ENVIRONMENTAL APPEALS BOARD

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C.

In re:	)	
	)	
Bayer CropScience LP, and Nichino America, Inc.	))	FIFRA Appeal No. 16-(01)
	)	
Docket No. FIFRA-HQ-2016-0001	)	
	)	

POST-ARGUMENT BRIEF OF THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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ACRONYMS

ALJ	Chief Administrative Law Judge
CID	Corrected Initial Decision
EAB 1	EAB Post-Argument Brief Attachment
EFED	EPA's Environmental Fate and Effects Division
EPA	Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
MAD	Registrants' Motion for Accelerated Decision
NOAEC	No Observed Adverse Effects Concentration
OPP	Office of Pesticide Programs
NOIC	EPA's Notice of Intent to Cancel
PAL	EPA's Preliminary Acceptance Letter
PBNX	Petitioner Registrants' Exhibits for Hearing
RAB	Registrants' Appeal Brief
RE	Respondent EPA's Exhibits for Hearing
Tr.	Transcript ("Administrative Tr."; "Oral Argument Tr.")
UAE	Unreasonable Adverse Effects on the Environment

INTRODUCTION

EPA submits this filing in response to the EAB's June 23, 2016 Order requesting the parties answer specific questions.

EPA'S RESPONSES

I. FIFRA Section 6(e) Authority

A. What authority does the Board have in a FIFRA section 6(e) proceeding to consider the lawfulness of a condition of registration, given that section 6(e) proceedings are statutorily limited to two issues: (1) whether a condition of registration has been violated, and (2) whether EPA's determination with respect to disposition of existing stocks is consistent with FIFRA?

FIFRA makes clear that the "only matters for resolution" at a hearing initiated pursuant to section 6(e) are, insofar as is relevant to this proceeding, whether a condition of a conditional registration has not been satisfied and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with FIFRA. FIFRA § 6(e)(2), 7 U.S.C. § 136d(e)(2). As EPA noted in its response to Registrants' Motion for Accelerated Decision, in raising the question of the legality of the voluntary cancellation condition before the ALJ, the Registrants were asking the ALJ to "go beyond the statutory scope of the FIFRA section 6(e) proceeding" (EPA Response to MAD at 4), and that EPA's detailed response to Registrants' contention that the condition was unlawful "should not distract the [ALJ] 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...." EPA Response to MAD at 5. In answer to the Board's question, EPA submits that the EAB lacks the authority to rule on an issue clearly beyond the well-defined and narrow scope of section 6(e). However, should the EAB disagree, EPA

submits for all the reasons set forth in its Response to Registrants' Motion for Accelerated Decision, that the challenged condition was clearly lawful.

B. If the Board does possess the authority in a section 6(e) proceeding to consider the lawfulness of a condition of registration, may a third party also challenge the lawfulness of either that condition or any other aspect of the registration?

While EPA would want to do a more thorough study of relevant case law and legislative history before answering this question definitively, EPA has significant doubts that any third party could challenge any condition of registration in a FIFRA section 6(e) proceeding. In terms of a party opposed to the registration raising such a challenge (and essentially asserting an additional grounds for cancellation), EPA believes that the Notice of Intent to Cancel (NOIC) establishes the bounds of the section 6(e) proceeding and that any additional grounds for cancellation not identified in the NOIC would be outside the scope of the proceeding. Parties opposed to a registration could attempt to challenge any portion of the registration when a registration is first issued or when EPA invites public comment on whether a registration should be issued (*see* https://iaspub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:30:0 and 40 C.F.R. § 152.102) and they could petition the Agency to initiate a cancellation proceeding based on whatever basis they wish to put forward (and get judicial review of any denial of such a petition). But EPA does not believe they could inject new issues into a section 6(e) hearing.

EPA does not believe that third parties could challenge as impermissibly restrictive any condition of another person's registration under section 6(e) or in any other proceeding. Even if the EAB were to determine that the scope of a 6(e) proceeding could be broader than the two issues identified in the statutory text, the appropriate and necessary process for seeking a modification of a registration is the submission of an application for amended registration (*see* p. *6, infra)*. FIFRA establishes a licensing scheme for pesticides sold or distributed in the United

States (*see* FIFRA § 3, 7 U.S.C. § 136a), and EPA submits that only the licensee can submit an application to amend its registration. Third parties can always encourage the licensee to seek a broader registration. But if a registrant is content with the terms of its pesticide license, and a third party prefers a less restrictive license, the third party's only recourse may be to seek its own registration with the terms it prefers.

C. If the Board were to conclude that the voluntary cancellation condition in the flubendiamide registrations is unlawful, what effect would such a holding have on the registration itself?

If the EAB decides it has the authority under section 6(e) to review the lawfulness of the cancellation condition, and finds it unlawful, the EAB should void the flubendiamide registrations. Counsel for Registrants explained at oral argument that they are asking the EAB to excise the cancellation condition from their registrations and otherwise leave the registrations in place. (Oral Argument Tr. at 28:6-8). As EPA discussed in EPA's Response to Motion for Accelerated Decision (at 36-41), the appropriate personnel in the Office of Pesticide Programs (OPP) have never made the necessary findings to support flubendiamide registrations without the limitations of the cancellation condition. Since 2008, neither Bayer nor Nichino has asked OPP to make such findings. The PAL made clear that conditions of the flubendiamide registrations are not severable, stating that if the Registrants do not agree "with any of the conditions of registration, they should consider any such registration to be null and void." RE 2 at 200013. "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." EPA Response to MAD at 41 (emphasis in original). If the condition is found to be unlawful, the whole registration must be voided because it has never been found to meet the standard for registration under FIFRA without the

cancellation condition. Although the EAB can rule on the legality of EPA's actions that are within the scope of the proceeding, the authority to issue a registration on different terms is reserved to OPP.

