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	)	
	)	

RESPONSE BRIEF OF THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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PRELIMINARY STATEMENT

Pursuant to 40 C.F.R. section 164.101, Appellee, U.S. Environmental Protection Agency ("EPA") submits this brief in response to Appellants' ("Registrants") Exceptions and Brief seeking reversal of rulings issued by the Chief Administrative Law Judge Susan Biro ("ALJ") concerning EPA's decision to cancel Registrants' flubendiamide pesticide registrations under FIFRA section 6(e). EPA responds under separate cover to Registrants' Motion to Reopen Hearing.

STATEMENT OF THE CASE

In 2008, Registrants received conditional registrations pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act, as amended ("FIFRA") section 3(c)(7)(C) for a new active ingredient, flubendiamide. The conditions of the four registrations at issue in this case, specified in the Notices of Registration (RE 3 and PBNX 7) and in the Preliminary Acceptance Letter ("PAL", RE 2 and PBNX 8), included a requirement to submit additional data, an understanding that EPA would review the data and discuss its review with Registrants, and a requirement that Registrants submit a request for voluntary cancellation pursuant to FIFRA section 6(f) should EPA determine that continued registration would result in unreasonable adverse effects on the environment ("UAE"). While the requirements set forth in the conditions may be unconventional, they are nonetheless quite clear: If, after reviewing the relevant data, EPA were to make a determination that the Registrants' products cause unreasonable adverse effects, Registrants were required to request voluntary cancellation pursuant to FIFRA section 6(f). The Registrants agreed to and were fully aware of this provision. EPA did in fact make that UAE

determination, but Registrants refused to request voluntary cancellation, and EPA issued a Notice of Intent to Cancel ("NOIC") the flubendiamide registrations for failure to comply with a condition of registration under FIFRA section 6(e).

While the scientific findings that ultimately triggered the condition requiring Registrants to submit a voluntary cancellation are not at issue in a proceeding under section 6(e), the record clearly establishes that EPA had concerns from the outset about the toxicity and persistence of this new product, and how it would break down in the environment into an even more toxic and persistent degradate. Data provided to the Agency with the Registrants' applications indicated that flubendiamide and its degradate had the potential to get into water, where their concentrations of both could increase to levels toxic to aquatic invertebrates. In reviewing the initial registration applications, EPA was uncertain of the extent to which flubendiamide would cause harm to the aquatic environment. In light of this uncertainty, EPA determined these registrations could only be granted for a limited period of time, and with certain conditions in order for EPA to make a no unreasonable adverse effects determination. Within this limited time period, Registrants were required to conduct additional studies based on the actual use of flubendiamide and the voluntary cancellation condition was included to allow flubendiamide to be quickly removed from the market-place if EPA's initial concerns were unresolved. The conditions Registrants agreed to for the registrations called for EPA to do one of three things at the end of the established time period: EPA would: (1) Approve the registration of the flubendiamide products unconditionally, notwithstanding any restriction that is deemed necessary; (2) mutually agree with the Registrants on a path forward, revising or providing additional data under a conditional registration; or (3) accept the voluntary cancellation of the registration of the flubendiamide products. To implement this last possibility, Registrants agreed

that if, after review of the data, the Agency made a determination that further registration of the flubendiamide products will result in unreasonable adverse effects on the environment, Registrants would within one week request voluntary cancellation of the flubendiamide registrations.

EPA reviewed the studies submitted by Registrants during the conditional registration period and multiple meetings were held involving EPA's and Registrants' scientists and regulatory personnel where the data and EPA's conclusions were discussed. Based on its review of all of the available information, including that provided by Registrants obligated by the conditional registration, EPA found that over time, flubendiamide and its degradates would be expected to persist and accumulate in water to levels toxic to benthic aquatic organisms. Based on this, EPA determined that the continued registration of flubendiamide would result in unreasonable adverse effects on the environment.

EPA informed Registrants of this determination and directed them to request voluntary cancellation pursuant to the terms of the conditional registration. Despite the fact that Registrants were well aware of this specific condition and the rationale for its inclusion into the approved registration, in a letter dated February 5, 2016, Registrants refused to request voluntary cancellation.

Based on the Registrants' refusal to comply with conditions of their registrations issued under FIFRA section 3(c)(7), EPA issued a Notice of Intent to Cancel ("NOIC") the flubendiamide registrations under the authority of FIFRA section 6(e). The decision to proceed under FIFRA section 6(e) is mandated by FIFRA, and is consistent with the flubendiamide Notices of Registration, each of which clearly states that FIFRA section 6(e) will be the cancellation authority used if any of the conditions of registrations are not complied with.

FIFRA section 6(e) is the companion cancellation provision added to FIFRA at the same time Congress authorized EPA to issue conditional registrations under FIFRA section 3(c)(7)(C).

FIFRA section 6(e) provides that the cancellation initiated in the NOIC is final within 30 days, unless a hearing pursuant to section 6(e) is requested in that time. Registrants requested a hearing, yet before the hearing, they filed a Motion for Accelerated Decision ("MAD") asking the ALJ to determine that the voluntary cancellation condition was unlawful and the proper cancellation proceeding had to be conducted pursuant to FIFRA section 6(b) rather than section 6(e). The ALJ agreed with the Agency's arguments that FIFRA section 6(e) was a proper proceeding for cancellation in this case and the voluntary cancellation condition was a lawful condition of their registrations. Because the Registrants stated in their Motion for Accelerated Decision that they intended to have experts provide testimony at the hearing related to the issue of whether flubendiamide causes unreasonable adverse effects on the environment, EPA submitted its Motion to Limit Scope of Testimony ("MTL") that would "bar any testimony at hearing related to the issue of whether flubendiamide causes unreasonable adverse effects on the environment because such testimony is not material to any permissible issue of fact that will be raised in the proceeding." Given the scope of a section 6(e) hearing is statutorily limited to whether the conditions were met and whether the Agency's existing stocks determination was consistent with FIFRA, the ALJ determined that UAE testimony was not relevant to the question of whether Registrants had complied with the relevant condition, and that because UAE issues were not considered by EPA in its existing stocks determination, factual testimony related to the issues was not material to whether the existing stocks determination was consistent with FIFRA. Thus, the ALJ determined that the question of whether flubendiamide causes "an unreasonable

adverse effect on the environment is not an issue for hearing, and evidence thereto is not admissible at hearing." MTL Order at 10.

The ALJ's Orders on the Motion for Accelerated Decision and Motion to Limit Scope of Testimony effectively and properly limited the scope of the hearing to whether the registration conditions were met and whether EPA's determination on disposition of existing stocks, as is proper in a FIFRA section 6(e) proceeding. The hearing requested by the Registrants was necessarily pursuant to the statutory authority of FIFRA section 6(e) because that is the authority EPA cited in its NOIC. It is clear based on Registrants' Appeal Brief, Motion to Reopen Hearing, and Notice of Exceptions, that they wish they were provided a hearing opportunity under a different authority. FIFRA section 6(e) entitles them to a particular hearing, one where the only issues to be determined are whether the conditions of registration were complied with and whether the Administrator's determination on existing stocks is consistent with FIFRA.

EPA demonstrated at hearing that the voluntary cancellation condition was agreed upon by representatives for the Registrants and the Agency, and understood to be an integral part of EPA's determination that the conditionally registered products would not cause UAE. The ALJ found that the Registrants did not comply with a required condition of their registrations, and therefore determined that the registrations should be cancelled pursuant to section 6(e).

Regarding existing stocks, EPA stated in the NOIC that any existing stocks in the possession of end users after cancellation can be used until exhausted, but no further sale or distribution by Registrants or any other person should be permitted, other than distribution solely for disposal or export. EPA based this determination on the Registrants' conduct in failing to comply with a condition of registration that Registrants understood played an important role in

EPA's decision to grant the registrations in the first place. The ALJ properly found this determination to be consistent with FIFRA. CID at 36.

