UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

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

REGISTRANTS' OPPOSITION TO RESPONDENT'S
MOTION TO LIMIT SCOPE OF TESTIMONY

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I. INTRODUCTION

As confirmed by the ALJ's recent Order, FIFRA § 6(e), 7 U.S.C. § 136d(e), gives the Registrants the right to request a hearing on EPA's existing stocks determination and requires this Tribunal "to examine whether the Agency's determination regarding existing stocks is consistent with FIFRA." April 25, 2016 Order on Petitioners' Motion for Accelerated Decision at 28 n.25. While conceding, as it must, that the Registrants have a right to challenge the merits of the Agency's existing stocks determination, EPA seeks in its Motion to Limit to protect its determination from review by arguing that the risk-benefit testimony and documentary evidence that the Registrants have prepared and exchanged in support of a broader existing stocks provision are immaterial and should be excluded.

EPA's relevance objections do not withstand scrutiny. EPA concedes that risk-benefit information "could be relevant" to the existing stocks determination and that the Agency at least partly considered these issues in reaching its own determination that only use of stocks in the hands of end-users should be permitted. Motion to Limit at 3; Written Testimony of Susan T. Lewis ("Lewis Testimony") at 16-17. EPA's own policy on existing stocks directs the Agency to incorporate detailed risk-benefit considerations into its existing stocks determinations. EPA thus cannot preclude the Registrants from presenting scientific, economic, and agronomic testimony establishing that a more appropriate consideration of the risks and benefits of the use of existing stocks justifies a much broader existing stocks provision.

Similarly, EPA cannot claim that it is prejudiced by the "burden" of responding to facts and arguments that the statute places within the defined scope of a § 6(e) hearing or that allowing the Registrants to present testimonial and documentary evidence that already has been produced and exchanged within the schedule established for this hearing would unduly delay this proceeding or EPA's proposed cancellation action. By contrast, it would be highly prejudicial to

the Registrants to preclude them from presenting evidence that is directly relevant to whether EPA's existing stocks determination is consistent with FIFRA and EPA's own policy.

Finally, as the Registrants have previously noted, the risks and benefits of flubendiamide and the merits of EPA's January 29, 2016 unreasonable adverse effects determination provide important factual and practical background for judging the lawfulness of EPA's "voluntary" cancellation condition and invocation of § 6(e) to cancel the registrations. Registrants' Motion for Accelerated Decision at 56-65; Registrants' Prehearing Exchange at 5. The Registrants understand that in denying the Registrants' request for an accelerated decision, the ALJ has concluded that EPA's approach is lawful and that this matter can properly proceed as a § 6(e) hearing. April 25, 2016 Order at 21. Nonetheless, the Registrants respectfully request the right to present the streamlined risk-benefit testimony and documentary evidence they have already prepared and exchanged during the limited time allotted for the hearing to complete the record for appeal and to prevent the potential need for remand and a further hearing if the EAB reaches a different conclusion on appeal.

II. STANDARD OF REVIEW

The Federal Rules of Evidence permit the admission of "relevant evidence"—that is, evidence having "any tendency" to make the existence of any fact of consequence more probable or less probable, provided it is not otherwise excluded by those Rules, the Constitution, or an Act of Congress, and its probative value is not "substantially outweighed" by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or the needless presentation of cumulative evidence. *Barnett v. PA Consulting Grp., Inc.*, 35 F. Supp. 3d 11, 16 (D.D.C. 2014) (citing Fed. R. Evid. 401–03). "Factual questions should not be resolved through motions in limine." *Graves v. District of Columbia*,

850 F. Supp. 2d 6, 11 (D.D.C. 2011) (quoting *Goldman v. Healthcare Mgmt. Sys., Inc.*, 559 F. Supp. 2d 853, 871 (W.D. Mich. 2008)).

The admissibility standard governing the present administrative hearing is even more permissive than the federal court standard:

> The Administrative Law Judge shall admit all relevant, competent and material evidence, except evidence that is unduly repetitious. Relevant, competent and material evidence may be received at any hearing even though inadmissible under the rules of evidence applicable to judicial proceedings. The weight to be given evidence shall be determined by its reliability and probative value.

40 C.F.R. § 164.81(a). EPA's Motion to Limit lacks any citation to the relevant rules and case law and provides no legal basis to exclude the Registrants' testimony.