This position is not at all unfair to Registrants. While they have consistently attacked the legality of the cancellation condition since refusing to comply with the voluntary cancellation condition on February 5, 2016, the more important question is whether the Registrants are entitled to registrations without the condition. Registrants could at any time after obtaining the original flubendiamide registrations have submitted an application for new (or amended) registration that did not include the cancellation condition. If this change to their registrations is at heart what Registrants desire, application for new or amended registration is the appropriate process under FIFRA, both to seek the registrations Registrants want, and to challenge the Agency decision if they are disappointed with it.

EPA must review all applications pursuant to FIFRA § 3(c), 7 U.S.C. § 136a(c). Where review of an application for new or amended registration reveals that the application cannot be approved as submitted, EPA generally provides the applicant the opportunity to amend or withdraw its application. If the registrant declines to amend or withdraw and instead demands a denial, EPA must issue a denial pursuant to FIFRA § 3(c)(6), 7 U.S.C. § 136a(c)(6). Upon EPA's publication of a notice of denial, that section provides that the registrant (or other interested person with the concurrence of the applicant) "shall have the same remedies as provided for in section 6." *Id.*

EPA has interpreted this provision to mean that publication of a notice of denial has the same procedural consequences as publication of a NOIC. *See* 40 C.F.R. §§ 164.3, 164.20(a), 164.21. Part 164 provides the denied applicant exactly the same post-notice procedures as those

provided to a registrant faced with cancellation pursuant to FIFRA section 6(b). Part 164 makes no substantive or procedural distinctions between denial proceedings and cancellation proceedings. A denial proceeding provides the same hearing on the record before an ALJ (§§ 164.20(c) and 164.40), the same rights to present and to cross-examine witnesses (§ 164.81), the same right to request referral of questions of scientific fact to the National Academy of Sciences (§ 164.50(e)), the same participation rights in affected third parties (§ 164.31), the same rights of appeal to the EAB (§§ 164.100 & 164.101), etc. The hearing afforded to one whose application for new registration has been denied is fully equivalent to the hearing afforded to a registrant who has received a notice of intent to cancel pursuant to FIFRA section 6(b).[1]

Registrants have advanced a number of unconvincing arguments for why the denial path was not a viable option. Claims by counsel for Registrants at oral argument regarding the fees that would need to accompany a new application for registration were simply incorrect.[2] While counsel correctly identified the sizeable fee under FIFRA section 33 for filing an application for registration of a product containing a new active ingredient not present in any currently registered pesticide product, the fees for a flubendiamide application after the first registration was granted (after which flubendiamide would not be a new active ingredient) would have been

[1] In fact, the registrant in the Reckitt Benckiser cancellation proceeding cited by Registrants used this process to obtain a denial hearing (combined by EPA with the related cancellation hearing) on applications for registration of two unregistered products that presented different risks and benefits (owing to their use of tamper-resistant bait stations) from the registered products subject to cancellation in that case. *See* 78 Fed. Reg. 8123, 8124 (Feb. 5, 2013).

[2] "And the other suggestions about options, sure, file a new application. The fees for a new application at the time were $500,000. Today, it's $675,000." Oral Argument Tr. at 104 (Szmuszkovicz).

substantially smaller. *See* FIFRA § 33(b)(3), 7 U.S.C. § 136w-8, Tables 2, 4 and 5.[3] It seems unlikely that the actual fee required under section 33 would have been a barrier to submitting an application for a registration without the cancellation condition.

As explained in EPA's Response Brief at 15-16, neither is there merit to Registrants' argument that the experience of Woodstream shows that applying for amended registration is not a practical pathway to a denial hearing equivalent to a section 6(b) cancellation hearing. The short answer is there is nothing in the record for flubendiamide, or of any other action, which suggests that EPA would have unreasonably delayed responding to an application from the flubendiamide registrants to remove the cancellation condition, and if EPA were to unreasonably delay its response Registrants would have a judicial remedy available. *See* 5 U.S.C. § 706(1).

The option of applying for amendments to remove the cancellation condition was available to Registrants from the time the conditional registrations were granted, and has been available every day since. It offered a clear path to a denial hearing fully equivalent to a section 6(b) cancellation hearing, and the hearing process would have provided a robust record for judicial review. This was the appropriate path to follow if Registrants wanted a registration without the cancellation condition, and if the application were denied, it would have provided them a hearing on the science issues they tried to impermissibly raise in this section 6(e) proceeding. Having made the business decision to accept the original flubendiamide conditional

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[3] While it is not clear which category in Table 2, 4 or 5 would apply to an application (depending in part on whether the application was accompanied by any new data), the most expensive of the possible categories is less than $27,000. For example, the flubendiamide registrations for Vetica Insecticide (EPA Reg. No. 71711-32) and Tourismo Insecticide (EPA Reg. No. 71711-33), are illustrative: for each registration, the registrant paid $4,360 for the initial registration, and paid no fee for any of the dozen applications for amended registration subsequently filed for each product. If the application met the terms of FIFRA § 3(c)(3)(B), 7 U.S.C. § 136a(c)(3)(B), there would not have been any application fee required at all.

registrations and then, for whatever reasons, never seeking to amend them, Registrants cannot reasonably object when they find themselves in a section 6(e) hearing where only their compliance with the conditions of those registrations is at issue.

