release for shipment of each of the four flubendiamide products – knowingly acknowledged and accepted that their flubendiamide registrations would be FIFRA section 3(c)(7) conditional registrations, and that they would include as a condition that a subsequent failure to satisfy a condition of those registrations might prompt EPA to issue a FIFRA section 6(e) notice of intent

to cancel, in which case the procedures governing the cancellation would be those of FIFRA section 6(e) and not FIFRA section 6(b). "The fact that [a registrant] was forced to make a business choice between accepting amended registrations with conditions and retaining unconditioned registrations does not render EPA's use of the conditions unlawful or arbitrary." *Woodstream II* at 180.

Again, the Registrants' contention that they were forced into agreeing to these necessary conditions is without merit. In fact, after all the back-and-forth between EPA and the registrant, the parties memorialized their agreement in a formal document signed by the Agency and the registrant, the PAL. This agreement acknowledged the registrant's acceptance of the conditions that were necessary for the Agency to issue the registration and nowhere is there evidence of them rejecting or objecting to these conditions.

vi. EPA Did Not Force the Registrants Into Accepting The Conditional Registrations

The Registrants want this tribunal to believe they were "powerless" during the negotiations leading up to the issuance of the registration as well as any time following the granting of the registrations. That could not be further from the truth. The Registrants cannot in good faith argue that they had no choice but to accept the conditional registration. The Registrants are very familiar with the registration process and should be knowledgeable about the options afforded to them under FIFRA. It was not until EPA invoked the conditions in the registration that they began to object to the cancellation condition. Respondent Attachment B at ¶ 24. The Registrants had at least four administrative remedies in the face of EPA's insistence on the cancellation condition: (1) they could have amended their applications for registration to further mitigate aquatic risk in some other way; (2) they could have withdrawn or abandoned

their applications for registration; (3) they could have requested an administrative denial hearing to challenge EPA's refusal to grant unconditional registrations; and (4) they could have accepted the conditional registrations and subsequently submitted an application to amend those registrations to remove the conditions, or applied for a new registration without the conditions, which if either were denied would allow them the opportunity for an administrative denial hearing. In fact, EPA expressly offered Registrants a FIFRA section 3(c)(6) denial proceeding if they chose not to accept the conditional registrations. Petitioner Exhibit 8 at p. 4. Each of the options listed above could have been exercised in 2008 (or thereafter if requesting an amendment or new registration) but instead the Registrants have waited until now (more than seven years since the issuance of the initial registrations) to object to the conditions of their registrations. Furthermore, EPA heard no objections to the conditions either during the inception of the registration or after the issuance. Respondent Attachment B at ¶ 24.

Several of these options were discussed in *Woodstream Corp. v. Jackson*, 2011 U.S. Dist. LEXIS 151994; 2011 WL 8883395 (D.D.C. 2011) (*Woodstream I*) (Preliminary injunction decision) in regard to another registrant's challenge to the conditions of some of its pesticide registrations:

> Plaintiff's first option was to withdraw its request for an amendment. This action would have only affected its bromethalin registrations, as those were not previously subject to the RMD or an expiration date. Had Plaintiff chosen this route, it could have continued to sell its bromethalin products under the terms of its prior registration until EPA initiated Section 6 cancellation [*18] proceedings. At the hearing, Plaintiff said this option was unacceptable because the amendments were commercially valuable to the company. While that may be a business decision for Woodstream to make, it does not negate withdrawal as a valid option.
>
> If Woodstream genuinely needed the commercial benefits of the amended registrations, it had an option to take advantage of those benefits while still challenging the conditions. Under its second option, Plaintiff could have accepted the conditions but immediately filed a new request for an amended

> registration removing the conditions. EPA presumably would have denied such a request, thereby entitling Woodstream to a denial hearing under § 3(c)(6). As that section makes clear, the denial hearing procedures mirror those of a Section 6 cancellation proceeding. *Id.* Woodstream thus could have forced EPA into a denial proceeding while continuing to sell under the amended registrations.
>
> Plaintiff's third option was to seek judicial review of the conditions EPA imposed. See 7 U.S.C. § 136n. Plaintiff finally chose this option, but only after waiting for almost three years. It could have instituted such a challenge in 2008. Having bypassed its first [*19] two options and postponed its third, Plaintiff cannot now claim that EPA's procedures robbed it of alternatives.

Inasmuch as FIFRA provides a variety of opportunities for an applicant for registration to challenge any conditions EPA insists must be part of a pesticide registration, there is no excuse for the Registrants to have sat on their rights for almost eight years and then object only once the voluntary cancellation condition has been invoked. The denial hearing process under FIFRA section 3(c)(6), which Registrants could have sought to initiate at any time in the last eight years, would have been the appropriate forum under FIFRA for them to litigate the scientific issues relevant to whether they were entitled to flubendiamide registrations without the cancellation conditions. This limited proceeding under section 6(e) of FIFRA, with a statutorily imposed time-limit for decision and where the statutory text specifies that the only issue for cancellation is whether Registrants complied with a condition of their registrations, is manifestly not the appropriate forum for Registrants to raise the science issues dotted throughout their Motion and their Request for Hearing and Statement of Objections.

Petitioners contend that they were forced into agreeing to the cancellation conditions memorialized in the 2008 PAL. Although the conditions agreed to for the flubendiamide registrations were unique to those registrations, it is not uncommon for EPA and pesticide registrants to negotiate a variety of appropriate conditions that are needed for a registration to

meet the FIFRA registration criteria – including conditions specifying cancellation procedures.[18] An example of another set of registrations where similar conditions were employed is pet "spot-on" products, where the Agency and a number of registrants, including Bayer Healthcare, LLC[19], worked together to develop necessary conditions of registration including labeling changes to better protect cats and dogs from adverse effect incidents. Those necessary conditions included expiration dates on registrations.

For those spot-on product registrations, EPA determined changes were necessary in the spring of 2009, when EPA noticed an increase in reports of adverse effects to pets involving "spot-on" pesticide products. These liquid flea and tick products are applied to a "spot" on the pet's skin, usually around the back of the neck or shoulder area, are absorbed into the pet's body, and poison fleas and ticks wherever they bite. EPA formed an expert veterinarian team to thoroughly analyze the incident data. *See* https://www.epa.gov/pets/epa-data-evaluation-records-spot-products. In March 2010, EPA determined that improved labeling and other additional product-specific changes would support a determination that the products continued to meet the FIFRA standard for registration as the investigation progressed. Because of uncertainties with the products on the market, EPA stated that henceforth the Agency expected to approve new spot-on products only as conditional, time-limited registrations to allow EPA to evaluate these products post-marketing and take appropriate regulatory action, if needed. *See* https://yosemite.epa.gov/opa/admpress.nsf/eeffe922a687433c85257359003f5340/76d2b52162bcedaa852576e9005c0d97!OpenDocument.

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[18] The following discussion also disputes Croplife America's contention that the flubendiamide registration conditions were unprecedented.

[19] Bayer Cropscience and Bayer Healthcare are both part of the Bayer Group. *See* http://www.bayer.com/en/homepage.aspx.