III. TESTIMONY REGARDING THE RISKS AND BENEFITS OF FLUBENDIAMIDE IS RELEVANT TO THE EXISTING STOCKS DETERMINATION.

A. EPA Concedes That the Risks and Benefits of Continued Use Are Relevant to Its Existing Stocks Determination.

Existing stocks are defined as "products that were 'released for shipment' before the effective date of cancellation." PBNX 20 at 11,560. Existing stocks thus include products held by the Registrants at the time of cancellation that have been "released for shipment," stocks in the hands of distributors and retailers, and unused product in the hands of end-users (growers and applicators). In reaching an existing stocks determination, EPA must necessarily decide where to draw the line and whether and to what extent to allow use, distribution, and sale of existing stocks by the different actors in the distribution chain.

In the NOIC, EPA stated its determination that continued use by end-users would be permitted, but that further sale or distribution of existing stocks held by retailers, distributors, and the Registrants would not be allowed. *Id.* To reach this result, EPA gave at least partial consideration to the question of whether "the risks posed by the quantities of existing stocks

expected to be in end users' hands are reasonable compared to the burdens and risks associated with recovering those existing stocks," and has produced testimony from its own witness on that subject. Motion to Limit at 3.[1] EPA also "concedes that scientific and economic testimony related to whether flubendiamide causes unreasonable adverse effects on the environment *could be relevant* to the issue of whether the Administrator's determination with respect to the disposition of existing stocks in the hands of end users is consistent with FIFRA." *Id.* (emphasis added). Having conducted and presented its own determination, and presented its own testimony on the subject, EPA cannot exclude on "relevance" grounds the testimony and documentary evidence Registrants have prepared that show that a fuller consideration of the risks and benefits of ongoing use and distribution of the limited existing stocks justifies a much broader existing stocks provision.

B. EPA's One-Sided Positions on Relevance and the Scope of This Proceeding Are Contrary to the Nature of an Adversarial Administrative Hearing.

EPA takes the position that risk-benefit information is only relevant when offered in support of EPA's position or when arguing for a more stringent risk-benefit standard. Specifically, in its Motion to Limit, EPA argues that "scientific and economic testimony related to whether flubendiamide causes unreasonable adverse effects" would only be relevant if the Registrants challenged EPA's determination to allow use of existing stocks in the hands of end-users, but cannot be used to argue the merits of a more permissive existing stocks provision. Motion to Limit at 3.[2] EPA cannot have it both ways. As outlined above, EPA has conceded

[1] *See also* Lewis Testimony at 16 (providing testimony on EPA's risk-benefit determination despite EPA's arguments that such testimony is "immaterial").

[2] EPA's one-sided view of when evidence should be excluded as "irrelevant" or "beyond the scope" is further evidenced in its Prehearing Exchange, in which the Agency contended that testimony related to "whether Registrants' acceptance of the condition was voluntary or 'coerced'" is "outside the proper scope of this proceeding," while at the same time providing,

that these issues were relevant to its own determination. EPA cannot now contend that the same considerations are irrelevant, without denying the Registrants' statutory right to challenge the merits of EPA's determination and to argue that a broader existing stocks position is consistent with FIFRA and EPA's own existing stocks policy.

C. EPA's Own Assertions Regarding Unreasonable Adverse Effects Belie the Agency's Claims That Risk Benefit Issues Are Beyond the Scope of This Proceeding.

In an effort to preclude relevant testimony, EPA claims on the one hand that it "has made no determination in regard to the risks posed by existing stocks held by the registrants, distributors, and retailers." Motion to Limit at 3. Yet in the very next paragraph, EPA assures the Tribunal that the Agency "believes that use of flubendiamide causes unreasonable adverse effects on the environment and that sale and distribution of existing stocks would not pass the risk-benefit test under FIFRA." *Id*. EPA cannot both assert irrelevance to preclude testimony on risk-benefit issues and at the same time offer representations meant to reassure the Tribunal about what that testimony would show. The Agency should not be permitted to prejudice the record with this and other unsupported, disparaging rhetoric regarding the purported harm caused by flubendiamide, [3] while seeking to preclude any countervailing testimony from the Registrants. Doing so would plainly prejudice the Registrants.

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without explanation or caveat, direct testimony from the Agency's own witness arguing at length that the Registrants voluntarily accepted the condition. Respondent's Prehearing Exchange at unnumbered page 2; Lewis Testimony at 9-11.

[3] *See, e.g.*, *id.* at 6 (referring to the need to turn the "tap" off and "prevent further sale and distribution of material that should never have entered the stream of commerce in the first place"); Respondent's Opposition to Mot. for Accelerated Decision at 13-14 (providing an unsupported "summary" of EPA's "side to the story" and the purported scientific bases for its unreasonable adverse effects conclusions while simultaneously maintaining that this is "not an appropriate issue in this proceeding").