II. What Standard of Proof is Required for an Order Issued After a FIFRA Section 6(d) Hearing?

A hearing to address the narrow scope of FIFRA § 6(e), 7 U.S.C. § 136d(e) must be conducted in accordance with FIFRA § 6(d), which states that an order issued after such a hearing "shall be based only on substantial evidence of record of such hearing." FIFRA § 6(d), 7 U.S.C. § 136d(d). The EAB's request also asked the parties to take into account that FIFRA section 16(b) requires the substantial evidence standard for appellate courts in reviewing EPA decisions following a hearing and the Supreme Court's decision in *Steadman v. SEC,* 450 U.S. 91 (1981). In *Steadman,* the Supreme Court held that:

> Where Congress has not prescribed the degree of proof which must be adduced by the proponent of ... [an] order to carry its burden of persuasion in an administrative proceeding, this Court has felt at liberty to prescribe the standard, for "[it] is the kind of question which has traditionally been left to the judiciary to resolve." *Woodby* v. *INS*, 385 U.S. 276, 284 (1966). However, where Congress has spoken, we have deferred to "the traditional powers of Congress to prescribe rules of evidence and standards of proof in the federal courts" absent countervailing constitutional constraints. *Vance* v. *Terrazas*, 444 U.S. 252, 265 (1980). *Steadman v. SEC,* 450 U.S. at 95-96.

Here, Congress has spoken as to the standard of proof for FIFRA section 6(d) hearings, requiring that the Administrator's orders resulting from such hearings (and therefore those of the ALJ and EAB) "shall be based only on substantial evidence of record of the hearing." FIFRA § 6(d), 7 U.S.C. § 136d(d) And, if the final decision by the EAB accepts[4] the decision of the ALJ, the Registrants can challenge such a decision in an appropriate court of appeals pursuant to

[4] 40 C.F.R. § 164.103 states that the EAB "may accept or reject all or part of the initial . . . decision of the [ALJ]."

FIFRA § 16(b), 7 U.S.C. § 136n(b). If challenged, the standard of review for the Court of Appeals is also substantial evidence.[5]

III. What "conclusions" are covered by the requirement in the flubendiamide conditional registration that EPA "shall engage in dialogue about the data and the Agency's conclusions?" Does EPA's determination on the toxic endpoint level constitute a "conclusion" within the meaning of the registration?

As discussed below, EPA believes that the endpoint selection used in its risk assessments was not a "conclusion" that needed to be discussed per the terms of the PAL. EPA continues to maintain that the EAB need not reach this issue because the ALJ properly determined that the Registrants did not raise the sufficiency of dialogue issue in a timely manner.[6] However, in the event that the EAB decides to consider Registrants' untimely argument, the Board should find that there is substantial evidence to show that, as discussed more fully in Section V. below, EPA fulfilled its commitment to engage in dialogue with the Registrants on these issues. As requested by the EAB, EPA now responds to the question presented.

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[5] "Substantial evidence means more than a mere scintilla but less than a preponderance; it is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Natural Resources Def. Council v. EPA*, 735 F.3d 873, 877 (9th Cir. 2013) (internal quotation marks and citations omitted). This standard is not *de novo*.

[6] The ALJ properly stated that the "Rules of Practice provide that '[a]ny document containing objections to an order of the Administrator of . . . his intent to cancel the registration . . . *shall clearly and concisely set forth such objections* and the basis for *each* objection, including relevant *allegations of fact* concerning the pesticide under consideration.' 40 C.F.R. § 164.22(a) (emphasis added). The Rules of Practice do not state the significance of a party's noncompliance with this requirement. However, Rule 164.22 is similar to Rule 9(c) of the Federal Rules of Civil Procedure, which provides that 'when denying a condition precedent has occurred or been performed, a party must do so with particularity.' Fed. R. Civ. P. 9(c). Further, case law holds that a party failing to deny with particularity in its answer that a condition precedent has been fulfilled is precluded from subsequently raising that issue. *See, e.g.*, *Digital Ally, Inc. v. Z3 Tech., LLC*, 2010 U.S. Dist. LEXIS 103715, *12 (D.Kan. Sept. 30, 2010) (citing *Myers v. Cent. Fla. Invs., Inc.*, 592 F.3d 1201 (11th Cir. 2010)). Applying a similar reading to Rule 164.22 would be especially appropriate here in light of the short 75 day period for holding a hearing and making a determination in this case. 7 U.S.C. § 136d(e)." CID at 28.

EPA believes a short summary of EPA's risk assessment process might be helpful. EPA followed the guidance contained in its *Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs*[7] document. EAB 1. The risk assessment process begins with a problem formulation phase that defines the parameters of the assessment process. During this process, EPA defines assessment endpoints. Endpoints are "explicit expressions of the actual environmental value that is to be protected" which are "operationally defined by an ecological entity and its attributes." EAB 1 at 200141. The ecological entity can include a species, group of species, or an ecosystem. *Id.* The attribute is a characteristic of the entity that is potentially at risk. *Id.* EPA laid out an assessment endpoint for freshwater invertebrates in Table 4 of the 2008 assessment. PBNX 27; PBN at 0478. The selection of endpoints provides the "direction and boundaries in the risk assessment for addressing . . . issues of concern." EAB 1 at 200141. Another way to think of an endpoint is as a measure of an effect from the exposure to a pesticide. *Id.* EPA's policy is to base risk assessments on the most sensitive species and endpoint found in the data to address a specific issue (e.g., effects to invertebrates in the aquatic environment). *Id.* at 200142.

The next phase is the analysis where exposure and effects are characterized. "The exposure characterization is based on environmental fate and transport data, modeling, and monitoring information." This includes properties such as degradation and persistence. *Id.* at 200144. The "effects characterization describes the types of effects a pesticide can produce in an organism and how those effects change with varying pesticide exposure levels." *Id.* at 200151.

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[7] This document can be found at https://www.epa.gov/sites/production/files/2014-11/documents/ecorisk-overview.pdf. EPA is also providing a copy of this document as an attachment (EAB 1) to this Brief. This document is also referenced in other exhibits, including PBNX 32 at PBN0909.