The ALJ correctly decided in her Corrected Initial Decision of June 3, 2016 that the voluntary cancellation provision was a lawful condition of the registrations and Registrants did not initiate and pursue appropriate action to comply with that condition, making these registrations properly subject to cancellation under FIFRA section 6(e). The ALJ also correctly decided that EPA's determination with respect to the disposition of existing stocks of the Registrants' conditionally registered product was consistent with FIFRA. EPA respectfully requests that Board uphold the Orders issued in the Motion for Accelerated Decision Order, the Motion to Limit Scope of Testimony, and the ALJ's Corrected Initial Decision, and order the cancellation of Registrants' flubendiamide registrations, subject to the existing stocks provisions in the NOIC.

ARGUMENT

I. The ALJ's Ruling to Deny the Registrants' Motion for Accelerated Decision was Proper and Should be Upheld by the EAB.

The Registrants' arguments in their Motion for Accelerated Decision were twofold. First, the Registrants argued that because EPA made a finding, as contemplated by the PAL, that use of flubendiamide causes unreasonable adverse effects on the environment, EPA was obligated to initiate any cancellation under FIFRA section 6(b). Second, the Registrants argued that the voluntary cancellation condition was unlawful. For the reasons set forth below, EPA requests that the EAB uphold the proper dismissal of the Motion for Accelerated Decision. The ALJ properly rejected both contentions.

A. The ALJ was Correct in Rejecting the Registrants' Arguments that Cancellation Must Proceed Under FIFRA Section 6(b).

The ALJ properly found that FIFRA's text, structure, legislative history, and federal court opinions allow for this cancellation to proceed under FIFRA section 6(e). MAD Order at 21. The ALJ correctly found that *Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34 (D.D.C. 2011), *Reckitt Benckiser, Inc. v. EPA*, 613 F. 3d 1131 (D.D.C. 2010), and other cases "[Registrants] cite to support their claim that EPA is required to go through a Section 6(b) proceeding to cancel pesticide registrations are all clearly distinguishable from the facts of this case because they involve general registrations, not conditional registrations." CID at 22. Regardless of whether EPA could have initiated cancellation pursuant to FIFRA section 6(b), the pesticide registrations in this case were conditionally registered under FIFRA section 3(c)(7)(C). When Registrants failed to satisfy certain conditions of those conditional registrations, the registrations were properly subject to cancellation pursuant to FIFRA section 6(e). The only constraint in FIFRA on EPA's choice between these cancellation authorities is that the language of FIFRA section 6(e) is mandatory (the "Administrator shall issue…") while the language of FIFRA section 6(b) is permissive ("the Administrator may issue…"). Inasmuch as the criteria for cancellation under FIFRA section 6(e) were clearly met, it was reasonable and appropriate for EPA to issue the NOIC pursuant to FIFRA section 6(e).

The EAB should reject Registrants' argument that, because EPA made a UAE determination regarding the flubendiamide products, EPA was obligated to issue the NOIC under FIFRA section 6(b). RAB at 6. EPA did make a UAE determination as specified in the PAL, but nothing in the PAL suggests that the UAE determination should trigger a section 6(b) proceeding. PBNX 8. In addition, the Notices of Registration for all of the flubendiamide registrations explicitly state: "If these conditions are not complied with, the registration will be

subject to cancellation in accordance with section 6(e) of FIFRA." RE 3 at 200015, 200017, 200019, and 200019B. Owing to the fact that the NOIC commenced this proceeding under FIFRA section 6(e), neither the Registrants' views on the merits of EPA's January 29, 2016 UAE determination (nor those of the ALJ) are relevant to this proceeding -- the only question about that determination that is relevant to this section 6(e) proceeding is whether EPA made a determination that would trigger the voluntary cancellation condition. Contrary to Respondents' claim that EPA has "bypass[ed] cancellation proceedings" (Respondent Opposition to MAD at 54), EPA has, in fact, utilized the statutory provision Congress designed specifically for situations where conditions of registration have not been met.[1] Cancellation under FIFRA section 6(e) is the statutorily mandated consequence of the Registrants' failure to comply with a condition of their FIFRA section 3(c)(7) conditional registrations. MAD Order at 22.

EPA was clear in its NOIC that the Agency was moving to cancel the registrations on the basis of Registrants' failure to meet the required conditions of registration, not on the basis of UAE. RE 8 (81 Fed. Reg. 11558 (Mar. 4, 2016)). The ALJ agreed that EPA's decision to proceed here under FIFRA section 6(e) was reasonable and appropriate. MAD Order at 28. The

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[1] In 1978, Congress added section 6(e) to FIFRA to provide a procedure for cancelling conditional registrations issued under FIFRA Section 3(c)(7). The legislative history of the conditional registration provisions suggest conditional registrations should be handled quickly and not unnecessarily drawn out. (MAD Order at 22). See H.R. Rep. No. 95-343, at 10-11 (1977) ("We strongly believe that the Agency should be required to cancel the registration if the conditions are not met within the appropriate time interval, and that any hearing on such cancellation should be confined to whether or not the conditions were met and how existing stocks should be handled. *Public resources should not be devoted to long, drawn-out cancellation procedures for these types of registrations.*") (emphasis added); S.Rep. No 95-334, at 10-11 (1977) (it was agreed "that the Administrator could cancel conditional registrations with only limited notice," and also "that the Administrator in implementing this provision should take necessary steps to assure that conditional registrations are granted only in circumstances in which the risk of unreasonable adverse effect would be minimal.")

ALJ rejected the Registrants' argument that because EPA determined flubendiamide causes unreasonable adverse effects, only cancellation under FIFRA section 6(b) is available. MAD Order at 21.

The EAB should similarly reject Registrants' argument that the voluntary cancellation provision was an unlawful attempt to avoid a FIFRA section 6(b) hearing process. RAB at 7. Registrants had opportunities to obtain a hearing on whether they are entitled to a registration without the condition, where they could have introduced risk-benefit information, by either refusing to accept the registrations because of the cancellation condition, by applying to amend their registrations to remove the conditions, or by applying for new unconditional registrations, and upon denial requesting a denial hearing per FIFRA section 3(c)(6). The latter option remains available in perpetuity, so EPA's exercise of its FIFRA section 6(e) authority is not, as Registrants contend, a shield against "required public transparency and review." RAB at 9.

Registrants have identified no statutory support for their position that FIFRA section 6(e) may not be used when section 6(b) conceivably could be used. EPA could have considered to pursue cancellation under 6(b), but EPA properly exercised its discretion to pursue cancellation under FIFRA section 6(e). *See* EPA's Opposition to MAD at 49. FIFRA provides a variety of grounds for cancelling a pesticide product, and EPA has some discretion to choose which to exercise when there appear to be alternative grounds for cancellation. *Id.* While FIFRA specifies no explicit hierarchy ranking for each of its various cancellation authorities, and a reasonable interpretation supports allowing EPA the discretion to choose which cancellation authority to use in any particular case, certain differences in statutory language used might arguably suggest use of one authority rather than another. EPA's Opposition to MAD at 51. FIFRA section 6(e) states that EPA "shall issue" an NOIC once EPA determines – as was the case here – that the

Registrants failed to comply with registration conditions. This contrasts with the "may issue" language in FIFRA section 6(b). The mandatory language of FIFRA section 6(e) contravenes Registrants' contention that the right to a FIFRA section 6(b) proceeding takes precedence to EPA's decision to cancel pursuant to FIFRA Section 6(e). EPA's Opposition to MAD at 52.

The EAB should reject Registrants' contention that the Corrected Initial Decision depends on a false conclusion that conditional registrations can only be cancelled under FIFRA section 6(e). RAB at 10-11. As authority for this contention, the Registrants offer a contrived reading of sentence fragments scattered through page 22 and footnote 21 on page 24 Order on MAD. RAB at 10-11. A fair reading of the cited text in context does not support an interpretation that conditional registrations can only be cancelled under FIFRA section 6(e); a reader can reach that conclusion only by deliberately supplying it him/herself. The ALJ was quite circumspect in avoiding broad statements and sticking to the circumstances of the case before her:

> Further, if [FIFRA section 6(b)] could be the basis for cancellation of conditional registrations *due to non-submission of required materials, e.g., the data required by a conditional registration,* then Section 6(e) would be rendered superfluous, and violate a cardinal rule of statutory construction. MAD Order at 22 (emphasis added).