Furthermore, while EPA contends that the Registrants' non-compliance with the "voluntary" cancellation condition was the only basis for its existing stocks determination, its own witness indicates otherwise, indicating that this purpose was "[a]mong the reasons" EPA determined not to allow sale or distribution of existing stocks, without disclosing what other reasons the Agency considered in reaching its existing stocks determination.[4] EPA should not be permitted to unilaterally determine the scope of the hearing by selectively disclosing the reasons for its decision, nor should it be permitted to prejudice the record by presenting its unsupported assurances and conclusions about what the facts would show while arguing that actual evidence the Registrants would offer to the contrary is irrelevant.

D. EPA's Existing Stocks Policy Requires EPA to Consider the Risks and Benefits of Continued Use and Distribution of Existing Stocks in These Circumstances.

As Registrants have consistently noted, EPA's 1991 Existing Stocks Policy, which EPA cited in the Notice of Intent to Cancel as the basis for its existing stocks provision, contradicts the position taken by EPA that the risks and benefits of flubendiamide are irrelevant to its existing stocks determination. PBNX 20 at 11,560 (citing the Existing Stocks Policy); PBNX 52 (Existing Stocks Policy); Request for Hearing and Statement of Objections ¶¶ 205-10; Verified Written Statement of Charlotte Sanson at 21:15-22:22.

EPA relied on the distinction between "general" and "special" conditions of registration to support its position that no sale or distribution of existing stocks would be permitted. PBNX

[4] Lewis Testimony at 13 ("*Among the reasons* we determined not to allow any further sale or distribution of existing stocks were *our belief* that registrants should not benefit from failing to follow through with commitments they make to obtain registrations; that much of the existing stocks at the time of a delayed cancellation may well never have entered the channels of trade if the flubendiamide Registrants had complied with the cancellation condition; and the impact that failure of registrants to comply with conditions could have on the registration program in the future.") (emphasis added).

20 at 11,560. However, those considerations fall under Part III.A.2 of the Policy, which applies to "[c]ancellations where a registrant has failed to comply with an obligation of registration" and "*where the Agency does not have significant risk concerns with respect to the cancelled pesticide*." PBNX 52 at 29,365 (emphasis added). More specifically, Part III.A.2.d explains that in considering existing stocks provisions for "[f]ailure to comply with the terms of a conditional registration," "[w]here a conditional registration is cancelled (*and the Agency has not identified significant risk concerns*), the Agency will base its existing stocks decision on the nature of any conditions that have not been met by the registrant," *i.e.*, whether the condition is "general" or "specific." *Id.* (emphasis added).

Here, EPA *has* identified "significant risk concerns" with flubendiamide, *see, e.g.*, PBNX 30 (January 29, 2016 Decision Memorandum). In those circumstances, Part III.A.1 of EPA's Policy directs the Agency to make a "case-by-case" determination focusing on whether "the social, economic, and environmental benefits associated with such distribution, sale, or use exceed the social, economic, and environmental risks." *Id.* Among other things, EPA should consider the "quantity of existing stocks at each level of the market"; the "risks resulting from . . . use," taking into account the limited nature of the use of existing stocks and whether the identified risk is acute; the "benefits resulting from the use of such stocks," including short-term problems from switching to alternatives, availability of alternatives, and economic effects; the "dollar amount users and others have already spent on existing stocks (which would be lost . . .)"; and "the nature, feasibility, and cost of proper disposal." *Id.*

EPA cannot realistically claim that factual issues its own Policy directs the Agency to consider are irrelevant and cannot be explored by the Registrants in their testimony to challenge

the merits of EPA's decision. Nor does the Agency attempt to do so in the Motion to Limit, which ignores the Existing Stocks Policy entirely.

E. The Risks and Benefits of Flubendiamide Are Relevant Even Under EPA's Punitive Approach.

Even if EPA were permitted to unilaterally determine what factual issues are relevant to its existing stocks determination by ignoring its own Policy and "electing" to disclose and focus on only a single basis for its determination, the risks and benefits of flubendiamide are still relevant to the Agency's purported purpose of punishing the Registrants and ensuring that they are not "financially reward[ed]" by their efforts to challenge the lawfulness of EPA's cancellation determination. Motion to Limit at 3. In reaching this decision, EPA would have to conclude that serving this punitive purpose outweighed the potential harm caused by the inefficiencies and unfairness of allowing further use only by those who happened to hold some product, the potential harm to growers caused by a sudden removal of a valuable tool for Integrated Pest Management and Insect Resistance Management, and the overall benefits of a product that poses no identified human health risks and has a favorable environmental profile compared to most likely alternatives. In doing so, the Agency would have relied on its "belief" that allowing the use of existing stocks would cause "unreasonable adverse effects." The Registrants should not be precluded from offering testimony to challenge the factual and scientific basis for EPA's "belief."