For aquatic invertebrates, the assessors use the lowest No Observed Adverse Effect Concentration ("NOAEC") after reviewing all the studies conducted as a basis for the risk conclusions. *Id.* at 200152. For flubendiamide, EPA specified the effects levels used for assessing effects to freshwater invertebrates in Table 22 of the 2008 risk assessment. PBNX 27; PBN at 0498-0499.

The next phase for risk assessment is when the assessors characterize the risk by integrating the effects and exposure estimates to determine the ecological risk from the use of the pesticide and the likelihood of effects on an environmental parameter (e.g., aquatic life). EAB 1 at 200156. It is here where the assessors synthesize the overall conclusions about risk that is used by risk managers in making risk management decisions.[8] This process has not changed since 2008. It is the conclusions determined in the risk characterization phase that EPA believes are the conclusions that the PAL requires be discussed with the Registrants.

As discussed above more fully, EPA also identified this term in its *Overview* guidance document on conducting ecological risk assessments. "Conclusion" appears in the document when describing the risk characterization phase, which is the final phase before sending the assessment to the risk managers. EPA believes the "conclusions" to be discussed pursuant to the PAL were the risk (and benefit) conclusions that the assessors provided to the risk managers. The risk managers, in turn, consider the conclusions in the supporting assessment documents to make the Unreasonable Adverse Effects (UAE) determination. Leading up to the final UAE determination, EPA made several intermediate conclusions regarding risks and benefits.

[8] See https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/technical-overview-ecological-risk-assessment-risk.

EPA's risk assessments generally contain "conclusions" sections. These sections tend to summarize the critical findings that form the basis of the conclusions in the risk assessment. For example, the conclusions in the June 28, 2008 Environmental Fate and Effects Division Risk Assessment for flubendiamide are set forth in sections 1.3 and 1.4 of that document. PBNX 27; PBN at 0464-0465. Those conclusions include the following:

- "Flubendiamide and its degradate's overall stability/persistence suggests that they will accumulate in soils, water column, and sediments with each successive application." PBNX 27; PBN at 0464.
- "Based on nominal water column concentrations, the des-iodo degradate appears to be more toxic than the flubendiamide parent to benthic invertebrates."[9] PBNX 27; PBN at 0465.

EPA's tagging of conclusions was consistent over time. Another example of what EPA considers to be "conclusions" for purposes of the PAL comes from the December 16, 2010 risk assessment Conclusions section.

- "Flubendiamide and des-iodo are expected to accumulate in the environment and pose chronic risk concerns for aquatic invertebrates." PBNX 35; PBN at 0993.

And, finally in the January 28, 2016 assessment, the Conclusion section states:

> After review of the all of the data submissions and previous risk assessments, EFED[10]'s conclusions on the environmental risks posed by flubendiamide at the time of writing are consistent with those identified in 2008. EFED originally concluded that "Flubendiamide and its degradate's overall stability/persistence suggests that they will accumulate in soils, water column, and sediments with each successive application". . . EFED's analysis of the registrant's field monitoring (farm pond) study concludes that there is 1) accumulation of both flubendiamide and des-iodo in the water column, sediment, and pore water for all ponds monitored; and 2) definitive evidence that VFSs [(Vegetative Filter Strips)] do not sufficiently control off-site transport of these chemicals to downstream waterbodies. In addition, stream and river monitoring conducted by the registrant and the U.S. Geological Survey over much of the United States indicates: 1) the

[9] The chronic toxicity endpoint of .28 micrograms/liter was a basis for this conclusion. PBNX 27; PBN at 0465.
[10] EFED is the Environmental Fate and Effects Division within the Office of Pesticide Programs.

> failure of VFSs to contain these chemicals is a widespread occurrence; and 2) the potential for water quality impacts is also widespread. Based on the California almond scenario presented above as well as the other recent modeling . . ., significant effects to aquatic organisms due to the use of flubendiamide could potentially occur in as little as 2 years. While the registrant has raised many issues as discussed in detail above and in the referenced documents, none have been persuasive that the original and subsequent risk assessment conclusions were inaccurate nor have they diminished confidence in those conclusions. Considering all the evolving lines of evidence, there is increased confidence in the conclusions contained in EFED's past risk assessments for flubendiamide. PBNX 31; PBN at 0870.

If argument about the "dialogue" requirement is considered timely, EPA maintains that the conclusions labeled as such in the Agency's risk assessments are what was required to be discussed. The endpoint selection was one of many components that support the conclusions in the risk assessment, but the endpoint selections were not themselves identified as conclusions in the flubendiamide risk assessments. It is simply not reasonable to conclude that every supportive component in the risk assessment was what the PAL required to be included in dialogue. Having said that, EPA would not have refused to discuss any component (such as the most sensitive endpoint) of a conclusion that Registrants wished to discuss in scientific meetings, and in fact (as discussed in Section V below) endpoint selection was discussed with Registrants.

IV. Appellants argue on appeal that EPA presented "new * * * conclusions * * * in the January 29, 2016 Decision and supporting documents that were not discussed with Registrants." If there were new conclusions presented in these documents, what were they, and where in the record are these conclusions detailed?

The EAB cites to the Registrants' Appeal Brief at page 22 for what the Registrants are arguing are "new conclusions." Registrants there claim that EPA lowered the toxicity endpoint without informing the Registrants before the EPA issued its January 29, 2016 decision. As stated in Section III above, the toxicity endpoint is not a "conclusion" that EPA had committed to discuss with the Registrants per the terms of the PAL. As the endpoint selection was not a

"conclusion" under the PAL, it cannot be a "new" conclusion. And, even though EPA maintains the endpoint is neither a conclusion under the PAL nor new, as stated in the Section V below, the record shows that there were several meetings and documents exchanged concerning the toxicity endpoint.