The italicized text above shows that the ALJ was aware that the particular factual circumstances offered as grounds for cancellation to determine which of the different cancellation authorities apply. Implicit in the inclusion of the italicized clause in the above statement is the presumption that the statement would have meant something different without it, and the necessity of its inclusion is evidence of the ALJ's understanding that conditional registrations could be cancelled on some basis other than a failure to meet conditions. And she took no position on what cancellation authorities might be appropriate under other circumstances.

The sentence fragment that appears most supportive of the Registrants' position, "the plain language of the statute entitles Petitioners to a cancellation proceeding only under FIFRA Section 6(e)" (RAB at 11) offers no support, once it is read in context. In the final sentence of a footnote, Registrants conveniently omitted the prefatory clause: "*as explained in this Order*, the plain language of the statute entitles Petitioners to a cancellation proceeding only under FIFRA Section 6(e)." MAD Order at 24 n.21 (emphasis added). The Registrants "applied for and received ... 'conditional registrations' for their flubendiamide products under FIFRA Section 3(c)(7)(C)" (MAD Order at 21), and the "NOIC states that EPA intends to cancel four of Petitioners' conditional pesticide registrations for flubendiamide 'owing to the registrants' failure to comply with a required condition of their registrations.'" MAD Order at 1. The circumstances were such that the only proceeding to which the Registrants were entitled upon receipt of the NOIC was a proceeding subject to section 6(e). Nothing in the Order on MAD or the Corrected Initial Decision supports the contention that the ALJ thought that conditional registrations could *only* be cancelled under FIFRA section 6(e) irrespective of circumstances.

The Registrants do not have a right to a FIFRA section 6(b) hearing in this proceeding because conditions precedent to such a proceeding have not been met: The Administrator has not issued an NOIC proposing to cancel on the basis of a conclusion that the Registrants' pesticide registrations does not comply with the provisions of FIFRA or, when used in accordance with widespread and commonly recognized practice, generally cause unreasonable adverse effects on the environment. This proceeding can therefore not be converted into a proceeding under section 6(b). The only hearing they have a right to is the hearing initiated by EPA under section 6(e), and only to the extent FIFRA allows issues to be raised in such a hearing. Registrants' essential argument is that, notwithstanding their clear failure to comply

with a condition of their conditional registrations (that they knowingly agreed to), and notwithstanding the statutory language that requires action under section 6(e) when a condition of a conditional registration is not met, section 6(e) may not be used if action under section 6(b) could have been initiated. FIFRA simply does not mandate such a result.

B. The ALJ was Correct in Determining that Conditions Agreed to by EPA and the Registrants were Lawful and Therefore Valid.

The ALJ properly found that the requirement to request voluntary cancellation was a lawful condition of Registrants' registrations from which they are not excused. CID at 32. All of the preconditions resulting in the Registrants' obligations to submit requests for voluntary cancellation of their flubendiamide registrations were fulfilled as of January 29, 2016. *Id.* (citing to RE 5). The ALJ rejected Registrants' contention that the voluntary cancellation condition is "unlawful" because it violated the text and structure of FIFRA and they were entitled to a judgment as matter of law and an order dismissing the proceeding under FIFRA section 6(e). MAD Order at 21. The ALJ agreed that the term "other conditions" as the Administrator may prescribe is not limited just to data conditions, and citing to *Woodstream Corp. v. Jackson*, 2011 U.S. Dist. LEXIS 151994; 2011 WL 8883395 (D.D.C. 2011) (Preliminary injunction decision) (*Woodstream I)* and *Woodstream Corp. v. Jackson*, 845 F.Supp, 2d 174 (D.D.C. 2012) (*Woodstream II*), recognized courts have upheld the Administrator's authority to impose a wide range of conditions, including those that terminate the conditional registrations without any further process.

The EAB should reject Registrants' contention that differences between their voluntary cancellation conditions and the conditions at issue in *Woodstream I* make the holdings of that case inapposite. The Registrants argue that the voluntary cancellation provisions in the flubendiamide registrations "unlike [those of] the plaintiffs in *Woodstream I* at *5 (D.D.C. June

3, 2011) ... go beyond what Congress authorized because, among other things, they are non-substantive and impose a purported condition that Registrants cannot satisfy without relinquishing their registrations." RAB at 10, n.3.

The conditional registrations at issue in *Woodstream I* were each subject to one of the following two conditions: (1) that the registrant must amend the registration to "comply with EPA's final Rodenticide Risk Mitigation measures for similar rodenticides when the [EPA] imposes such measures, on the same time schedule as those similar rodenticides;" or (2) "this registration is approved only subject to the condition that the registration shall expire on June 4, 2011." *Woodstream I* at *5. There is no apparent basis for the Registrants' claim that the flubendiamide conditions are somehow more "non-substantive" than the *Woodstream* conditions, as they clearly had similar substantive effects on the subject registrations. In regard to the contention that the *Woodstream* conditions could be satisfied "without relinquishing their registrations," that argument is patently false in regard to those registrations with the expiration date conditions. Therefore, the Registrants have presented no credible rationale for distinguishing *Woodstream I*, nor any reason to suppose that the flubendiamide conditions "go beyond what Congress authorized" while the *Woodstream* conditions did not. In point of fact, the *Woodstream I* decision did not turn upon the nature of the conditions at all, rather "[i]n light of Plaintiff's options [to decline to accept the condition; to accept the conditions but submit a new application to force a denial hearing; to seek judicial review of the conditions], the Court finds that EPA's actions did not circumvent FIFRA's Section 6 cancellation procedures and that they were reasonable." This rationale appears equally applicable regardless of the type of condition at issue.

The ALJ analogized Registrants' challenge to the voluntary cancellation condition to a similar claim rejected by two judges of the D.C. District Court in the two *Woodstream* cases. The ALJ noted that, just as in the *Woodstream* cases, Registrants were not forced to accept the conditions because they could have (1) withdrawn their applications for registration; (2) accepted the conditions and submitted an application to amend the registration to remove the conditions; (3) accepted the conditions and submitted new applications for registration without the conditions; or (4) refused to accept the conditions and pursued a denial hearing. Options 2-4 all offer a path to a denial hearing equivalent to a Section 6(b) hearing, and options 2 and 3 would allow them to do so while selling product under the original conditional registration. None of these options were selected, and the Registrants' claim of being forced into accepting the condition was unpersuasive. MAD Order at 27. The ALJ also recognized that correspondence between the Registrants' and EPA shows the Registrants took an "active part in drafting the conditions in the PAL containing the voluntary cancellation provisions and were well aware of their significance." MAD Order at 27. The ALJ rejected Registrants' assertion that the voluntary cancellation condition serves no regulatory purpose because the e-mails demonstrate that the Registrants recognized that EPA was concerned with the ability to quickly cancel the conditional registrations if the initial concerns regarding flubendiamide could not be addressed. The ALJ did not excuse Registrants from the 2008 legal agreement they knowingly made for a "fast death" cancellation condition, where for seven years after entering into it they failed to exercise any of their options for challenging the condition, but instead refused to comply when EPA triggered the cancellation condition.[2]

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[2] Indeed, EPA submits that Registrants' conduct here, where they accepted registrations with a condition they had discussed in advance with the Agency and accepted without challenge, prevents them from now challenging the validity of the cancellation condition. The principle of

The EAB should reject Registrants' argument that EPA's delay in responding to two applications for amendment filed by Woodstream in 2011 is evidence that applying to amend their registrations was not a viable option for Registrants if they wished to challenge the PAL conditions. The Registrants cite briefs filed in *Woodstream II* to argue that EPA's failure to respond formally to Woodstream's requests to amend its registrations by removing offending conditions shows that such amendments do not provide a path to a denial hearing under FIFRA section 3(c)(6). EPA disagrees. Inasmuch as a denial decision requires publication of a notice in the Federal Register detailing reasons and factual basis for the denial, and which (within 30 days) may become the basis for a hearing equivalent to that mandated by FIFRA sections 6(b) and (d), the issuance of a formal denial is a regulatory effort that requires a level of effort fully comparable to that required for a notice of intent to cancel pursuant to FIFRA section 6(b). Per the briefs cited by the Registrants, Woodstream filed its suit for injunctive relief from the registration conditions less than three months after its first application to amend. Defendant's Opp. to Mot. for Summary Judgment at 13 (ECF No. 12), *Woodstream Corp. v. Jackson*, 845 F. Supp. 2d 174 (D.D.C. 2012). EPA submits that three months is not an unreasonably long time for the preparation and Federal Register publication of a FIFRA section 6(b) NOIC or a FIFRA