IV. EPA'S DESIRE TO "SIMPLIFY" THE HEARING DOES NOT GIVE THE AGENCY THE RIGHT TO EXCLUDE EVIDENCE.

EPA admits that its strategy in presenting the basis for its existing stocks determination is an effort to render flubendiamide's risks and benefits irrelevant to "simplify" the hearing. Motion to Limit at 3. While EPA may wish for a "simpler" hearing, this sentiment is not a basis to exclude relevant testimony on the risks and benefits of flubendiamide and whether EPA's

existing stocks provision properly takes them into consideration as required under EPA's own Policy. EPA notes that consideration of "risk-benefit issues" in its NOIC and at the hearing "would have required significantly more time and resources." Motion to Limit at 5. Yet neither the Federal Rules nor the regulations under 40 C.F.R. Part 164 suggest that evidence should be excluded and issues deemed irrelevant simply because they require time and effort from the Agency to address.

EPA also suggests that drastic "simplification" of the issues is necessary because "it is highly doubtful that the 75-day limitation in section 6(e) of FIFRA could accommodate a full and fair hearing on risk-benefit issues; cancellation hearings under section 6(b), which focus on risk-benefit issues, typically require significantly more hearing preparation, witnesses, and hearing days, than can fit into an expedited hearing such as is required under section 6(e)." *Id.* This is overstated. As discussed below, the Registrants have worked within the constraints of the § 6(e) schedule to develop targeted testimony from a limited number of witnesses that addresses the most significant aspects of EPA's cancellation determination and approach, and the Agency's existing stocks determination. The Registrants have done so in a manner that fits within the schedule established by the ALJ and that is far less burdensome to the Agency and this Tribunal than a full hearing would have been. The Agency's refusal to make a similar effort to address the relevant scientific and factual issues in a streamlined manner is not a basis to exclude the Registrants' testimony.

V. TESTIMONY REGARDING THE RISKS AND BENEFITS OF FLUBENDIAMIDE WILL COMPLETE THE RECORD FOR CONSIDERATION ON APPEAL OF THE LAWFULNESS OF EPA'S CANCELLATION APPROACH.

In their statement on the scope of the hearing in the Prehearing Exchange, the Registrants explained that testimony and documentary evidence on the risks and benefits and whether

continued registration of flubendiamide would cause unreasonable adverse effects are relevant to the question of whether EPA's forced "voluntary" cancellation condition was lawful and consistent with the cancellation requirements Congress established under FIFRA § 6, 7 U.S.C. § 136d. Registrants' Prehearing Exchange at 4-5. Among other things, the Registrants noted that such testimony and documentary evidence would demonstrate that EPA has adopted this unlawful practice to shield from review an unreasonable adverse effects determination that is scientifically unsound, and that the unlawful cancellation would deprive growers of a crop protection tool that is extremely beneficial and important. *Id.* The Registrants believe these practical considerations are highly pertinent to determining the lawfulness of EPA's approach. In its Prehearing Exchange and Motion to Limit, EPA took the position that testimony related to the "legality" of its cancellation approach was irrelevant and that the "appropriateness or lawfulness of the condition is not a subject for [this] hearing." Respondent's Prehearing Exchange at unnumbered page 2; Motion to Limit at 2.

In its April 25, 2016 Order Denying the Registrants' Motion for Accelerated Decision, this Tribunal implicitly acknowledged its authority to address the legality of EPA's actions and concluded that EPA's "voluntary" cancellation condition was lawful and that this matter could lawfully proceed under FIFRA § 6(e). Order on Petitioners' Motion for Accelerated Decision at 21. Given the limited timeframe available under § 6(e), the Registrants will not request certification of the April 25, 2016 Order for immediate appeal to the Environmental Appeals Board ("EAB"), but do intend to take exception to the Order and request review from the EAB upon issuance of the Initial Decision. Thus, the lawfulness of the condition and EPA's cancellation actions will also be considered and addressed by the EAB. Because the 75-day deadline for issuance of the final order after EAB review does not allow sufficient time to

remand the matter for further hearing and testimony, the Registrants respectfully request the right to present at the hearing the evidence that has already been developed and exchanged regarding flubendiamide's risks and benefits with respect to both the existing stocks and the lawfulness of the cancellation decision in order to ensure a complete record for consideration by the EAB.