There are no documents in the record that show the selection of the endpoint was new as Registrants argue. In fact, EPA has been relying since 2008 on the same spiked water concentration of 0.28 micrograms/liter as its endpoint for determining chronic risks to benthic invertebrates in the water column and continued to rely on this endpoint in the final decision memo in 2016.

The following provides some factual background to help address the EAB's question. As explained more fully in Section III, when assessing risks to aquatic environments, EPA uses the most sensitive endpoint for a particular exposure pathway and duration. EAB 1 at 200142. Registrants' quarrel is with the particular endpoint EPA uses to address chronic toxicity of flubendiamide to benthic aquatic invertebrates. For assessing chronic toxicity in an aquatic environment, EPA looks at the NOAEC from a variety of studies (the NOAEC is the highest concentration that shows no adverse effect to the test organism).[11] As noted, EPA generally utilizes the most sensitive endpoint for regulation, which in this case would be the lowest NOAEC from the chronic toxicity studies for aquatic invertebrates. PBNX 30 at PBN0847 Based on the use patterns for flubendiamide and its degradate des-iodo, EPA considered and reviewed studies by the Registrants concerning both spiked water and spiked sediment endpoints for both flubendiamide and its des-iodo degradate. In the 2008 and 2010 risk assessments, EPA

[11] See https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/technical-overview-ecological-risk-assessment-risk

identified 0.28 micrograms/liter of the des-iodo degradate in spiked water as the most sensitive endpoint; only spiked water study endpoints for flubendiamide and the des-iodo degradate were available at the time of those assessments. Because of concerns that spiked sediment studies might result in a more sensitive endpoint than from the spiked water studies, spiked sediment studies were conducted. PBNX 27 at PBN0455; PBNX 28 at PBN0588. On July 19, 2011 EFED completed the review of an additional study which was a study of the effects of des-iodo degradate in a spiked sediment study which showed a NOAEC of 19.5 micrograms/liter. PBNX 34 at PBN0943. In February 2015, EPA's review rejected Registrants' proposed alternative endpoints and continued to rely on the NOAEC for des-iodo of 0.28 micrograms/liter based on the spiked water study. PBNX 35 at PBN0991-92. There is no evidence in the record to suggest that EPA at any time agreed that the less sensitive endpoint of 19 micrograms should be used instead of 0.28 micrograms for the des-iodo degradate. EPA used 0.28 micrograms/liter in its June 2008 ecological risk assessment as well as in its December 2010, February 2015, and its January 2016 risk assessments that were the bases for the ultimate determination of unreasonable adverse effects on the environment. PBNX 35, PBNX 27, PBNX 29, and PBNX 31. While Registrants apparently believe that EPA should have discarded the most sensitive endpoint and used the less sensitive endpoint from the spiked sediment study, EPA instead continued to use the most sensitive endpoint -- the spiked water endpoint. EPA discussed with Registrants their scientific policy disagreement as to which endpoint is appropriate, but the record does not indicate an actual change in EPA's position on the appropriate endpoint. EPA has been consistent in its discussions with the Registrants as well as in the Agency's risk assessments since 2008 - the spiked water concentration is the most sensitive endpoint and that endpoint has always been 0.28 micrograms/liter. PBNX 27, PBNX 29, and PBNX 31. There is no evidence in

the record that EPA's decision to rely on the spiked water NOAEC (the most sensitive endpoint) was new, nor is there evidence in the record that that particular NOAEC changed over time.

EPA has considered both the spiked water and spiked sediment studies submitted by the Registrants to fully evaluate the chronic toxicity of the benthic invertebrates found in the water column and the sediment. *See* PBNX 31. All of these studies were important to the risk characterization. But EPA's assessments have always been consistent with EPA's policy to use the most sensitive species and endpoint.[12]

While EPA believes, for the reasons stated in Section III above, that the selection of a particular chronic toxicity endpoint is not a conclusion under the PAL, it is clear that the spiked-water endpoint of 0.28 micrograms/liter was known to the Registrants well before 2016.

V. EPA relied upon a toxic endpoint level from the Des-iodo - Spiked Water 28-Day Study (MRID 46817023), among other evidence, in its January 29, 2016 unreasonable adverse effects determination for flubendiamide. What does the record show as to whether Appellants were notified of EPA's intent to use this toxic endpoint level prior to January 29, 2016?

The Registrants allege that the "Agency affirmatively withheld critical positions and conclusions from Registrants" and the Agency began "pursuing cancellation based on a directive coming from a political level within the Agency, including the Assistant Administrator." RAB at 20. As explained above, the record demonstrates that EPA openly and consistently treated the chronic toxicity endpoint from the Des-iodo - Spiked Water 28-Day Study (MRID 46817023) as the appropriate regulatory endpoint, and neither withheld information regarding the endpoint, nor changed its endpoint selection at any time between 2008 and the issuance of the NOIC.

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[12] See https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/technical-overview-ecological-risk-assessment-risk and EAB 1.

There can be no dispute that in June 2008, EPA determined that "[t]he corresponding NOAEC for the des-iodo degradate is 0.28 micrograms/liter. … [F]or the purposes of this risk assessment and in consideration of the use of data as prescribed in the Agency's Risk Assessment Overview Document, risk calculations will be based on the chronic endpoints established for each chemical specifically." EPA EFED Risk Assessment for the Section 3 New Chemical Registration of Flubendiamide (June 23, 2008), PBNX 27 at PBN0461; see also PBN0465 and PBN0523-24. EPA reiterated that determination in its August 2008 decision to register flubendiamide for a limited period of time. EPA Decision Memorandum for Registration of Flubendiamide (August 1, 2008), RE 1 at 200007.