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laches disfavors allowing a party challenge to an alleged wrong where the party has acquiesced in the alleged wrong or has shown a lack of diligence in challenging the wrong. *Southern Pacific Co. v. Bogert*, 250 U.S. 483, 488 – 489 (1919). Here, Registrants acquiesced in the condition and failed to initiate a timely challenge to the condition. And it is not at all clear that the statute of limitations allows a challenge to the legality of any part of the registrations more than six years after the registrations were issued. Registrants' lack of timeliness in challenging the condition raises two practical issues: EPA has never made a finding (or been asked to make a finding) that the flubendiamide registrations meet the standard of FIFRA without the cancellation condition (EPA submits that because of this, the appropriate remedy if the EAB were to find the condition illegal would be to invalidate the registrations as no longer supported by appropriate findings under FIFRA), and factual issues related to the adoption of the condition are difficult to resolve because many of the participants in the discussions between EPA and the Registrants during the development of the condition (see RE 4) no longer work for EPA or the Registrants.

section 3(c)(6) denial, but since Woodstream brought suit for injunctive relief instead of unreasonable delay, reasonability remains a matter for conjecture. Woodstream's choice of remedy was no doubt influenced by the approaching June 4, 2011 expiration date, but as it could have begun its challenge to the conditions as early as July 2006, that time constraint was of its own making. Here, Registrants had more than seven years in which they could have, but failed to, initiate a challenge to the condition.

The EAB should reject the Registrants' contention that the MAD Order suggests that there are no limits to what EPA could impose as conditions of registration. The Registrants urge rejection of the decision that the voluntary cancellation conditions were valid, arguing that the ALJ adopted the extreme position that there are no limits on the range of possible conditions permitted under FIFRA section 3(c)(7). RAB at 10. The ALJ's statement that "[t]he term 'other conditions' in the statute is in no way limited" (MAD Order at 24) is simply a finding that FIFRA section 3(c)(7) puts no explicit limits on the scope of permissible conditions, and nowhere else in FIFRA is there any express limitation. Contrary to Registrants' contention that this is an "extreme position," the District Court in *Woodstream II*, 845 F. Supp. 2d 180, 181, rejected such a contention ("The plain language of the statute does not restrict EPA's authority as to the type of conditions that may be placed on registrations. . . . There is nothing to suggest that Congress intended to limit conditions on registrations to test data."). The Registrants simply misread the ALJ's statement in order to make the decision appear unsound. The fact that one can readily imagine hypothetical conditions inconsistent with the FIFRA section 33 pesticide registration service fees, the Constitution, or other federal laws does not suggest EPA would or could impose such conditions. And such fanciful imaginings should not invalidate the ALJ's

decision that the voluntary cancellation conditions was within the scope EPA's authority under FIFRA section 3(c)(7)(C).

The EAB should reject the Registrants' contention that the ALJ's orders and *Woodstream* would oblige registrants to file straw man applications to defend due process rights in registrations they already hold. The Registrants argue that "[t]he MAD Order and the *Woodstream* decision likewise fail to explain why registrants should be required to file straw man applications to defend due process rights in registrations they already hold, or why it would serve administrative or judicial efficiency to require them to do so." RAB at 16. The Registrants' contention is based on the mistaken presumption that the registrant of a pesticide conditionally registered pursuant to FIFRA section 3(c)(7) holds some inalienable right to hearing conforming to the requirements of a FIFRA section 6(b) even when EPA proposes to take that registration away for failure to comply with a condition of registration. There simply is no such right.

The right to a FIFRA section 6(b) proceeding is a procedural right created by statute. To the extent that a pesticide registrant has other due process rights in regard to revocation of its license, those rights are specified in the Administrative Procedure Act at 5 U.S.C. § 558. The procedural rights specified by APA section 558 are much more limited than -- and amply met by -- the procedures used in the instant proceeding, so it is reasonable to focus solely on FIFRA and the regulations promulgated thereunder. Becasue the right to a FIFRA section 6(b) proceeding is created by FIFRA section 6(b), it is FIFRA section 6(b) that defines the scope of that right.

In regard to registered pesticide products,[3] FIFRA section 6(b) specifies that the only circumstances in which one has[4] a right to a hearing pursuant to FIFRA section 6(b) are as follows: Where the Administrator concludes that it appears that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of FIFRA or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, and on that basis the Administrator has issued a notice of the Administrator's intent either (1) to cancel its registration or to change its classification together with the reasons (including the factual basis) for the Administrator's action, or (2) to hold a hearing to determine whether or not its registration should be canceled or its classification changed.[5]

To the extent that the options of filing applications to amend the registration, or for new, duplicative registrations might be considered "straw men," such strategies are unnecessary if the registrant elects to challenge the conditions of registration *before* accepting said conditions. But once a registrant has accepted a registration subject to certain conditions, the registrant has bypassed the most direct route to challenge the conditions, and might reasonably *want* other options, even if inferior to the one they let slip through their grasp. But if a registrant accepts without challenge a registration with a particular condition, and makes no attempt to obtain a

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[3] FIFRA section 3(c)(6) also provides that applicant for registration (or other interested person with the concurrence of the applicant) has a right to a hearing pursuant to FIFRA section 6(b) when the Administrator has published in the Federal Register a notice of denial of registration pursuant to FIFRA section 3(c)(6).

[4] It might be argued that from the date a registration is first issued, the registrant holds a contingent right to a FIFRA section 6(b) hearing *in the event that* the conditions stated in the above paragraph are met, but this is a matter of form rather than substance, as it leads to the identical conclusion that the right is dependent on the conditions described being fulfilled.

[5] In order to perfect this right, within 30 days from receipt by the registrant, or publication, of such notice, a person adversely affected must file a request for a hearing in accordance with 40 CFR part 164.

registration without the condition, that registrant cannot complain when the appropriate statutory remedy – section 6(e) – is invoked when the condition is not satisfied.

C. The Registrants Knowingly and Willingly Accepted the Registration Conditions and the ALJ Correctly Found Registrants' Were Afforded Due Process.

The EAB should uphold the finding made by the ALJ that the registration conditions were agreed to, and not "forced" upon them as they argued in their Motion for Accelerated Decision. The ALJ found that the Registrants' characterization that they were "forced" into these conditions "... or gave them a 'Hobson's choice,' . . . . [to be] unpersuasive." MAD Order at 27. Part of the ALJ's rationale was based on the fact that the Registrants had other regulatory avenues they could have pursued, but instead chose to agree to the conditions. See MAD Order at 27, n. 23. In addition to making substantive changes to their proposed use patterns to further mitigate aquatic risks, the Registrants had at least four options 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; (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; or (4) they could have accepted the conditional registrations and 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. Registrants' argument that they were "forced" into accepting the conditions is contrary to the facts.

The ALJ also found that the Registrants were active participants in the discussions concerning the conditions that ultimately were agreed to. *Id.* at 27. The best examples in the record are the back-and-forth emails between EPA and the Registrants showing the parties negotiated the conditions ultimately found in the PAL. The Registrants acknowledge the PAL

"document as a 'legal document.'" MAD Order at 27 (citing to AX D; PX 8). Even more telling is the following email exchange between the Registrants' representative and an EPA senior manager regarding the need for the voluntary cancellation condition - "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." *Id.* (citing to AX D (RE 4 at 200036). These exchanges make clear that the Registrants understood the conditions, willfully participated in the negotiations and voluntarily accepted the conditions in the PAL. Consistent with case law allowing waiver of process rights, the Registrants' voluntarily agreed with knowledge and intelligence to the limited hearing rights afforded in FIFRA sections 6(e) and 6(f) and waived any additional due process rights they may have possessed. *D. H. Overmyer Co. v. Frick Co.*, 405 U.S. 174, 185–86 (U.S. 1972).