Among the registrants subsequently applying for registration of spot-on products was Bayer Healthcare, LLC, which agreed to a conditional registration for a spot-on product for use on cats in June 2010 that had an expiration date tied to the release for shipment of its product. *See* https://www3.epa.gov/pesticides/chem_search/ppls/011556-00152-20100624.pdf . In addition to the expiration date, the registrant agreed to non-data conditions on its registration concerning enhanced adverse incident reporting. And, that registration, like the flubendiamide registrations at issue here, stated that the product would be cancelled under FIFRA section 6(e) if the conditions were not met.

The fact that an entity related to Bayer, two years after the flubendiamide registrations were issued, accepted a registration with conditions similar to those included in the flubendiamide registrations further calls into question the notion that Bayer was "powerless" and "coerced" into accepting the flubendiamide conditions. Instead, it suggests the company is either engaging in revisionist history, or feels free to promise whatever is necessary without feeling compelled to keep its word in order to trick the Agency into issuing registrations it might otherwise not be able to issue (because it otherwise could not make the statutorily required findings). Whichever is the case, this Tribunal should not countenance such behavior and should not reward it by going beyond the statutory requirements of section 6(e) and considering Bayer's very untimely complaints about its flubendiamide registrations.

vii. The Cancellation Conditions Are Not Severable From the Flubendiamide Registrations

Registrants argue that their flubendiamide registrations should continue to remain in effect without being subject to either the voluntary cancellation conditions or to cancellation pursuant to FIFRA section 6(e) owing to their failure to comply with the voluntary cancellation

conditions, in effect, asking this Tribunal to rewrite the terms and conditions of their registrations. If one or more terms or conditions of a pesticide registration were found inappropriate or unlawful, EPA maintains that the appropriate remedy would be to invalidate the entire registration and remand the decision to EPA. FIFRA registration is not an abstract approval of a pesticide active ingredient for any and all uses; instead, it is a highly specific determination regarding a particular use or uses of a particular product described in terms of its formulation, labeling, container design, and other terms and conditions of registration. EPA makes its registration eligibility decision on the specific product taken as a whole, and all of its terms and conditions are material.[20] To the extent that certain conditions might be interchangeable (e.g., a decrease in the amount applied per acre might offset a reduction in the interval between application and when workers are allowed back into the field) while still enabling EPA to make the no unreasonable adverse effects finding, each registration is in the end the unique result of a negotiation between EPA and the registrant, and no term or condition can be presumed nugatory. For a reviewing body to strike one term or condition from a registration would be the same as the reviewing body unilaterally approving a registration on terms of its own devising, and would be inconsistent with FIFRA section 3.

EPA's 2008 registration decision was a conclusion that the flubendiamide registrations would not cause unreasonable adverse effects on the environment under the specific terms and conditions specified in those registrations. EPA has never made a determination that flubendiamide products would be eligible for registration under terms and conditions that do not include the cancellation conditions. Since July 2008, the Registrants have requested neither

[20] Because FIFRA section 12(a)(1)(B) prohibits sale and distribution of a registered pesticide with claims that differ from those approved, in some cases EPA does include in a registration non-essential terms requested by the registrant, but that is not the case here.

amendment to remove the cancellation conditions from their existing registrations nor registration of new flubendiamide products without the cancellation conditions. There is therefore no administrative record to support a flubendiamide registration without the cancellation conditions. Accordingly, if a particular term or condition of the flubendiamide registrations were to be found unlawful, the proper remedy would be to void those registrations and remand the decision to EPA.

If, instead of voiding the registrations and remanding the registration decision to EPA, the Tribunal were to rule that Registrants flubendiamide registrations should continue to remain in effect without being subject to either the voluntary cancellation conditions or to cancellation pursuant to FIFRA section 6(e) for failure to comply with the voluntary cancellation conditions, the Tribunal would be making a pesticide registration decision for which EPA has not made the necessary findings. Such a registration decision would plainly be inconsistent with FIFRA, which "places '(t)he burden of establishing the safety of a product requisite for compliance with the labeling requirements . . . at all times on the applicant and registrant.'" *Environmental Defense Fund at* 1004, 1012-18 (*citations omitted*). Inasmuch as the information submitted in 2008 by the Respondents was not found sufficient to support flubendiamide registrations of unlimited duration (i.e., was not sufficient for EPA to conclude that the product would not cause unreasonable adverse effects over the long term), those products remain ineligible for such unlimited registration until the appropriate authorities are asked to make such a scientific decision, or make a contrary scientific determination and the Agency's denial decision is invalidated after a denial proceeding under FIFRA section 3(c)(6). The mere fact that Registrants submitted studies in accordance with the deadlines in the PAL does not shift the Registrants' burden of proof, nor does it remove the condition EPA determined was essential

when it granted the registration in 2008. No registrant is entitled to a registration under FIFRA before the terms and conditions of that registration have been found to meet the standard for registration under FIFRA. And notwithstanding any contrary suggestions by Registrants, EPA has simply not made the necessary findings under FIFRA to support flubendiamide registrations without the cancellation conditions.

Registrants reference a recent Ninth Circuit Court of Appeals case involving the pesticide Enlist Duo. Petitioner Motion at 50. That case involved challenges by a number of environmental groups to EPA's decision to register Enlist Duo; the Petitioners in the case claimed that EPA's registration of Enlist Duo was unlawful for a variety of reasons. During the briefing of the merits of the case, EPA learned of information that could have changed EPA's registration decision that the registrant had provided to the U.S. Patent Office before the registration was granted, but had not provided to EPA. Because EPA was no longer assured that it had made the appropriate registration decision, EPA moved that the court vacate the registration and remand the decision granting the registration back to the Agency.

Although the Ninth Circuit granted EPA's motion to remand the registration decision to EPA for reconsideration, it did not vacate the registration. Registrants in this proceeding cite to this Ninth Circuit's Enlist decision for the proposition that "existing registrations cannot be "vacated" without following the prescribed administrative process, and rejects another creative yet unlawful attempt by EPA to achieve cancellation while bypassing required cancellation procedure." *Id.*

While registrants are overstating the terms of the court's order,[21] it appears that Registrants, are asking this Tribunal to do something very similar to what they claim EPA tried to do inappropriately in the Enlist case. Here, Registrants want this Tribunal to give them a registration without an important limitation included in the initial registration, without the appropriate personnel in EPA having made the necessary findings to support such a registration, and without going through the appropriate process (submitting an application for an amended or new registration without the offending condition) they have avoided for almost eight years. Registrants are well aware that EPA never determined that the Petitioners were entitled to a registration without the condition, as there was never a determination that such a registration would meet the standard for registration. They simply want a registration without the cancellation condition without having to go through the necessary regulatory process and without subjecting their application to review by the appropriate regulatory authorities. These registrants are presumably well aware of the regulatory options they have to request EPA to consider the removal of the condition or to issue a new registration application without the condition. To not do this is short-circuiting the FIFRA regulatory process – the very thing they argue EPA tried to do in the Enlist Duo case.