In May 2010, EPA conducted a flubendiamide risk assessment in response to Registrants' application to amend their registrations to add certain new uses. This risk assessment reaffirmed that the regulatory endpoint was a NOAEC of 0.28 micrograms/liter for the des-iodo degradate and its chronic toxicity to benthic aquatic invertebrates. EPA EFED Risk Assessment for Legume Vegetable and Christmas Tree New Uses for the Insecticide Flubendiamide (May 17, 2010), PBNX 28 at PBN0610; see also PBN0643-44, PBN0648-49. In December 2010, EPA used the same endpoint in another risk assessment evaluating another amendment requesting to add additional new uses of flubendiamide. EPA EFED Ecological Risk Assessment for the New Use of Flubendiamide on Alfalfa and Certain Other Crops (Dec. 16, 2010), PBNX 29 at PBN0778; see also PBN0776, PBN0782-83. Both of these risk assessments were contemporaneously shared with Registrants.

In February 2015, EPA completed, and shared with Registrants, a review of three reports submitted by Registrants related to a three-year flubendiamide water monitoring project in support of the conditional registration of flubendiamide. EPA EFED Review of Three Reports re

Three-Year Flubendiamide Water Monitoring Project (Feb. 20, 2015), PBNX 35. In its review, EPA acknowledged Registrants' comment proposing use of endpoints higher than 0.28 micrograms/liter and responded as follows:

> EFED has evaluated all of these studies and provided a Data Evaluation Record (DER) for each with the exception of the aforementioned midge study that has yet to be submitted to the Agency. Some of these registrant-calculated endpoints differ slightly from the Agency determined endpoints. If the registrant believes the Agency-calculated endpoints are in error, the appropriate course of action would be to rebut the individual DERs. **This report ([the newly submitted study identified as] MRID 49415302) does not contain sufficient explanation and analysis for the Agency to reconsider the endpoints.** However for purposes of evaluating the studies submitted with the monitoring study ([the two newly submitted studies identified as] MRIDs 49415301 to 49415303), the Agency will use the registrant-calculated endpoints to avoid diverting focus from the issues the Agency has with the submitted monitoring and aquatic exposure reports.

PBNX 35 at PBN0991-92. (emphasis added). This text clearly shows that when Registrants proposed higher endpoints in February 2015, EPA did not accept Registrants' proposed alternative endpoints, and did not consider the reviewed studies sufficient basis to warrant reconsideration of the Agency's 0.28 microgram/liter endpoint.

In July 2015, EPA responded to new information submitted by Registrants regarding the quantities of flubendiamide and its des-iodo degradate in waterbodies. EPA EFED Response to Bayer CropScience's "Flubendiamide Aquatic Risk: Evaluations of (1) USGS Stream Monitoring and (2) Proximity of Farm Ponds to Crop Areas with Flubendiamide Use" (no MRID number) submitted through email dated June 22, 2015 (July 8, 2015), PBNX 36. Although the studies at issue did not relate specifically to the Agency's endpoint selection, they address whether levels in waterbodies could be expected to exceed the Agency's 0.28 microgram/liter endpoint. Accordingly, if EPA's endpoint selection had changed significantly from the position consistently held from 2008 through February 2015, such change might reasonably be expected

to be reflected in EPA's July 2015 review. EPA response (contemporaneously shared with Registrants) indicates no change in position:

> "**After consideration of this information, EFED concludes that the information contained in this submission would not change the conclusions of previous EFED responses subsequent to the pond studies or previous EFED risk assessments.**" PBNX 36; PBN1001-02 (bold and underline emphasis in original text).

The evidence before the ALJ included testimony that a meeting regarding flubendiamide science was held with Registrants on January 6, 2016. (Administrative Tr. 70:20-22, 71:1-13). Judge Biro determined that "while it is clear from the record that Petitioners were not in agreement with EPA as to the toxicity end-points chosen to the Agency's ultimate determination, they clearly were aware of them, and the rationale behind them, and had an opportunity to respond to EPA and engage in dialogue with Agency officials about these issues." CID at 32. In addition, as Registrants' Counsel stated at the EAB oral argument, the "registrants spent most of the holidays trying to figure out what was going on and digesting what had been said in the meetings in December, and that everybody immediately gave high attention to reviewing EPA's documents." (Oral Argument Tr. 41:2-6) Registrants did not seek to include these December 2015 documents among their exhibits.

Because Registrants' Notice of Objections did not allege that there had been insufficient scientific dialogue (and the question was not properly raised in this proceeding), EPA did not introduce documents into the record addressing the dialogue that did occur. *See* Respondent Post-Hearing Brief at 9; Response Brief of the U.S. EPA at 26; Oral Argument Tr. 67:14-22, 68-69:1-20. Although Registrants did introduce (and proffer) a number of scientific documents, they did not introduce or seek to introduce into the record the documents that were provided by EPA prior to the January 6, 2016 meeting. In accordance with the EAB's directive in its June 23, 2016 Order on Post-Argument Briefing not to submit new affidavits or declarations, EPA

has not included with this Brief the materials provided to Registrants before the January 6, 2016 meeting. While EPA submits that the record put forth by Registrants demonstrates that EPA has consistently relied on the 0.28 microgram/liter endpoint since 2008, EPA must point out that the record is not complete in this regard. Had the dialogue issue been properly raised in Registrants' Objections, the record would be a fuller one and would certainly have included the following documents that Registrants did not provide:

1. Email from Nancy Delaney, Bayer CropScience, December, 18, 2015 to Richard Gebken, EPA, acknowledging receipt of EFED science documents.