EPA included in the PAL language to make clear how important these conditions were to the ultimate decision to grant the registration. Specifically, the PAL says, "[i]f either Nichino or Bayer does not agree with any of the conditions of registration, they should consider any such registration to be null and void." PBNX 8 at PBN0022. The PAL continues on to explain the available administrative process afforded to the parties "[i]f either Nichino or Bayer notifies EPA that it is unwilling to accept any of those conditions, EPA will commence the appropriate denial process under section 3(c)(6) of FIFRA." *Id.* Again, Registrants had multiple avenues to challenge the conditions, or to forego registration, but made a business decision to accept the conditional registrations. Accordingly, it is disingenuous for the Registrants to continue to argue that they were "forced" and had no real remedy. MAD Order at 27. Therefore, for all the reasons

stated above, EPA requests that the EAB uphold the ALJ's decision to deny the Motion for Accelerated Decision.

II. The ALJ's Ruling to Grant EPA's Motion to Limit Scope of Testimony was Proper and Should be Upheld by the EAB.

In the Notice of Intent to Cancel Flubendiamide (RE 8), EPA announced its determination to not allow any sale or distribution of existing stocks of flubendiamide if the registrations were cancelled, and based that determination on the failure of Bayer and Nichino to comply with the relevant condition of their registrations, and that the Registrants should not be permitted to benefit from their failure to comply with the condition. *See* RE8 at 200084. EPA observed that "[t]his is not a case where the registrants have made a diligent effort to comply with the condition of registration, only to fail through circumstances beyond their control. Rather, they simply refuse to comply with a condition they earlier chose to accept in order to obtain the registration initially." *Id.* The NOIC rationale for the existing stocks decision focused entirely on the conduct of the registrants, and not at all on whether the sale or distribution of existing stocks would result in unreasonable adverse effects on the environment. That rationale is consistent with FIFRA. After the Registrants made clear in their Motion for Accelerated Decision that they intended to introduce testimony in the hearing related to the risks and benefits associated with use of flubendiamide, EPA filed a Motion to Limit Scope of Testimony asking the ALJ to exclude testimony related to risks and benefits from the hearing.

After considering the information provided to the ALJ by the parties along with the relevant statutory provisions and legal precedent, the ALJ determined that EPA's Motion to Limit Scope of Testimony was well-founded and consistent with the applicable law. The ALJ's decision to exclude from the hearing evidence as to the risks and benefits associated with the use of flubendiamide is consistent with FIFRA.

A. The Excluded Evidence Could Not Have Altered the ALJ's Cancellation Decision.

To the extent that Registrants argue that the MTL Order excluding from the hearing evidence as to the risks and benefits associated with the use of flubendiamide resulted in an improper cancellation decision, that argument is without merit. As explained above, the only facts relevant to this 6(e) cancellation decision (as opposed to a 6(e) existing stocks decision) are those that illuminate whether the conditions of registration have been satisfied. In the NOIC, EPA alleged that Registrants failed to submit a request for voluntary cancellation of their flubendiamide registrations within one week of EPA notifying them of its determination that those products will result in unreasonable adverse effects on the environment. The Order limiting the scope of testimony admitted in this proceeding did not exclude evidence regarding whether registrants had submitted requests for voluntary cancellation of their flubendiamide registrations. It did not exclude evidence regarding whether EPA had made the determination specified in PAL conditions 6(d) and 8(d), or that EPA had failed to notify the Registrants of its determination. It did not exclude evidence regarding the meaning of the PAL conditions and did not exclude evidence regarding whether the conditions were part of the flubendiamide registrations. The excluded evidence regarding the risks and benefits associated with the use of flubendiamide simply are not relevant to the question of whether Registrants complied with the condition obligating them to submit requests for voluntary cancellation, and therefore, could not alter the conclusion that the registrations must be cancelled.

B. The ALJ Properly Found that Because EPA, in Exercising Its Discretion, Relied on the "Consistent with FIFRA" Standard for Determining Existing Stocks, Evidence as to Whether Existing Stocks would not Cause Unreasonable Adverse Effects on the Environment was Irrelevant for the FIFRA Section 6(e) Hearing.

Insofar as is relevant to flubendiamide, FIFRA limits hearings under section 6(e) to two issues: whether the registrants complied with the relevant condition, and "whether the Administrator's determination with respect to the disposition of existing stocks is consistent with [FIFRA]." As noted above, risk-benefit issues have no relevance whatsoever to whether Registrants complied with the relevant condition. As to existing stocks, EPA made clear in its Motion that EPA was not relying on risk-benefit concerns to justify its existing stocks determination, but was instead taking a "much simpler" position:

> The conditions at issue in this proceeding were included in the initial registrations because of EPA's concerns with the environmental risks posed by flubendiamide. The conditions were discussed extensively by the parties prior to the issuance of the registration, and registrants were well aware of the conditions when they accepted the registrations. Their failure to comply with important conditions that they knowingly and willingly accepted, and taken no steps to challenge in more than seven years, is appropriate grounds for both cancellation and for disallowing any further sale or distribution of existing stocks after cancellation. MTL at 5.

Put simply, the position advanced by EPA in its Motion (and in the NOIC) made risk-benefit issues and testimony immaterial to the existing stocks question. EPA has throughout asserted that the conduct of the Registrants in reneging on a condition that was central to their getting their conditional registrations in the first place was all that EPA was relying upon in determining that it was consistent with FIFRA to not allow any sale and distribution of existing stocks. *See* MTL at 3 ("there is no scientific or economic testimony that could reasonably bear upon the question of whether it would be inconsistent with the purposes of FIFRA to allow the registrants to reap the financial rewards of their refusal to comply with a condition of their registrations…"). While EPA could have elected to bolster its existing stocks determination with other arguments, it elected to rely exclusively on Registrants' conduct to support its determination, and to live with the consequences if either the ALJ or the EAB were to determine

that it is not consistent with FIFRA to prohibit sale and distribution of existing stocks based solely on the Registrants' failure to comply with conditions of their registrations..

In her Order granting EPA's Motion to Limit Testimony, the ALJ agreed that EPA was not obligated to consider risks and benefits in making its existing stocks determination. MTL at 9. In her Corrected Initial Decision, the ALJ upheld EPA's existing stocks position on essentially two grounds. CID at 32-37. First, the ALJ determined that because it is generally unlawful under FIFRA to sell or distribute unregistered pesticides and the statute is permissive and does not ever obligate EPA to allow sale and distribution of existing stocks of cancelled pesticides, EPA could simply stay silent on the question of sale and distribution of existing stocks and allow the general statutory prohibition to take effect. CID at 35. The ALJ then went on to examine the record in this case and correctly determined that not allowing the sale and distribution of existing stocks under the circumstances presented here is consistent with FIFRA. *Id.* at 35-37.

EPA respectfully requests the EAB reject Registrants' argument the ALJ improperly excluded evidence related to flubendiamide's risks and benefits from the hearing and uphold the ALJ's Order granting EPA's Motion to Limit Scope of Testimony.

III. The ALJ's Corrected Initial Decision Dismissing the Registrants' Objections and Approving EPA's Cancellation of the Flubendiamide Registrations was Proper and Should be Upheld by the EAB.

After correctly denying the MAD and granting the MTL, a proper 6(e) hearing was held. The parties offered testimony and exhibits for consideration. In the Corrected Initial Decision, the ALJ made the following three findings:

> (1) Petitioners have not initiated and pursued appropriate action to comply with the condition or conditions set forth within their conditional registrations within the time provided;

(2) The condition or conditions set forth within Petitioners' conditional registrations have not been satisfied within the time provided, and
(3) The Administrator's determination with respect to the disposition of existing stocks of the Petitioners' conditionally registered flubendiamide products is consistent with FIFRA.