Although EPA believes this Tribunal should not find that the condition is unlawful, if the ALJ does so, the registration should be declared void *ab initio*. Such an action would be consistent with the express terms of the registration, as stated in the PAL: "If either Nichino or

[21] In fact, the Enlist court merely issued a terse statement to the effect that "[t]he motion for voluntary vacatur of the registration of Enlist Duo is denied without prejudice to the rights of the either party to litigate that question before the agency." Because the court did not draft an opinion explaining its language in the order, it is complete conjecture on the part of the Petitioners to assume that the court ruled against EPA because it believed the Agency had to follow the cancellation proceedings in FIFRA section 6.

Bayer does not agree with any of the conditions of registration, they should consider any such registration to be null and void." Petitioners' Exhibit 8 at 4. Under no circumstances is it appropriate to provide Registrants with registrations that EPA's appropriate pesticide personnel have never determined, ***and never even been asked to determine***, meet the standard for registration under FIFRA.

B. Right to 6(b) Hearing is not Absolute; Right to Unreasonable Adverse Effects Determination is not Absolute

The Registrants' second main argument is their contention that EPA's 2016 determination that continued registration of the flubendiamide product would cause unreasonable adverse effects necessarily requires that EPA afford Registrants and other adversely affected persons a hearing in accordance with FIFRA section 6(b) that supersedes any authority to cancel pursuant to FIFRA section 6(e). The Registrants' contention is based on flawed understandings of conditional registrations issued under FIFRA section 3(c)(7) and the triggers for cancellation proceedings under FIFRA section 6.

i. Registrants' Procedural Rights Depend on the Nature of the Cancellation Proceeding

The right to a full FIFRA section 6(b) hearing on the merits of whether a particular pesticide does or does not cause unreasonable adverse effects on the environment is not an absolute right that may be invoked in any and every situation. EPA does not dispute that it made an unreasonable adverse effects determination here, but like all FIFRA determinations, it was a particular, circumstance-dependent determination. What is important for purposes of what hearing rights the registrant is provided depends on both the terms and conditions of the particular registration, and the way in which EPA chooses to cancel the pesticide. In regard to

flubendiamide, EPA's 2016 finding of unreasonable adverse effects was the finding specified in conditions 6(d) and 8(d) of the PAL as the condition precedent triggering the Registrants' obligation to request voluntary cancellation. While a comparable finding might support an EPA decision to pursue cancellation under the authority of FIFRA section 6(b), EPA has made no such decision, and has taken no action that could be characterized as an effort to cancel flubendiamide registrations on any grounds specified in FIFRA section 6(b). Which of the FIFRA hearing procedures applies is contingent upon whether EPA is attempting to cancel based on grounds specified in FIFRA section 6(b) or is attempting to cancel based on grounds specified in FIFRA section 6(e).[22] A registrant cannot exercise whatever rights FIFRA section 6(b) offers until EPA issues an NOIC alleging that the product causes unreasonable adverse effects and proposing to cancel pursuant to FIFRA section 6(b).

FIFRA grants pesticide registrants certain due process rights in regard to the cancellation of a pesticide registration. Inasmuch as Congress expressly provided in FIFRA section 6(e) a procedure separate and distinct from the FIFRA section 6(b) cancellation process, the due process rights in regard to cancellation for failure to satisfy any condition of a conditional registration differ from those provided by FIFRA section 6(b). The registrant of a product subject to a FIFRA section 6(e) notice of intent to cancel a conditional registration for failure to satisfy a condition simply does not have a right to a FIFRA section 6(b) hearing, because FIFRA mandates a different cancellation process. The condition requiring a request for voluntary

[22] Many of the procedures associated with a FIFRA section 6(b) proceeding are actually codified in FIFRA section 6(d) and incorporated into FIFRA section 6(b) by reference. FIFRA section 6(e) also incorporates the FIFRA section 6(d) procedures to the extent that they are not inconsistent with FIFRA section 6(e). For clarity and convenience, this brief will simply refer to FIFRA sections 6(b) and 6(e) when distinguishing between their applicable procedures.

cancellation is a valid condition and since the registrants have not complied with the condition, the appropriate due process rights are those set forth in FIFRA section 6(e).

In the instant case, EPA issued a FIFRA section 6(e) notice of intent to cancel the Registrants' conditional registrations for flubendiamide products on account of the Registrants' failure to satisfy a condition of those registration. Because the notice of intent to cancel was issued pursuant to FIFRA section 6(e), the Registrants' due process rights in regard to this notice of intent to cancel are as prescribed in FIFRA section 6(e), and not FIFRA section 6(b). This outcome was clearly foreseeable from the inception of the conditional registrations of these flubendiamide products; in fact, the cancellation condition would be meaningless if EPA were obligated to proceed under FIFRA section 6(b) if it determined after the five-year time period of the registrations that flubendiamide posed unacceptable risks to the aquatic environment. When Registrants accepted conditional registrations pursuant to FIFRA section 3(c)(7), they accepted registrations that, as a class, are subject to cancellation in accordance with FIFRA section 6(e) in the event that they should fail to comply with any condition of registration. This fact was expressly stated in the NOR: "Your release for shipment of these products constitutes acceptance of the conditions of registration as outlined in the preliminary acceptance letter for flubendiamide, dated July 31, 2008. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA." Petitioner Exhibit 7. The Halder email (Respondent Attachment B ¶¶ 21-22) demonstrates that Registrants were well aware that EPA would not proceed under section 6(b) if the Agency were unable to conclude that it could make a no unreasonable adverse effects on the environment determination; Mr. Halder acknowledged that Registrants understood the Agency's position and acquiesced in it: "We understand this, so have little problem with fitting in the "fast death" approach, i.e. voluntary

cancellation within a week of the decision." Respondent Attachment B ¶ 21. Conditional registrations pursuant to FIFRA section 3(c)(7) include certain procedural rights, including the right to a FIFRA section 6(b) proceeding in the event that EPA pursues a cancellation under FIFRA section 6(b) by issuing an notice of intent to cancel the registrations based on one or more of the grounds specified in FIFRA section 6(b). However, FIFRA section 6(b) is not the only provision of FIFRA by which a pesticide may be cancelled. Whether or not evidence might exist that would support a decision to pursue cancellation of Registrants' flubendiamide products pursuant to FIFRA section 6(b), it is unquestionably true that those products were registered under FIFRA section 3(c)(7), and that Registrants failed to satisfy certain conditions of those registrations, and are therefore subject to cancellation pursuant to FIFRA section 6(e). Registrants have cited to no case law that says that when EPA can proceed under two different provisions under FIFRA each of which, by their own terms, clearly establishes a statutory process for cancellation, that only section 6(b) may be utilized.

FIFRA also allows products to be voluntarily cancelled under section 6(f), and specifically contemplates that voluntary cancellation could go forward where the Agency determines a product causes unreasonable adverse effects on the environment (and could therefore presumably be cancelled pursuant to section 6(b)). *See* p. 12, *supra*. In fact, FIFRA section 6(f) not only allows voluntary cancellations to go forward in such circumstances, it calls for the reduction of a comment opportunity from 180 days to thirty days when a product is found to cause unreasonable adverse effects on the environment. *Id.* And this provision has been used in the past when registrants have declined to challenge initial determinations by EPA that a pesticide appears to cause unreasonable adverse effects on the environment. Respondent Attachment B ¶ 24. It is clear from Mr. Halder's email that Registrants were committing to

proceed under 6(f) instead of 6(b); Registrants have cited to no provision of law that would suggest that registrants cannot waive their rights to a 6(b) hearing and elect the other processes available under section 6, and in the *Woodstream* case, the court upheld a condition voluntarily agreed to by a registrant (just as the Registrants here did with flubendiamide) that led to cancellation without resort to section 6(b).