2. Agenda for January 6, 2016 meeting.

3. Attendance sheet from meeting.

4. Attachments for meeting:

   A. Transmittal of Ecotoxicity Study DER Addenda to Correct Sediment-dwelling Invertebrate Toxicity Endpoint Values, December 18, 2015

   B. Comparison of Four Regulatory Scenarios for Multiple Crops based on the Standards EFED Aquatic Modeling Procedures, dated December 18, 2015

   C. Additional Characterization of Ecological Risk through Consideration of a Subset of Crops Proposed as Posing Limited Ecological Risk to Aquatic Macroinvertebrates, dated December 22, 2015

   D. PowerPoint Presentation: Flubendiamide: Discussion on Revised Ecological Endpoints Based on Time-Weighted Average Endpoints and Risk Assessment of Registrant-Proposed Uses.

VI. FIFRA section 6(f) mandates that voluntary cancellation requests may not be acted upon by EPA until a notice-and-comment procedure has been completed. If Appellants had requested voluntary cancellation of the flubendiamide registrations under section 6(f), could they have challenged EPA's unreasonable adverse effects determination during the notice-and-comment period?

FIFRA section 6(f)(1) provides that a registrant may request voluntary cancellation of any or all uses of its pesticides, but that before acting on such requests, the Administrator must

provide for a 30-day public comment period.[13] FIFRA § 6(f)(1), 7 U.S.C. § 136d(f)(1). Nothing in FIFRA suggests that the registrant could not submit comments during the comment period, so Registrants could have used the public comment period to submit any documents and argumentation they desired regarding EPA's unreasonable adverse effects determination.

FIFRA section 6(f) does not require a hearing on the record, and therefore, a voluntary cancellation decision would not come before an ALJ or the EAB. However, comments submitted during the section 6(f) comment period would become part of the Agency's records and, to the extent relevant to EPA's cancellation decision, could be expected to be part of the administrative record if someone appealed EPA's decision to approve or deny the voluntary cancellation request to the federal courts.

It is not clear whether or to what extent a federal court reviewing an EPA decision whether to accept a particular voluntary cancellation, would be willing to consider whether the pesticide meets the FIFRA registration criteria. However, it is not essential to resolve this question for two reasons. First, the posited scenario did not occur in this case, and the necessary circumstances are unlikely to be recur in the future. As noted previously by both Registrants and EPA, the structure of the flubendiamide cancellation conditions was unprecedented, and the flubendiamide experience shows that a condition requiring a registrant to request cancellation pursuant to section 6(f) is significantly less reliable than a condition that would allow a

[13] In addition, FIFRA § 6(f)(1)(C), 7 U.S.C. § 136d(f)(1), requires a 180-day comment period in regard to pesticides registered for a minor agricultural use (defined in FIFRA § 2(ll)(2), 7 U.S.C. § 136(ll)). Note that registrants may, at their discretion, waive the 180-day comment period Congress provided for users of minor use pesticides, but may not waive the 30-day comment period provided in FIFRA § 6(f)(1)(B), 7 U.S.C. § 136d(f)(1(B). Similarly, EPA can waive the 180-day period if it determines continued use of the pesticide causes unreasonable adverse effects on the environment.

registration to simply expire. EPA is unlikely to grant in the future a registration with conditions that depend on a registrant requesting cancellation pursuant to section 6(f).

Second, determining whether in this particular case the Registrants could have obtained a full review of the basis for EPA's decision before a federal court by challenging a section 6(f) cancellation is not critical to the resolution of this case, because Registrants indisputably had (and still have) available to them a more certain and appropriate opportunity to fully challenge EPA's determination that they are not entitled to a registration without the cancellation conditions: they could have pursued a denial hearing. *See* pp. 4-5 *supra*.

VII. Is the doctrine of laches legally applicable to this proceeding? If so, explain how the record supports this conclusion.

Laches is a long-established doctrine "focused on one side's inaction and the other's legitimate reliance, [which] may bar long-dormant claims for equitable relief." *City of Sherill v. Oneida Indian Nation*, 554 U.S. 197, 217 (2005). Further, laches is "essentially the equitable substitute for a statute of limitations...and serves to protect defendants from prejudice caused by stale evidence [and] prolonged uncertainty about legal rights and status." *Smith v. Caterpillar*, 338 F.3d, 730, 733 (7th Cir. 2003) (finding laches applied where plaintiff waited over eight years to file an employment discrimination claim). Specifically, a claim is barred by laches, when "the delay in filing the claim (1) is unreasonable and inexcusable and (2) materially prejudices the defendant." *Id.*, *see also Environmental Defense Fund, Inc. v. Alexander*, 614 F.3d 474, 478 (5th Cir. 1980) (explaining the elements of laches). EPA concedes that if the flubendiamide proceeding is properly limited to the narrow scope set forth in section 6(e), laches would not be an issue. But if the EAB were to determine that the appropriateness of the cancellation condition is an appropriate issue for resolution, EPA submits that laches would apply to this proceeding;

there is substantial evidence in the record to support a finding by the EAB that the Registrants' delay of almost eight years in challenging the condition is unreasonable and materially prejudices EPA because critical witnesses to the development of the condition are no longer available.

As to whether the government could claim laches against a private party, the caselaw is clear that various federal agencies have successfully asserted laches. *See* Oral Argument Tr. at 87 (Question by Judge Stein at oral argument); *See Zelazny v. Lyng*, 853 F.2d 540 (7th Cir. 1988) (USDA); *Wilmes v. United States Postal Service*, 810 F.2d 130 (7th Cir. 1987); *Environmental Defense Fund, Inc. v. Alexander*, 614 F.3d 474 (5th Cir. 1980) (Army Corps of Engineers); *Sworob v. Harris*, 451 F. Supp. 96 (E.D. Pa. 1978) (HUD).