For the reasons set forth in the Correct Initial Decision and stated below, the ALJ properly found for EPA and EPA respectfully requests that the EAB uphold each of these findings.

A. Registrants are not Excused from Compliance with the Cancellation Conditions for EPA's Alleged Failure to Engage in Dialogue.

The Registrants contend that the condition requiring them to request voluntary cancellation was not triggered because the cancellation provisions required "open, measured scientific dialogue on the data and EPA's conclusions" before EPA demands cancellation. RAB at 18. The ALJ agreed with EPA's argument that this objection was untimely because it was not raised in Registrants' Objections and only raised at the evidentiary hearing and post-hearing briefs. That decision was appropriate and should be upheld.

The ALJ further stated that even if the new arguments could be raised, she found the arguments to be without merit. The Registrants now appeal to the EAB claiming that the ALJ erred by not finding that EPA did not engage in a scientific dialogue on the data submitted by the Registrants or the Agency's conclusions. Although EPA addresses this issue below, the EAB need not go further than determining that Registrants' argument was untimely to uphold the ALJ's determination.

1. The ALJ Correctly Found that the Registrants Failed to Properly Assert Their Objection that EPA's Alleged Failure to Engage in Dialogue Excused the Registrants from Compliance with the Cancellation Conditions.

The ALJ properly prohibited the Registrants from raising any new arguments at hearing. She supported this determination as follows:

> 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, caselaw 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.

The ALJ determined that Registrants' Objections failed to include an objection alleging EPA's lack of transparency and refusal to engage in the open, good-faith scientific dialogue required under the PAL, and that arguments to that point are therefore untimely. The Registrants assert that the Objections "include extensive, detailed allegations objecting to EPA's lack of transparency and refusal to engage in the open, good-faith scientific dialogue required under the PAL." AB at 23. The Registrants did include in their Objections the factual allegations cited on pages 23 and 24 of the Appeal Brief, but nowhere in the Objections did Registrants assemble those factual contentions into a claim upon which relief could be granted. It is not the responsibility of the ALJ or EPA, much less the EAB, to infer a cause of action that the Registrants did not articulate. The fact that the Registrants can articulate today a cause of action based on those facts does not make up for their failure to do so in their Objections. But the Registrants' point is moot in any case, because the ALJ did in fact consider their contentions and found them unpersuasive. CID at 28.

2. *The ALJ Properly Found that EPA Engaged in a Good Faith Dialogue with the Registrants.*

If the EAB determines Registrants' Objections did include the contention that EPA did not engage in good-faith dialogue on the data and its conclusions, the EAB should nonetheless reject the contention as inconsistent with the record. SThe Registrants dispute the ALJ's finding that there is "no evidence of a lack of good faith" on the part of EPA, and contend that specific testimony and correspondence in the record shows the absence of good-faith. RAB at 20. However, read in the light most favorable to the Registrants' argument, the most that the cited evidence shows is that the Registrants' witnesses were willing to attribute the Agency's actions to a lack of good faith. The record shows that EPA's scientists and regulatory personnel repeatedly engaged in serious discussions with the Registrants' representatives on the data submitted during the review period and on the Agency's conclusions drawn from those data. *See* CID 28-32. The ALJ expressly stated that "the evidence indicates that Petitioners' and EPA's scientists *did* engage in a good faith dialogue." CID at 30 (emphasis in the original).

There is no question that there is scientific disagreement between the parties. But the relevant condition does not require scientific agreement; it clearly provides that the obligation to request voluntary cancellation is triggered if EPA makes the relevant determination. And the record clearly reflects that EPA made such a determination.

B. The ALJ Properly Found that the Registrants Failed to Comply with the Conditions Set Forth in their Pesticide Registrations.

After determining in the Order on the Motion for Accelerated Decision that the voluntary cancellation condition was lawful, and then finding in the Corrected Initial Decision that the additional arguments raised by the Registrants at the hearing and in their post-hearing brief to support the argument that the conditions precedent had not been met to require them to comply

with the voluntary cancellation condition were new, and therefore prohibited, the ALJ found that EPA "established all the necessary elements of a prima facie case showing that Petitioners failed to comply with the conditions of the flubendiamide registrations . . . ." CID at 28. Once the ALJ determined that the Registrants did not comply with the conditions, she held that the flubendiamide products must be cancelled. The record supports the ALJ's decisions and they should be upheld by the EAB.

C. The ALJ Properly Found that EPA's Existing Stocks Provision for the Cancellation of these Registrations was Consistent with FIFRA.

In their Appeal Brief, Registrants challenge EPA's failure to conduct a risk-benefit analysis in regard to the existing stocks decision (RAB at 35-37); the exclusion of risk-benefit information (*Id.* at 37-39, 40); and the general appropriateness of EPA's decision to not allow sale and distribution of existing stocks based on Registrants' behavior (*Id.* at 35, 39-40). In addition, Registrants challenge the ALJ's determination that an EPA decision not to allow sale or distribution of existing stocks might effectively be unreviewable. RAB at 30-34. None of those arguments warrant overturning the ALJ's decision with respect to existing stocks.

FIFRA section 6(a)(1) gives EPA[6] broad discretion in regard to the disposition of existing stocks of cancelled pesticides, and EPA's existing stocks decision was based on the following facts: EPA had important risk concerns at the time the original flubendiamide registration was granted, and EPA was not comfortable granting a registration at that time for an unlimited period

[6] Per Delegation 5-7, the authority "[t]o perform the EPA functions and responsibilities relative to the administrative review ... as set forth in FIFRA... Section ... 6." is delegated to the Assistant Administrator for Chemical Safety and Pollution Prevention. *See In the Matter of Reckitt Benckiser LLC, et al.*, FIFRA Docket No. 661, "Order on Motion ..." Feb. 3, 2014 *slip op.* at 17 n.2 ("Powers granted to the "Administrator" in Section 6(a)(1) ("Existing Stocks"), and her delegates pursuant to Agency delegation manuals, cannot be imputed to the presiding ALJ.")

of time. RE 10 at 200098-10; CID at 10-11. Registrants were aware of EPA's concerns, and there was much back-and-forth between the parties over how the registrations would address that concern. MAD Order at 27; RE 10 at 200100-200103. The end result was a condition being added to the registrations that obligated the registrants to request voluntary cancellation within seven days of notification by EPA that EPA had determined that flubendiamide caused unreasonable adverse effects on the environment. RE 10 at 200104; PBNX 8 at PN0019. Registrants were aware of the condition before they accepted the registrations, and they knew that the condition was an important factor in EPA's granting the registrations. RE 10 at 200100. Registrants did not challenge the condition at the time they accepted the registration, and they did not take any steps thereafter to obtain registrations without the condition. RE 10 at 200103-04. Not until late in 2015, when Registrants first learned that EPA might trigger the cancellation condition, did Registrants intimate to EPA that they had legal concerns with the condition. *Id.* In 2016, Registrants sent a letter to the Director of the Office of Pesticide Programs explaining why they were declining to comply with the condition, noting that they believed the condition was unlawful, and that EPA was incorrect on the science. PBNX 17. In that letter, Registrants did not assert that the condition had not been appropriately triggered, an issue they were later to raise for the first time in any detail at hearing. CID at 27-28. Instead of receiving a voluntary cancellation request in early February of 2016, EPA has had to initiate a formal hearing process that will not result in cancellation before July of 2016. It is against this factual backdrop that EPA made its existing stocks determination.