Moreover, the Registrants could have obtained a hearing equivalent to a FIFRA section 6(b) proceeding by refusing to accept the conditional registration and insisting upon a FIFRA section 3(c)(6) denial hearing. In the almost eight years since, Registrants have also failed to request amendments removing the conditions, and failed to apply for new, unconditional registrations, which also offer paths to the equivalent hearings. So the Registrants have had ample opportunities to obtain the hearing they claim to seek; to the extent that EPA's commencement of a cancellation proceeding under FIFRA section 6(e) forecloses some of these opportunities, it is simply a matter of Respondents having let their time run out.

To the extent that the Registrants argue that their property interests in their registrations entitle them to registrations from which the cancellation conditions are severed (Petitioner Motion at p. 46), they are mistaken, because their property interests are circumscribed by the scope of the registrations themselves, and for the registrations at issue in the present case that includes two separate conditions concerning cancellation:

- As FIFRA section 3(c)(7) conditional registrations, they are according to statute subject to cancellation pursuant to FIFRA section 6(e) if any conditions are not met.
- The conditions of registration expressly include a prescribed process for voluntary cancellation when and if certain circumstances occur.

Therefore, whatever property interests registrants generally might hold in their registrations, the interests of these Registrants in regard to the flubendiamide FIFRA section 3(c)(7) conditional registrations are limited both by the potential for cancellation per the conditions stated in the PAL, and by the potential for cancellation pursuant to FIFRA section 6(e) if the conditions of registration are not met. The Registrants' property interest do not sever the cancellation conditions from the other terms and conditions of their registrations.

ii. Absent EPA Pursuing Cancellation Under FIFRA Section 6(b), Third Parties Do Not Have a Right to Such a Hearing

Registrants argue that the cancellation conditions deprive other stakeholders (U.S. Department of Agriculture (USDA) or the Department of Health and Human Services (HHS), growers, and other adversely affected parties) of their rights to participate in a cancellation proceeding. Petitioner Motion at p. 55. Persons other than the registrant who are adversely affected by a FIFRA section 6(e)(2) notice of intent to cancel have the right to request a FIFRA section 6(e) hearing. This right created by FIFRA section 6(e)(2) is also constrained as follows:

> The only matters for resolution at that hearing shall be whether the registrant has initiated and pursued appropriate action to comply with the condition or conditions within the time provided or whether the condition or conditions have been satisfied within the time provided, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this Act. ... Notwithstanding any other provision of this section, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing.

The above FIFRA section 6(e)(2) conditions are not severable from the right to request a hearing pursuant to that section, and the rights provided by that section are more limited than the rights of persons adversely affected by a notice of intent to cancel issued pursuant to FIFRA section 6(b). If EPA had proposed to cancel alleging that the pesticide does not comply with FIFRA, or when used in accordance with widespread and commonly recognized practice,

generally causes unreasonable adverse effects on the environment -- the criteria for cancellation under FIFRA section 6(b) – then persons adversely affected by such notice would have the right to request a hearing pursuant to that section. But in the absence of initiating cancellation upon grounds encompassed by FIFRA section 6(b), no person has a right to such a proceeding.

Congress provided in FIFRA for USDA, HHS, and SAP review before EPA can initiate a proceeding under FIFRA section 6(b). But just as the statute does not require UDSA, HHS, or SAP review before an application can be granted or denied under section 3, it does not provide for USDA, HHS, or SAP involvement in proceedings under section 6(e) or 6(f). That is a choice made by Congress. But nowhere did Congress specify in FIFRA that a 6(b) proceeding must be held when 6(e) or 6(f) can properly be invoked, and in the case of 6(f) there is statutory text that strongly suggests otherwise.

The limits on the rights of third parties to participate in a cancellation action is particularly apparent under FIFRA section 6(f). On occasion registrants exercise their rights under FIFRA section 6(f) to request voluntary cancellation of certain registered uses or all of a registration in order to prevent EPA from initiating a FIFRA section 6(b) cancellation process. Respondent Attachment B at ¶ 26. Where registrants exercise this right, it creates a situation where growers' rights are limited as provided in FIFRA section 6(f). And as noted, Congress specifically provided for a *shorter* comment period when EPA has made an unreasonable adverse effects determination. It is clear that Congress has allowed registrants to effectively restrict the rights of growers to a 6(b) hearing, and to bypass the involvement of USDA, HHS, and SAP where registrants desire to do so. In flubendiamide, Registrants knowingly and voluntarily agreed to accept registrations with conditions (related to risk issues associated specifically with flubendiamide) that obligated them to pursue the process afforded by FIFRA

section 6(f). Registrants can hardly argue that they cannot affect the hearing rights of others when they elect to pursue cancellation under FIFRA section 6(f), and it seems surpassingly strange for them to argue that they can effectively alter the rights of others to a 6(b) proceeding, but they cannot alter their own rights to such a proceeding. And as the Halder email makes clear, Registrants knowingly elected to forego their rights to a 6(b) hearing in order to get earlier, but necessarily limited, registrations for flubendiamide.

For the forgoing reasons, the rights of persons other than the registrant to participate in a FIFRA section 6(e) proceeding are both created by, and limited to, the right that this section confers upon any person adversely affected by the notice of intent to cancel. Such rights are contingent in this case upon the filing of a notice of intent to cancel pursuant to FIFRA section 6(e), and they are different from the rights that would exist had EPA issued a notice of intent to cancel pursuant to FIFRA section 6(b). Inasmuch as EPA pursued cancellation of these flubendiamide registrations pursuant to the authority of FIFRA section 6(e) and not FIFRA section 6(b), persons adversely affected by the section 6(e) notice of intent to cancel have no right to a section 6(b) proceeding and the contention that Registrants cannot waive the rights of third parties is false.

iii. In General, FIFRA Provides EPA Flexibility to Choose Whether to Pursue Cancellation under FIFRA section 6(b) or FIFRA section 6(e)

EPA has the discretion to issue conditional registrations under FIFRA section 3(c)(7)(C) that include requirements to submit data post-registration as well as comply with other necessary conditions. Once EPA determines that a condition has not been fulfilled by the registrant in the time required by the condition, pursuant to FIFRA section 6(e), the Agency "shall issue a notice of intent to cancel" the registration. At that point, EPA had an obligation to issue a notice of intent to cancel the registration under FIFRA section 6(e) and it did so in a timely manner. This

process is consistent with the plain language Congress set forth in FIFRA section 6(e) to distinguish it from FIFRA section 6(b) hearings as well as the legislative history that states, "[u]nder the new provision [6(e)], the Administrator is required to issue a notice of intent to cancel a 'conditional' registration issued under section 3 of FIFRA if (1) during the period provided for the satisfaction of the condition, the Administrator determined that the registrant has failed to initiate and pursue appropriate action to satisfy any imposed condition, or (2) at the end of the period provided for satisfaction of the any condition, the condition has not been satisfied." S. Rep. 95th Congress 2d Session Committee on Agriculture, Nutrition, and Forestry (January 1979).