After negotiating and agreeing to the conditional registrations at issue here, and enjoying the economic benefits of the registrations, Registrants waited almost eight years to challenge an integral condition of their registrations. Registrants were fully aware of the condition and could have challenged it at any point. RE 10 at 100103. Registrants have provided no credible rationale for the long wait in challenging it and, at oral argument, explained that they simply never thought the condition would occur as it did. (Oral Argument Tr. at 45-47). Thus, their almost eight-year delay in challenging the condition is both unreasonable and inexcusable. *See Sworob v. Harris*, 451 F. Supp. 96, 101-02 (E.D. Pa. 1978) (applying laches where residents waited eight years to challenge a housing construction project despite the fact that they were involved in all phases of the proposed construction).

As a result of Registrants' delay, EPA has been prejudiced. Evidentiary prejudice can occur when, due to the lapse in time, witnesses become unavailable or available witnesses' memories have faded. *See Smith*, 338 F.3d at 735 (finding that the unavailability of witness

testimony and physical evidence showed prejudice). The longer the delay, the less evidence of prejudice need be shown. *See id.* at 734 (noting that after an "inexcusable eight and one-half year delay, [defendant] need not present a mountain of evidence establishing prejudice in order to succeed on its laches defense"); *see also Zelazny v. Lyng*, 853 F.2d 540, 543 (7th Cir. 1988) (explaining that because of an eight-year delay, the defendant would need less evidence of prejudice). Here, the key negotiators of the cancellation condition and the initial registrations were unavailable to serve as witnesses. EPA's primary decision makers on flubendiamide in 2008 are no longer with the Agency (Administrative Tr. 78:6-11); Bayer's Vice President of Regulatory Affairs, who signed the PAL, is retired from Bayer (Administrative Tr. 117:19-22;118:1-9); and Charlotte Sanson, Director of Federal Registration for Bayer, who testified for Respondents on the initial registration, did not even work for Bayer in 2008. (PBNX 116; PBN1593) If the appropriateness of the condition is an issue in the proceeding, this lack of available witness testimony could materially prejudice the Agency.

As requested by the EAB, the following is a list of more recent applicable laches case law, with a short summary of the relevant facts and holdings:

City of Sherill v. Oneida Indian Nation, 554 U.S. 197 (2005)

Facts: In 1997 and 1998, the Oneida Indian Nation (OIN) tribe re-purchased land that had previously been part of their reservation in New York pursuant to a 1794 treaty. OIN refused to pay taxes to the City of Sherill because the 1794 treaty gave them sovereignty. However, history showed that there had been a move away from the 1794 treaty and towards non-native settlement. The city raised the affirmative defense of laches.
Holding: The court held that laches applied based on changed conditions. The land value had increased and there had been a two century lapse in control. It also explained that laches applied to Native American tribes' territorial disputes with municipalities in the same way it applies to territorial disputes between states.

Smith v. Caterpillar, Inc., 338 F.3d 730 (7th Cir. 2003)

Facts: After an eight-year delay, former employee requested a Right-to-Sue letter from the Equal Employment Opportunity Commission and sued defendant, alleging gender discrimination and retaliation in violation of Title VII of the Civil Rights Act.
Holding: Laches was appropriate given that several key employees who participated in the termination were either deceased, out of the court's jurisdiction, or retired and out of contact with the company. In addition, the Defendants established that memories of other witnesses had faded and physical evidence, including performance reviews and attendance records were unavailable after Plaintiff's delay.

Zelazny v. Lyng, 853 F.2d 540 (7th Cir. 1988)

Facts: Eight years after being terminated from his employment with the U.S. Department of Agriculture, appellant sought reconsideration of his termination with an opportunity to make an appearance before the commission that made the termination decision.
Holding: Laches applied because appellant failed to dispute his lack of diligence in not pursuing his claim and because the government was prejudiced by appellant's eight-year delay in filing his action.

Wilmes v. United States Postal Service, 810 F2d 130 (7th Cir. 1987)

Facts: Two years after Plaintiff filed an age discrimination action, he amended the complaint to allege that defendant Postal Service had violated its regulation providing for preferential consideration for veterans seeking employment. Plaintiff provided no reasons for this delay.
Holding: In the absence of any explanation for the delay in bringing suit, the court presumes Defendant was prejudiced by the delay. Because no issue of material fact existed as to Plaintiff's unreasonable delay in bringing his claim and prejudice is presumed, laches is appropriate.

Environmental Defense Fund, Inc. v. Alexander, 614 F.3d 474, 478 (5th Cir. 1980)

Facts: Congress gave the Army Corps of Engineers permission to build a 170 ft. canal. In 1967, the Corps conducted analysis of the site and concluded that the canal should be 300 ft. wide. EDF did not sue until 1976. EDF claimed that they had delayed because they did not know that the Corps actions were questionably legal until 1976.
Holding: The Fifth Circuit held that EDF's delay in bringing the claim was unreasonable and inexcusable because "laches does not depend on subjective awareness of the legal basis on which a claim can be made."

Sworob v. Harris, 451 F. Supp. 96 (E.D. Pa, 1978)

Facts: Philadelphia residents sought an injunction to prohibit the building of a housing project because the Secretary of HUD failed to obtain an environmental impact statement under the National Environmental Policy Act.

Holding: Laches barred the action because the residents failed to show a good cause for their eight-year delay in bringing the action and that defendants would have been prejudiced were the action to continue.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 1st day of July, 2016, before 12:00 pm EDT a true and correct copy of *Post-Argument Brief of the United States Environmental Protection Agency* was filed electronically using the EPA EAB e-filing system and served in the following manner to the below addresses:

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