Registrants contend that EPA's failure to conduct a risk-benefit assessment as part of its existing stocks determination is violative of both FIFRA and EPA's existing stocks policy. RAB at 35-37. Registrants' argument with respect to FIFRA appears to consist solely of the fact that

in order to register a pesticide, EPA must apply a risk-benefit standard as part of the registration decision. *Id.* at 35. But FIFRA provides no general right to any person to sell or distribute an unregistered or cancelled pesticide, and there is nothing in FIFRA that suggests EPA must conduct a risk-benefit assessment where it takes no affirmative action to allow sale or distribution of existing stocks of a cancelled pesticide. Further, nothing in FIFRA suggests that EPA may not apply criteria other than risks and benefits in determining whether to allow sale or distribution of existing stocks or that, if those other criteria provide sufficient rationale to not allow sale or distribution of existing stocks, EPA must nonetheless perform a risk-benefit analysis to address the issue.[7]

As to EPA's compliance with its policy statement on existing stocks, EPA concedes that its flubendiamide existing stocks determination is not entirely consistent with the policy statement, which states that registrants who fail to comply with specific conditions of registration would generally not be allowed to sell or distribute existing stocks, but does not state that the prohibition would generally apply to other sellers or distributors. RE 9 at 200091. But a policy statement is not a binding rule, and need not be followed in all circumstances. *Cement Kiln Recycling Coal. v. EPA*, 493 F.3d 207, 226 n.14 (D.C. Cir. 2007) (noting that policy statements have no binding effect and leave decision makers free to exercise discretion). And in the case of flubendiamide, EPA has a valid reason for taking a more stringent approach to its existing stocks determination.

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[7] In fact, EPA's existing stocks policy statement cited by Registrants specifically provides that sale or distribution of existing stocks by registrants will be disallowed or circumscribed in various circumstances without regard to risk-benefit issues. *See, e.g.*, RE 9 at 200088-89 ("There may be unusual circumstances where the Agency will place restrictions on the distribution, sale, and use of existing stocks beyond those limits otherwise identified in a risk/benefit analysis (e.g., to prevent stockpiling by distributors and users).").

In the case of flubendiamide, Registrants knowingly made a commitment to request voluntarily cancellation of their registrations if EPA, in its sole judgement, determined that flubendiamide posed an unreasonable risk. Registrants understood at the time they accepted the condition that this commitment played a significant role in EPA's decision to grant the registration MAD Order at 27-28. Yet when EPA made a determination to trigger that condition, Registrants conveniently concluded that the condition to which they had agreed was now "illegal" and they were therefore free to ignore it. Registrants' flouting of their obligation to request cancellation was frankly not anticipated by EPA (PBNX 128), and this set of circumstances was simply not contemplated in the existing stocks policy statement. EPA considers Registrants' failure to live up to the commitments they made in order to obtain their registrations to be a very serious matter that could have harmful consequences for EPA's registration program. PBNX 128; RE 10 at 200109. Under the circumstances, any departure from EPA's non-binding policy statement on existing stocks is neither arbitrary nor capricious.

Inasmuch as EPA's decision on existing stocks was based on Registrants' behavior and not a risk-benefit determination, there was no reason for EPA to conduct a risk-benefit analysis with respect to existing stocks and it was appropriate for the ALJ to conclude that evidence on risks and benefits was not material to the existing stocks portion of the hearing. If the EAB determines that it is not consistent with FIFRA for EPA to react strongly to the actions of Registrants in this case, EPA's rationale for not allowing the sale and distribution of existing stocks of flubendiamide would not stand. But EPA submits that because FIFRA does not provide any person with a right to sell or distribute existing stocks, its decision to not allow any sale or distribution of existing stocks because of Registrants' decision to walk away from the commitment they made to obtain the registrations in the first place is consistent with FIFRA.

Finally, EPA addresses Registrants' assertion that EPA is punishing them because they requested this hearing in "bad faith". RAB at 39. EPA's quarrel is not with Registrants' request for a hearing, but rather with Registrants' failure to live up to the commitment they made to obtain the registrations initially. EPA's existing stocks determination in the NOIC predates Registrants' request for hearing. Registrants' legal view of the condition did not prevent them from complying with their commitments. Instead, Registrants appear to be quite comfortable with the notion that they should not have to live up to their commitments if any argument to excuse their compliance bears fruit. EPA believes that Registrants' renouncing of commitments that were so clearly important to EPA's ability to make the risk finding necessary to approve the registrations in the first place lacked good faith. Deterring registrants from intentionally violating important, specific conditions of registration is essential to the viability of the conditional registration authority, and is sufficient support for EPA's conclusion that its existing stocks position is consistent with FIFRA.

As to whether a decision not to affirmatively allow sale or distribution of existing stocks is effectively unreviewable, EPA respectfully submits that the EAB need not address this issue, and should instead affirm the ALJ's alternative finding that EPA's decision in flubendiamide is consistent with FIFRA. While EPA believes the argument that any EPA failure to act on existing stocks is unreviewable may well have merit, it was not raised or briefed before the ALJ, and given the time constraints of a 6(e) proceeding, EPA is not certain that time remains to create a record on this issue adequate to withstand judicial scrutiny. Given that the parties have fully addressed whether EPA's existing stocks determination is consistent with FIFRA, EPA is comfortable with the EAB reviewing the decision against that standard.

The EAB should reject the Registrants' contention that the ALJ's rulings leave no avenue for challenging EPA's existing stocks determinations. The Registrants argue that FIFRA creates a statutory right to challenge the existing stocks provision of an NOIC, and that the ALJ's rulings in the instant proceeding and *In the Matter of Reckitt Benckiser* have the effect of eliminating that right. Registrants err in their contention that "there is no situation in which stakeholders could meaningfully invoke their statutory right to challenge an existing stocks provision". RAB at 16-17. This argument is refuted by the facts of this very case. Registrants have challenged the existing stocks determination for flubendiamide; they could have, and did, argue that EPA's existing stocks determination is fatally flawed because EPA did not take risks and benefits into account in reaching the determination, and that their conduct did not warrant the limitations on existing stocks that EPA believes to be consistent with FIFRA. The standard for review of EPA's determination is deferential, and the determination should be upheld by the EAB, but Registrants have been afforded an opportunity to challenge the determination.

Existing stocks determinations are made under FIFRA section 6(a)(1), which commits those decisions to the broad discretion of the Administrator. *In the Matter of Cedar Chemical Co., et al.*, 2 E.A.D. 584, 587-88 n.7, 1988 WL 525242 (June 9, 1988). To the extent that FIFRA creates any right to challenge such existing stocks determinations, it does so in FIFRA section 6(e) and FIFRA section 3(c)(2)(B), each of which states that "whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this Act" is a matter for resolution at a hearing commenced pursuant to either FIFRA section 6(e) and FIFRA section 3(c)(2)(B). This statutory language signals a deferential standard for review of the Administrator's existing stocks determination. Even under the narrowest view of the FIFRA section 6(e) right to review of the Administrator's existing stocks determination, a decision to

allow sale, distribution or use of existing stocks of a pesticide cancelled pursuant to FIFRA section 6(e) would be subject to challenge by affected stakeholders. It is likely that the stakeholders most likely to challenge a decision to allow sale, distribution or use of existing stocks of a cancelled pesticide would be advocates for workers or the environment, or registrants of competing pesticide products, but the fact that the registrant of the cancelled pesticide is unlikely to mount such a challenge does not mean the statutory provision has no effect.

D. The EAB Should Reject the Registrants' Contention that Excluded Evidence Regarding the Type of Registrations (Conditional or Unconditional) at Issue in the *Reckitt* Case is Relevant to EPA's Authority to Cancel the Flubendiamide Registrations under FIFRA Section 6(e).

The Registrants offer to prove that half of the registrations at issue in the cancellation proceeding *In the Matter of Reckitt Benckiser* were conditional registrations, presumably in order to dispute the ALJ's statement that conditional registrations could only be cancelled under FIFRA section 6(e) irrespective of circumstances. RAB at 12. As explained in section I.A. above, there is no merit to Registrants' contention. If the Board considers it relevant, EPA has no objection to the Board taking official notice of the fact that some of the registrations at issue in *In the Matter of Reckitt Benckiser* were conditional registrations, but that fact changes nothing. If a registrant of a conditionally registered pesticide product fails to comply with a condition of registration, FIFRA section 6(e) authorizes the Administrator to issue a notice of cancellation pursuant to that section. If it appears to the Administrator that a conditionally registered pesticide product fails to comply with other provisions of FIFRA, FIFRA section 6(b) authorizes the Administrator to issue a notice of cancellation if action under that section is appropriate. And if the registrant of a conditionally registered pesticide product requests voluntary cancellation pursuant to FIFRA section 6(f), the Administrator will proceed with cancellation pursuant to the procedures of that section. Any of these provisions could apply to a conditionally

registered pesticide product, depending on the circumstances. This interpretation of the FIFRA section 6 cancellation authorities is contested by no one, save for where the Registrants' unjustifiably attribute such an interpretation to the ALJ.