Although once EPA determines a condition has not been met it has an obligation to issue a notice of intent to cancel under FIFRA section 6(e), EPA may use discretionary authority to first resolve its concerns through other methods such as cancellation under 6(b). FIFRA provides a variety of grounds for cancelling a pesticide product, and gives EPA the discretion to choose which to exercise when there appear to be alternative grounds for cancellation. FIFRA expressly provides eight discrete and distinct authorities for cancelling pesticides:

- FIFRA section 3(c)(1)(F)(iii) requires EPA to cancel without further hearing the registration of a pesticide on account of the registrant's failure to participate in a certain procedures, agreements or arbitration decisions concerning data rights compensation.
- FIFRA section 4(d)(5) authorizes EPA to cancel the registration of a pesticide "by order and without a hearing" on account of the registrant's failure to file certain notices associated with seeking reregistration.

- FIFRA section 4(e)(3)(A) requires EPA to cancel the registration of a pesticide, by order and without hearing, on account of the registrant's failure to submit certain data in support of reregistration.
- FIFRA section 4(e)(3)(B)(iii) authorizes EPA to cancel the registration of a pesticide on account of inadequacies in responses to certain reregistration requirements. "If a hearing is requested, a hearing shall be conducted under section 6(d), except that the only matter for resolution at the hearing shall be whether the registrant made a good faith attempt to conform its submission to such guidelines. The hearing shall be held and a determination made within 75 days after receipt of a request for hearing." *Id.*
- FIFRA section 4(i)(1)(H) authorizes EPA to cancel the registration of a pesticide, by order and without hearing, on account of the registrant's failure to pay required maintenance fees.
- FIFRA section 6(b) authorizes EPA to cancel the registration of a pesticide because the pesticide does not comply with FIFRA, or when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment.
- FIFRA section 6(e) requires EPA to cancel a section 3(c)(7) conditional registration of a pesticide on account of the registrant's failure to initiate and pursue appropriate action toward fulfilling a condition or failure to satisfy any condition. "If a hearing is requested, a hearing shall be conducted under subsection (d) of this section. The only matters for resolution at that hearing shall be whether the registrant has initiated and pursued appropriate action to comply with the condition or conditions within the time provided or whether the condition or conditions have been satisfied within the time provided, and

whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this Act. ... Notwithstanding any other provision of this section, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing." *Id.*

- FIFRA section 6(f) authorizes EPA to cancel upon the registrant's voluntary request.

It is possible that several of these provisions could simultaneously pertain to a single pesticide product. For example, a pesticide conditionally registered pursuant to FIFRA section 3(c)(7) with a condition requiring submission of a two-generation reproductive health study by a date certain, could be subject to cancellation per FIFRA section 6(e) for failing to meet that deadline, while also being subject to cancellation per FIFRA section 4(i)(1)(H) for failure to pay maintenance fees. In such cases, it would be unreasonable to read FIFRA as requiring EPA to commence three separate cancellation actions. As FIFRA specifies no hierarchy regarding its various cancellation authorities, it is reasonable to read FIFRA as allowing EPA the discretion to choose which cancellation authority to utilize in any particular case.

Although FIFRA specifies no hierarchy among its various cancellation authorities, certain differences in the language used might arguably suggest the use of one authority rather than another, as some of these provisions are expressed in language that may be read as mandatory[23] while others are phrased in language that implies a measure of agency discretion.[24]

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[23] FIFRA section 3(c)(1)(F)(iii) ("the Administrator shall deny the application or cancel the registration..."), FIFRA section 4(d)(5) ("the Administrator shall issue a notice of intent to cancel..."), FIFRA section 4(e)(3)(A) ("the Administrator, by order and without hearing, shall cancel..."), FIFRA section 6(e) ("The Administrator shall issue a notice of intent to cancel...").

[24] FIFRA section 4(e)(3)(B)(iii) ("the Administrator may issue a notice of intent to cancel..."), FIFRA section 4(i)(1)(H) ("the Administrator, by order and without hearing, may cancel..."), FIFRA section 6(b) ("the Administrator may issue a notice of the Administrator's intent ... to cancel...").

EPA has not attempted to finely parse these various provisions; it is sufficient for the purposes of the instant case to observe that comparison of the "*may* issue" language of FIFRA section 6(b) and the "shall issue" language of FIFRA section 6(e) does not support Respondents' contention that the right to a FIFRA section 6(b) proceeding is superior to EPA's decision to cancel pursuant to FIFRA section 6(e). If anything, where both FIFRA sections 6(b) and 6(e) arguably apply, FIFRA would appear to mandate that EPA pursue cancellation under section 6(e) rather than FIFRA section 6(b). This would be a prudent use of the nation's resources, given the greater burdens typically associated with a FIFRA section 6(b) proceeding relative to a FIFRA section 6(e) proceeding.

EPA has announced its intent to cancel on account of the Registrants' failure to comply with terms of their conditional registrations; EPA has not proposed to cancel on account of unreasonable adverse effects. The NOIC is clear and unambiguous; a few examples will suffice:

- Unit II "Legal Authority" notes that the registrations at issue were conditional registrations issued pursuant to FIFRA section 3(c)(7) and discusses the applicability of FIFRA section 6(e) to cancellations of conditional registrations. 81 Fed.Reg. at 11,558-59. Nowhere in the Legal Authority unit – nor elsewhere in the NOIC – is section 6(b) mentioned.
- Unit III "Registrants' Failure To Comply With a Required Condition of Registration" describes the conditions of the flubendiamide registrations and the Registrants' conduct in regard thereto, and concludes as follows: "Once EPA exercised the registration condition set forth in the NOR, the registrants' failure to comply with that condition of registration by submitting requests for voluntary cancellation makes the flubendiamide

products identified in Unit I.A. subject to cancellation under FIFRA section 6(e)." 81 Fed.Reg. at 11,559-60.

- Unit V "Scope of Proceeding" focuses solely, but in detail, on the scope of a hearing under FIFRA section 6(e).

As the NOIC is abundantly clear, there is no reasonable basis to argue that EPA has commenced a proceeding to cancel the subject flubendiamide products pursuant to the authority of FIFRA section 6(b).

EPA's decision to proceed here under section 6(e) given the conditions in the flubendiamide registrations and the reasons behind those conditions was reasonable and appropriate. A FIFRA section 6(b) proceeding is slow and resource-intensive compared to a FIFRA section 6(e) proceeding. Regardless of whether or not evidence might exist that would support a decision to pursue cancellation of Registrants' flubendiamide products pursuant to FIFRA section 6(b), it is unquestionably true that those products were registered under FIFRA section 3(c)(7), and that Registrants failed to satisfy certain conditions of those registrations, and are therefore subject to cancellation pursuant to FIFRA section 6(e). It would be a misuse of public resources to pursue a section 6(b) proceeding when the conditions for a section 6(e) cancellation have been met. It would also subject the aquatic environment to additional risks that were specifically found by EPA to be inappropriate at the time the registrations were initially issued, and have manifestly not been found to be appropriate by EPA at any subsequent time.