VI. EPA HAS NOT SHOWN THAT ANY PREJUDICE WILL RESULT FROM THE INTRODUCTION OF REGISTRANTS' RISK-BENEFITS EVIDENCE.

EPA contends that allowing the Registrants to present evidence regarding the risks and benefits of flubendiamide and the "scientific and economic issues related to flubendiamide" would "further delay the cancellation of flubendiamide." Motion to Limit at 4. This is not correct. Pursuant to the 75-day deadline applicable under § 6(e), and the 22-day extension, which was the amount of time EPA suggested, the EAB will have either rejected EPA's cancellation decision or upheld that decision and approved EPA's existing stocks order by July 6, 2016.[5] The Registrants' introduction of testimony and documentary evidence on flubendiamide's risks and benefits cannot extend that final deadline and will not prejudice EPA. Despite EPA's claims to the contrary, this Tribunal can and should permit as "full and fair [a] hearing on risk-benefit issues" related to flubendiamide as can be managed within the statutory timeline.

EPA complains that a FIFRA § 6(e) hearing cannot accommodate presentation and consideration of risk-benefit issues, but the most time- and resource-intensive work to develop that testimony and evidence has already been completed, and the relevant materials have already

[5] Susan Lewis seeks to justify the punitive existing stocks determination by contending that the Registrants, by exercising their right to challenge the lawfulness of the "voluntary" cancellation condition, "will likely delay a cancellation by a minimum of 3 months." Lewis Testimony at 13. This is based on the claim that the "scheduled end of this hearing" is "August 1, 2016." Registrants' counsel asked EPA's counsel to provide an explanation for this stated hearing end-date, and was informed that it was a mistake.

been exchanged. Despite a highly compressed schedule, Registrants have proven capable of preparing nearly 150 pages of detailed fact and expert testimony, much of which relates to flubendiamide's alleged risks and established benefits to agriculture and the environment. EPA, in its own words, "elected" not to "present any factual testimony on risk-benefit issues in this section 6(e) proceeding." Motion to Limit at 5. EPA *could have* presented risk-benefit testimony and evidence, but it made a conscious choice not to do so. EPA on its own initiative also pledged that, *regardless of the outcome* of the Tribunal's ruling on this motion, the Agency will not contest the risk-benefits evidence put forward by Registrants. Motion to Limit at 3-4, 6.

Nor is the timing of the ultimate decision on cancellation and existing stocks likely to be impacted by exclusion of Registrants' evidence. Because the April 4, 2016 Order Scheduling Hearing and Prehearing Procedures ("Scheduling Order") required the exchange of written direct testimony, a process that is already completed, the entirety of the evidentiary hearing will be devoted to cross-examination, and redirect and rebuttal testimony, if necessary. If EPA follows through on its pledge not to contest the risk-benefits evidence put forward by Registrants, then it may have no need to cross-examine any of the Registrants' four expert witnesses, and the parties will not even require the full four days allocated by the Tribunal.[6] The post-hearing portion of the Scheduling Order is also unlikely to change if Registrants' evidence is excluded. Registrants will exercise their right to submit a post-hearing brief and the Tribunal will issue its Initial Decision following that briefing. The remaining time will be required for the parties to lodge their appeals and file their responses thereto, for the issuance of a final decision by the Environmental Appeals Board after review of both the Tribunal's Order on Registrants' Motion for Accelerated Decision and its Initial Decision.

[6] Registrants have the right to cross-examine EPA's sole witness, and intend to exercise that right.

VII. CONCLUSION

In conclusion, EPA cannot dispute the relevance of Registrants' evidence nor can the Agency show that it would be prejudiced if that evidence is deemed relevant and admissible. In contrast, Registrants have established that the exclusion of this evidence will severely prejudice Registrants in the lawful exercise of their rights to contest EPA's cancellation decision and existing stocks proposal. The Registrants therefore respectfully request that EPA's Motion to Limit be denied.

Dated: April 26, 2016

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 26th day of April, 2016, a true and correct copy of the foregoing Registrants' Opposition to Respondents' Motion to Limit Scope of Testimony using the EPA OALJ e-filing system; and served in the following manner to the below addressees:

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