As for the Registrants' contention that exploration of the registrations at issue in *In the Matter of Reckitt Benckiser* might show inconsistency or disparate treatment, there is no conflict or inconsistency here: In the instant proceeding, the Registrants failed to comply with a condition of registration and EPA issued an NOIC pursuant to FIFRA section 6(e); in *In the Matter of Reckitt Benckiser*, there was no allegation that the registrants had failed to satisfy any condition of registration, so when EPA determined that those pesticide products caused unreasonable adverse effects in violation of FIFRA, EPA issued an NOIC pursuant to FIFRA section 6(b). And in the case of *Woodstream*, where that registrant's failure to comply with certain conditions of its registration occasioned the expiration of its registrations, those registrations expired automatically by operation of law on June 4, 2011, and on August 5, 2011, EPA issued a cancellation order to Woodstream and similarly situated registrants to govern disposition of existing stocks of those products. *See* 76 Fed. Reg. 51031(Aug. 17, 2011). It is the factual circumstances of each case that dictate which cancellation authorities are available to the Agency, and in each of these cases, EPA exercised the authorities appropriate to the factual circumstances presented.

E. A Hearing on the Risks and Benefits of Flubendiamide was Neither Proper nor Necessary under FIFRA Sections 6(e) and 6(f)(1).

The ALJ was correct in determining that the scope of the section 6(e) hearing should not include a hearing on the risks and benefits of flubendiamide and consistent with the statutory language in 6(e) that the only issue for hearing is whether the registrant complied with the conditions of registration. CID at 3; *See* section II. *supra.*

The EAB should reject the Registrants' contention that the ALJ's refusal to examine, or to allow the Registrants to contest, the scientific soundness of EPA's decision-making resulted in an erroneous decision. RAB at 28. This contention is misguided, as the cancellation decision and the existing stocks decision do not rely on whether the "scientific findings" were reasonable or not, but instead on the Registrants' conduct as license-holders. Even if the scientific findings were to be proven wholly erroneous, the cancellation decision and the existing stocks decision would be the same, because those decisions were based on the Registrants' conduct. The ALJ followed the statutory standard under FIFRA section 6(e) and properly limited the hearing to whether the conditions of registration were met. To make that determination, the ALJ did not need a full scientific hearing. Instead, she admitted evidence that went specifically to the issue for a 6(e) hearing – whether the conditions were met. On that point, the Agency's evidence is uncontroverted, so it was necessary and proper that the flubendiamide registrations be cancelled pursuant to FIFRA section 6(e). And as discussed in section III.C. *supra*, evidence on risks and benefits was irrelevant to the existing stock determination and therefore properly excluded.

The Registrants mischaracterize the Corrected Initial Decision as backtracking on the ALJ's commitment not to entertain arguments regarding the merits of EPA's scientific decision-making, by accepting the Agency's scientific conclusions as established fact. RAB at 29. This is a mischaracterization because what the ALJ found as fact was that the Agency made a particular determination specified in conditions 6(d) and 8(d) of the PAL, (PBNX 8 at PBN0019), and that triggered the voluntary cancellation conditions. As stated before, 6(e) does not provide for more than a hearing on whether the conditions have been met. Here, EPA satisfied the condition precedent by informing the Registrants of its finding. CID at 29-30. The ALJ did not agree or disagree with the Agency's January 29, 2016 UAE decision, she only needed to determine

whether EPA did in fact make the decision specified in PAL conditions 6(d) and 8(d). The science behind EPA's decision that invoked the obligations of the Registrants is beyond the scope of a FIFRA section 6(e) hearing. The ALJ's discussion of scientific or unreasonable adverse effects issues was nothing more than determinations that upon a facial review, the Agency's decisions and documents are the decisions and documents what they are represented to be. Registrants err in mistaking this for an "acceptance" of the merits of EPA's findings, as the ALJ had already determined that questions of science or unreasonable adverse effects were irrelevant to determining whether the Registrants met their obligations. MAD Order at 22-24, 28. So, there was no acceptance of the finding, just an acceptance that EPA informed the Registrants of its finding and the record is clear that occurred and the Registrants do not contest that fact.

The Registrants challenge EPA's assertion, accepted by the ALJ, that the time constraints of a 6(e) hearing could not accommodate a full and fair hearing on risk benefit issues. RAB at 27. EPA's point was that the FIFRA section 6(e) scope limitations and the 75-day limit are interrelated, and both reflect Congress' intent that such hearing be fundamentally different from FIFRA section 6(b) hearings. See MAD Order at 21-23. Even if additional hearing days could have been made available to accommodate the Registrants' desire to present evidence (days that would themselves cut into the time available to review and digest all of the evidence), the time constraint imposed by FIFRA section 6(e) is secondary to the limits it imposes on the scope of the hearing. The ALJ's decisions were consistent with this jurisdictional limit.

F. The ALJ's Factual Recitation of EPA's Analysis and Conclusions with Respect to Flubendiamide's Risks was not Contrary to her MTL Order.

The EAB should reject the Registrants' contention that the ALJ's discussions of EPA's analysis and conclusions with respect to flubendiamide's risks in the Corrected Initial Decision is contrary to the Motion to Limit Scope of Testimony Order excluding evidence on these

issues as irrelevant. RAB at 29. The Registrants complain that the ALJ "uncritically recites in substantive detail EPA's analysis and conclusions" contrary to the Motion to Limit Scope of Testimony Order. This contention misinterprets how these statements were cited to in the Corrected Initial Decision, where they were used to describe what the parties did and when.[8]

It is absurd to argue that when an ALJ cites to statements from record documents in the factual background, the substance of which is not at issue in the proceeding, that the ALJ is necessarily agreeing with or endorsing the merits of those document. The ALJ did not make a finding on the science contrary to the Motion to Limit Testimony Order by reciting these facts. The ALJ made clear in in both the MAD Order and the MTL Order the issue of risks and benefits was not at issue in this proceeding, so it cannot be true that by acknowledging the existence of EPA's UAE determination she was agreeing or disagreeing with the science that supports it.

The record amply demonstrates that the ALJ understood that the Registrants disagree with the Agency's UAE determination, and she acknowledges that the Registrants submitted over 300 pages in support of their disagreement with EPA's science. CID at 17. She allowed Registrants to make an offer of proof without opining on whether she agreed or disagreed with the information. Transcript at 64. And that is proper, because the only issues for the ALJ were whether the conditions of registration were met and whether the existing stocks decision was consistent with FIFRA, not whether EPA's science triggering Respondents' obligation was

[8] For example, the Registrants' citation to page 10, footnote 21 to support their contention is misplaced as that is the "Factual Background" section. The ALJ is merely reciting relevant facts in its discussion about EPA's statutory obligation to review before making its 2008 flubendiamide decision. For example, the ALJ cites to EPA's findings made in 2008 Registration Decision as a factual matter. RE 1 The ALJ is not making a finding here that she agrees or disagrees with these facts. The correctness of the 2008 decision is not before this ALJ. Instead she merely recites what was in that decision to register the pesticide.

correct.

CONCLUSION

For the reasons stated above, EPA respectfully requests that the EAB affirm the ALJ's decisions above, and order that (1) the Registrants' flubendiamide registrations be cancelled, and (2) existing stocks of the canceled products be allowed to be distributed and used only as specified in the NOIC. For the reasons set forth in EPA's separate filing of Opposition to the Registrants' Motion to Reopen the Hearing, the EAB should deny this Motion.

Dated: June 20, 2016

Respectfully Submitted,

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STATEMENT OF COMPLIANCE WITH WORD LIMITATION

I hereby certify that this Response Brief, including all relevant portions, contains fewer than 14,000 words.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 20th day of June, 2016, a true and correct copy of the foregoing Response Brief of the United States Environmental Protection Agency, was filed electronically using the EPA EAB eFiling System, and served in the following manner to the below addressees:

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