Registrants' suggest that EPA's decision to proceed under FIFRA section 6(e) was motivated by concerns that "the Agency's cancellation determination is not supported by the science and would not withstand required review." Petitioner Motion at p. 9. EPA disagrees, and notes that the Registrants' ongoing failure to exercise their right to a FIFRA section 3(c)(6)

denial proceeding could also support an implication that Registrants' believe their position is not supported by the science and would not withstand close scrutiny. Although EPA has no window into the Registrants' strategic deliberations, it is conceivable that the Registrants recognize that their position has no merit and simply seek to extend the life of their flubendiamide products as long as they can before an inevitable defeat. Whatever their reasons, the essential fact is that Registrants have not taken advantage of the multiple opportunities available to them to attempt to obtain flubendiamide registrations without the cancellation conditions, and they cannot hijack this proceeding to make up for their inaction.

iv. Congress Intended for FIFRA Section 6(e) Cancellations to be Limited in Scope

To the extent that Registrants argue that a FIFRA section 6(e) hearing is not appropriate because this process is inadequate for litigating the scientific determination of unreasonable adverse effects, EPA agrees that the FIFRA section 6(e) process is inadequate for litigating the scientific determination of unreasonable adverse effects, but maintains that Congress intended that such issues should be irrelevant to a 6(e) cancellation of pesticides conditionally registered under FIFRA section 3(c)(7).

It is self-evident from FIFRA section 6 that Congress intended that registrations issued under FIFRA section 3(c)(7) should be cancelled using the FIFRA section 6(e) procedures if any condition of the registration has not been met. Congress limited the scope of a FIFRA section 6(e) hearing by the provision that "[t]he only matters for resolution at that hearing shall be whether the registrant has initiated and pursued appropriate action to comply with the condition or conditions within the time provided or whether the condition or conditions have been satisfied within the time provided, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this Act." This limitation on the scope of a

FIFRA section 6(e) proceeding effectively precludes the scientific, economic and other fact-finding that might be encountered in a FIFRA section 6(b) hearing, and therefore precludes the detailed consideration of EPA's unreasonable adverse effects determination that is the usual focus of a FIFRA section 6(b) proceeding. This conclusion is reinforced by the 75-day limit on FIFRA section 6(e) proceedings: It is simply impractical to conduct the evidentiary hearing mandated by FIFRA section 6(b) – not to mention SAP review – within the 75-day limit mandated by FIFRA section 6(e)(2).

Thus, a section 6(e) proceeding is limited in scope relative to the section 6(b) proceeding. *See Woodstream II* at 177 (D.D.C. 2012) ("While a hearing may be requested, [FIFRA section 6(e)] has a slightly narrower scope than a hearing under Section 6(b). The only matters for resolution at a Section 6(e) hearing are whether the registrant has satisfied the condition (or initiated and pursued the appropriate action to comply with the condition) within the time provided, and whether EPA's determination with respect to the disposition of existing stock is consistent with the subchapter.")

Accordingly, as EPA stated in its NOIC, "the only matters for resolution in any hearing requested regarding this matter shall be whether the registrants satisfied the condition of registration requiring them to submit timely requests for voluntary cancellation when notified by EPA of its determination that the registrations caused unreasonable adverse effects on the environment, and whether the proposed existing stocks provision is consistent with FIFRA." 81 Fed.Reg. at 11,561. This is the statutorily mandated consequence of the Registrants' failure to comply with a condition of their FIFRA section 3(c)(7) conditional registrations by failing to request voluntary cancellation in accordance with conditions 6(d) and 8(d) of the PAL.

v. Yes, EPA has concerns about the risks of flubendiamide, but that does not trigger a right to a 6(b) hearing

EPA readily agrees that it has concerns about the risks of flubendiamide: Flubendiamide is a mobile, persistent, and toxic insecticide. Flubendiamide degrades only through aquatic photolysis and anaerobic aquatic metabolism into des-iodo, which does not further degrade except slowly through photolysis. EPA has identified chronic toxicity concerns for flubendiamide to aquatic system invertebrates, and its des-iodo degradate is ten times more toxic to aquatic invertebrates than the parent flubendiamide. *See* Respondent Attachment C at 2-4. EPA agrees that these concerns were behind the difficulties in making a long-term no unreasonable adverse effects finding for flubendiamide, and that Registrants agreed to mollify those concerns by accepting a limited registration that would terminate quickly if the Agency's risk concerns were validated after the five-year period. However, EPA acknowledges these concerns not to assert the truth of the underlying scientific conclusions, but merely to make clear EPA's position that these scientific concerns are not material to the instant proceeding.

The Registrants' acceptance of conditional registrations pursuant to FIFRA section 3(c)(7) did not take away all rights to a FIFRA section 6(b) hearing: The Registrants remain entitled to a FIFRA section 6(b) hearing in the event that EPA should pursue cancellation pursuant to that section. But where EPA proposes to cancel conditional registrations pursuant to FIFRA section 6(e) on account of the Registrants' failure to satisfy a condition of those registrations, the Registrants' due process rights are as specified in FIFRA section 6(e).

Respondents mistakenly contend that EPA's position regarding a FIFRA section 6(e) hearing differs in the instant case from a position stated in a brief in another matter. (Petitioners' Request for Hearing at paragraphs 151-154) In the footnote 4 of that brief that was selectively

quoted by the Registrants, EPA summarized the distinctions FIFRA makes between FIFRA sections 6(b) and 6(e) proceedings:

> If [a registrant who holds a section 3(c)(7) conditional registration] subsequently fails to satisfy those outstanding data requirements, the conditional registration is subject to cancellation under Section 6(e), where "[t]he only matters for resolution at that hearing shall be whether the registrant has initiated and pursued appropriate action to comply with the condition or conditions within the time provided or whether the condition or conditions have been satisfied within the time provided, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this Act." Thus a section 6(e) cancellation is about the registrant's failure to meet its obligations, and not about a problem with the pesticide product itself. A pesticide cancelled pursuant to section 6(e) is not being cancelled on account of risks, and, despite cancellation, remains "a pesticide and proposed use [that] are identical or substantially similar to [a] currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment..." FIFRA section 3(c)(7)(A).

Petitioner Exhibit 55 at pp. 4-5 & n.2.

EPA maintains that its statement in the earlier brief accurately represents the distinction between FIFRA section 6(b) and 6(e) *adjudications* and the different consequences of the respective adjudications, and that it illustrates why the scope of the instant proceeding must be limited to the questions of whether Respondents have complied with the conditions of the subject registrations and if not, whether the existing stocks provisions proposed in the NOIC are consistent with the purposes of FIFRA.[25] Nothing in the above statement, or elsewhere in the

[25] For the same reasons, EPA believes that FIFRA section 6(e) cancellations should not be subject to 40 C.F.R. part 164 subpart D, because a section 6(e) cancellation is not based on the thorough substantive evaluation of the risks and benefits that characterize the section 6(b) and 6(c) proceedings that were the original focus of the 1975 amendment that created subpart D. 40 Fed.Reg. 12261, 12262 (1975) ("Because of the extensive notice and hearing opportunities mandated by FIFRA and the Administrative Procedures Act before a final cancellation or suspension order may be issued, EPA has determined that such orders may not be reversed or modified without affording interested parties—who may in fact have participated in lengthy cancellation proceedings—similar notice and hearing opportunities.").

brief that was its source, supports Respondents' contention that existence of risk concerns necessarily give rise to a right to a FIFRA section 6(b) proceeding.

The Registrants' position could read section 6(e) out of FIFRA, because every FIFRA data requirement, be it imposed by regulation or as a condition of registration, is necessarily targeted at assessing the risks or benefits of the pesticide product, and every failure to comply with data requirements potentially leaves the registrant unable to sustain its burden of showing that the product does not cause unreasonable adverse effects. Every condition of registration imposed by EPA is related in some way to the risks and benefits of the pesticide, so every failure to comply with a condition of registration is to some degree related to the ultimate question of whether the pesticide product causes unreasonable adverse effects. Respondents' contention would lead to the absurd result that every failure to comply with a condition of registration would, because it relates in some way to the risks and benefits of the product, entitle the registrant to a FIFRA section 6(b) cancellation proceeding, leaving no scope for FIFRA section 6(e) proceedings.[26] Inasmuch as the Registrants' position would effectively read section 6(e) out of FIFRA, it must be rejected. And *Woodstream II* rebuts any suggestion that 6(b) cancellations are required for conditions that are not related to data generation.

Although EPA does have concerns about the adverse effects of flubendiamide, EPA also has serious concerns about registrants willfully choosing not to comply with the terms of their registrations. To the extent that alternative paths to cancellation present themselves, it is reasonable and appropriate for EPA to choose the most efficient path. As the Registrants note, "An accelerated decision will also serve fairness and efficiency by resolving the lawfulness of

[26] Or for that matter, cancellations pursuant to pursuant to sections 3(c)(1)(F)(iii), 4(d)(5), 4(e)(3)(B)(iii), 4(i)(1)(H), and 6(f). *See infra* section V.C.ii.

EPA's proposed cancellation approach before the hearing is conducted, thus avoiding the potential unnecessary burden on the parties and the ALJ of conducting an unlawful hearing. *See, e.g., Merit Motors, Inc. v. Chrysler Corp.*, 417 F. Supp. 263, 267 (D.D.C. 1976), aff'd, 569 F.2d 666 (D.C. Cir. 1977) ("Summary judgment is a valuable instrument for avoiding unnecessary, lengthy, and costly trials.")." While EPA disagrees with Registrants' characterization of the instant hearing as unlawful, their point is valid in regard to the burdens associated with an unnecessary hearing, and a FIFRA section 6(b) hearing is unnecessary where grounds for cancellation under section 6(e) exist.

vi. EPA's Decision to Pursue FIFRA Section 6(e) Cancellation was Reasonable Because the Conditions Precedent were Met

FIFRA section 6(e)(1) provides that, among other things, "[t]he Administrator shall issue a notice of intent to cancel a registration issued under section 3(c)(7) of this Act if ... at the end of the period provided for satisfaction of any condition imposed, that condition has not been met." Beginning on August 1, 2008, EPA issued Notice of Registrations (NOR) for flubendiamide products which, among other things, stated that "[T]his product is conditionally registered in accordance with FIFRA section 3(c)(7) ..." Petitioner Exhibit 7 at 1. The NORs for each of the flubendiamide registrations went on to state that "[y]our release for shipment of these products constitutes acceptance of the conditions of registration as outlined in the preliminary acceptance letter for flubendiamide, dated July 31, 2008. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA." The July 31, 2008, "preliminary acceptance letter" (PAL) included the following condition: "If, after EPA's review of the data as set forth in 6(b) above, the Agency makes a determination that further registration of the [flubendiamide product] will result in unreasonable

adverse effects on the environment, within one (1) week of this finding, to be effective no earlier than September 1, 2013, [the registrant] will submit a request for voluntary cancellation of the [flubendiamide product] registration." EPA reviewed the data as provided in the PAL, EPA scientists engaged in dialogue with the Registrant's scientists about the data and the Agency's conclusions therefrom, and on January 29, 2016, EPA sent a letter to the Registrants notifying them on Agency's determination that further registration of these pesticide products would result in unreasonable adverse effects on the environment. One week later, and to the present date, the Registrants failed to request voluntary cancellation of the flubendiamide products under FIFRA section 6(f). On February 5, 2016, the Registrants responded to EPA's January 29, 2016, letter confirming that the Registrants were declining to request voluntary cancellation of its products as required by the conditions of registration. The conditions precedent having been met, EPA issued a Notice of Intent to Cancel these pesticide products pursuant to FIFRA section 6(e) on March 4, 2016.

As the Registrants have indisputably failed to request voluntary cancellation in accordance with conditions 6(d) and 8(d) of the PAL, the flubendiamide products conditionally registered under FIFRA section 3(c)(7) are subject to cancellation pursuant to FIFRA section 6(e). Under the circumstances, EPA's decision to initiate such cancellation is eminently reasonable.

C. The Due Process Afforded Petitioners was Appropriate Pursuant to FIFRA Sections 6(e) and 6(f)

The following discussion addresses Petitioners' arguments about the breadth of their property interest and due process rights. Petitioner Motion at p. 46. EPA agrees that a pesticide registration provides a registrant with a limited property interest and certain due process rights.

EPA disagrees, however, that Petitioners' registrations provide as broad a property interest as they claim. As described at various points in this filing, Congress provided varying levels of hearing rights for pesticide registration actions. In this case, the appropriate due process rights are afforded under FIFRA section 6(f) (had the registrant complied with the condition of registration) and now because they failed the narrow hearing rights under FIFRA section 6(e).

The Petitioners' claim that they were forced or threatened into agreeing to the limited due process afforded by FIFRA sections 6(e) and 6(f). This claim is absurd. As demonstrated by the email correspondence between EPA and the registrants, the Petitioners had the proper intelligence and knowledge about the EPA registration process to know what they were agreeing to as part of their registration. Therefore, Petitioners have only themselves to blame for any limitation of their due process rights that would be afforded under FIFRA sections 6(e) and 6(f). They knowingly and willfully agreed to this level of due process.[27]

Petitioners also cite to the Administrative Procedure Act (APA), 5 U.S.C. § 558(c) for the proposition that the APA requires that an agency cannot remove a license without notice and the "opportunity to demonstrate or achieve compliance with all lawful requirements." It appears that the Petitioners are trying to argue that they are entitled to a full evidentiary hearing under FIFRA section 6(b) and that the APA supports this contention. Although the APA states that a licensee has the right to notice and an opportunity to show how they have complied with all the legal requirements of their license, it does not support the idea that only a FIFRA section 6(b) hearing

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[27] It can be argued that Petitioners waived or reduced their due process rights from a fuller FIFRA section 6(b) hearing to the more limited FIFRA sections 6(e) and 6(f) rights to get their products to market quicker. Consistent with the caselaw on waiving due process rights, Petitioners voluntarily with knowledge and intelligence agreed to the limited hearing rights afforded in FIFRA sections 6(e) and 6(f). *See D. H. Overmyer Co. v. Frick Co.*, 405 U.S. 174, 185-186 (U.S. 1972).

would meet this section of the APA. Here, the license at issue specifically includes a condition, knowingly accepted by Registrants, which leads to a hearing opportunity under FIFRA section 6(e) if the condition is not met. Consistent with section 558 of the APA, Registrants have an opportunity under FIFRA section 6(e) to demonstrate that they have complied with all the lawful requirements of their registrations. The fact that they cannot demonstrate that they complied with all the lawful requirements of their registrations – because in fact they did not comply with the lawful requirements of the registrations - does not mean that the hearing opportunity provided by section 6(e) is deficient under the APA.

D. Registrants are not Entitled to Equitable Relief Amending the Terms and Conditions of Their Registrations

This proceeding was convened pursuant to FIFRA section 6(e), and that section prescribes that the only issues for resolution at the hearing are whether a registrant failed to comply with a condition of registration and the disposition of existing stocks. The Registrants, having no argument to make on whether they complied with the conditions of their registrations, instead urge this Tribunal to determine that the condition at issue in this proceeding is inappropriate or unlawful. Because the Registrants' arguments take this Tribunal outside the scope of FIFRA section 6(e), those arguments could, and should, be dismissed summarily.

The procedural regulations applicable to this proceeding allow Administrative Law Judges to take actions and make decisions "in conformity with statute or in the interests of justice." 40 C.F.R. section 164.40(d). This authority is inherently an equitable authority, and to the extent that the Registrants' are urging this Tribunal to exercise its equitable authority under 40 C.F.R. section 164.40(d), equitable considerations do not support the Registrants' position any more than the law and facts discussed *supra* do.

Contrary to the narrative provided in their Motion, the Registrants were well aware that EPA in 2008 had significant concerns with the flubendiamide applications stemming from flubendiamide's persistence in water, its potential to get into water and remain in aquatic sediment, and the high toxicity of flubendiamide and its principal degradate to aquatic invertebrates. EPA determined, among other conditions, that the anticipated adverse effects of flubendiamide use could only be considered reasonable for a limited period of time (five years) to allow the Registrants an opportunity to conduct additional studies to assess the impact of certain registration conditions intended to prevent flubendiamide from contaminating water bodies, and only with an additional requirement that the registration terminate in five years if EPA were not satisfied that the new studies would support a conclusion that water resources would be sufficiently protected. The Registrants understood at the time that the five-year limitation was an important component of EPA's findings to support issuance of a registration, as the wording of the limitation was the subject of discussion between EPA and the Registrants before the license was issued. Respondent Attachment B at ¶¶ 21-23. The Registrants never suggested to the Agency that they considered the cancellation condition unlawful, and they never availed themselves of any of the opportunities available to them to either challenge the condition or seek a hearing on whether they were entitled to registrations without the condition.[28] Only now, almost eight years after issuance of the initial registrations that the Registrants willingly --

[28] In addition to their initial 2008 acceptances of the cancellation conditions, the Registrants continued to regularly acknowledge the applicability of the cancellation conditions from May 2013 through December 2015. This is apparent from four letters requesting successive extensions of the original September 1, 2013 deadline. See Letter from George J. Sabbagh (Bayer) May 30, 2013 ("This letter is to touch base with your regarding the time limited registration of flubendiamide. The product was conditionally registered for five years ... Under the conditional registration, ... The Agency is to ... decide on the future of the registration for flubendiamide and its end-use products *by September 1, 2013*." Emphasis in original); Letter from Nancy Delaney (Bayer) August 20, 2015 ("Request for Extension of the Time Limited Registration for flubendiamide ..."); Letter from Nancy Delaney (Bayer) December 4, 2015 ("Request for Extension of the Time Limited Registration for flubendiamide ..."); Letter from Nancy Delaney (Bayer) December 16, 2015 ("Request for Extension of the Time Limited Registration for flubendiamide ..."), collectively Attachment E.

and to all appearances happily -- accepted in 2008, have the Registrants decided to challenge a condition that was integral to the Agency's determination to give them their registrations in the first place. The Registrants essentially are asking this Tribunal to amend their registration and give them an unlimited registration that the Office of Pesticide Programs never made the necessary findings to support, and that the Registrants have never applied for through the appropriate channels.

Equitable factors do not favor parties who accept a license with a condition that they were well aware of and had negotiated for, who avail themselves of the benefits of the license, and who then wait almost eight years to challenge the condition at the moment it is exercised against them. Equitable factors also do not favor parties who could have applied for the registrations they appear to desire through the appropriate channels at any time in the last eight years, but for reasons known only to themselves choose not to do so. Registrants instead are wholly inappropriately asking this Tribunal to modify their registrations into registrations they have never asked the proper authorities to grant. To the extent that the Registrants seek equitable relief from the NOIC, the equitable principles of latches[29] and equitable estoppel[30] oppose the Registrants' cause.

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[29] Laches is among the principles that may bar or limit equitable relief. As the Supreme Court said long ago, "laches is not like limitation, a mere matter of time; but principally a question of the inequity of permitting the claim to be enforced." *Galliher v. Cadwell*, 145 U.S. 368, 373 (1892). *See Ashley v. Boyle's Famous Corned Beef Co.*, 66 F.3d 164 (8th Cir. 1995) (discussing application and history of laches).

[30] The doctrine of equitable estoppel precludes a litigant from asserting a claim or defense which might otherwise be available to him against another party who has detrimentally altered her position in reliance on the former's misrepresentation or failure to disclose some material fact. *See Portmann v. United States*, 674 F.2d 1155, 1158 (7th Cir. 1982).

In addition to the equitable factors discussed above, Registrants should be barred from pursuing their claim on a statute of limitations basis. While there is no statute of limitations included in the pesticide registration process, it makes sense to apply the six year general statute of limitations for civil actions against the United States. *See* 28 U.S.C. §2401(a). After a registration is issued, the Agency is responsible for no immediate formal, additional review procedures. Thus, the statute of limitations begins to run. *See Impro Products, Inc. v. Block*, 722 F.2d 845, 850-51 (D.C. Cir. 1983) (applying six year statute of limitations with action accruing when agency review has been exhausted). Alternatively, the statute of limitations could begin to run upon the release for shipment of the relevant products. Even using the later date – the release for shipment date – any cause of action accrued shortly after August 1, 2008. Thus, if the Registrants had an issue with any of the agreed-upon conditions in the pesticide registrations, they should have filed an action within six years of sometime in August of 2008. They did not do so. And, they should not be given the opportunity now, only after they are dissatisfied with a condition they agreed to over six years ago, to protest this condition.

VI. CONCLUSION

For the reasons set forth above, EPA moves this Tribunal to DENY Petitioners' Motion for an Accelerated Decision and move forward with this hearing pursuant to FIFRA section 6(e).

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Respectfully Submitted,

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