UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

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

PREHEARING EXCHANGE OF
BAYER CROPSCIENCE LP AND NICHINO AMERICA, INC.

In accordance with the Administrative Law Judge's Order Scheduling Hearing And Prehearing Procedures dated April 4, 2016 ("Scheduling Order"), Bayer CropScience LP and Nichino America, Inc. hereby submit their prehearing exchange of discovery materials.

I. WITNESSES

The following are Petitioners' witnesses, in the order Petitioners plan to present them. Because the length of Respondent's cross-examination and any potential redirect examination is not known at this time, Petitioners may need to propose to change the order as timing becomes more certain, due to the availability of some of the witnesses. Petitioners would advise the Tribunal and Respondent as promptly as possible if this becomes necessary.

1. Charlotte Sanson, Bayer CropScience LP (fact witness)
2. Lee Hall, Bayer CropScience LP (fact witness)
3. Jeffrey Johnson, Nichino America, Inc. (fact witness)
4. Bernard Engel, Ph.D. (expert witness, curriculum vitae provided at PBNX 50)
5. Dwayne R. J. Moore, Ph.D. (expert witness, curriculum vitae provided at PBNX 43)
6. David Ames Herbert Jr., Ph.D. (expert witness, curriculum vitae provided at PBNX 37)
7. John Palumbo, Ph.D. (expert witness, curriculum vitae provided at PBNX 110)

II. VERIFIED WRITTEN STATEMENTS

The verified written statements of Petitioners' witnesses are attached. Two hard copies will be delivered to the Office of Administrative Law Judges ("OALJ"). Petitioners will provide additional copies at the OALJ's or Respondent's request.

III. EXHIBITS INTENDED TO BE INTRODUCED INTO EVIDENCE

Petitioners' Exhibit list is attached.

Petitioners intend to introduce into evidence Exhibits 7 to 37 and 39 to 52 from Registrants' [Petitioners'] Motion for Accelerated Decision. For efficiency, Petitioners have used in subsequent submissions and will continue to use the same numbers for these exhibits with an additional prefix "PBNX" (abbreviation for Petitioners Bayer and Nichino Exhibit). This abbreviation conforms to the Tribunal's Scheduling Order (Paragraph 1(C) on p. 3). In addition to Exhibits PBNX 7 to 37 and 39 to 52, today Petitioners are providing additional Exhibits PBNX 80 to 84, 100, and 110 to 115. Petitioners have prepared two hard copies of the new Exhibits for the OALJ and will provide additional copies of any or all Exhibits to the OALJ or EPA as requested, and will have copies of all Exhibits available for any hearing.

IV. STATEMENT REGARDING THE SCOPE OF THE HEARING

The Scheduling Order provides that the parties may, as part of their Primary Discovery Prehearing Exchange, submit a statement "identifying any objections to the scope of the hearing and the factual and legal bases in support of the objections." Scheduling Order at 3. The "Scope of the Hearing" section of the Scheduling Order identifies two "preliminary legal conclusions" that the parties may contest:

- The validity or invalidity of any condition of registration is not an issue in this proceeding.
- The issue of whether or not the conditions of registration have been satisfied is not an issue in this proceeding.

Id. at 2-3. For the reasons stated below and in their previous filings, the Registrants object to both. The lawfulness of EPA's forced "voluntary" cancellation condition is a threshold jurisdictional issue that must be resolved for the hearing to proceed and cannot be separated from the question of whether the condition was satisfied. Moreover, because EPA's unreasonable adverse effects determination is unsound and invalid, the purported obligation to "voluntarily" cancel the registrations was never triggered.

The Registrants agree that the scope of the hearing properly includes consideration of "whether the Administrator's determination with respect to the disposition of existing stocks is consistent with FIFRA." *Id.* at 3. However, in its Motion to Limit Scope of Testimony, EPA contends that Registrants' testimony and evidence regarding the risks and benefits of permitting existing stocks to clear the channels of trade should be excluded from the hearing.[1] EPA concedes that these issues were relevant to its own consideration of crafting an overall existing stocks provision, Motion to Limit at 3, and EPA's existing stocks policy requires the Agency to take flubendiamide's risks and benefits into account in its existing stocks proposal. PBNX 52 at 29,364. Registrants' fact and expert testimony and documentary evidence challenging the alleged risks posed by flubendiamide[2] and establishing its many benefits[3] falls squarely within the scope of a FIFRA § 6(e) hearing and will be the *only* relevant evidence on existing stocks before the Tribunal in light of EPA's choices about how to present its positions.

[1] Registrants will respond to EPA's arguments in the Motion to Limit in greater detail in their Opposition, to be filed on April 26.
[2] *See, e.g.*, Verified Written Statement of Dwayne Moore ("Moore Statement") at 18:10-31:3.
[3] *See, e.g.*, Verified Written Statement of Lee Hall ("Hall Statement") at 4:21-13:7; Verified Written Statement of Ames Herbert ("Herbert Statement"); Verified Written Statement of John Palumbo ("Palumbo Statement").

A. A Determination of the Validity of the Voluntary Cancellation Is Necessarily Within the Scope of the Hearing.

The question of whether EPA can lawfully devise and employ a forced "voluntary" cancellation condition to cancel the flubendiamide registrations under FIFRA § 6(e) rather than follow the required process for cancellation based on an "unreasonable adverse effects" determination under § 6(b) is the core question in this proceeding and has been briefed in the Registrants' Statement of Objections, their Motion for Accelerated Decision and Reply, and CropLife America's Amicus Curiae Brief. If the Registrants' Motion for Accelerated Decision is not granted, the lawfulness of the "voluntary" cancellation condition and EPA's cancellation approach will remain a threshold jurisdictional question that must be resolved to determine whether EPA's proposed cancellation is properly before the Tribunal under § 6(e), and whether the hearing should proceed in the first place.

Prerequisites for filing a Notice of Intent to Cancel ("NOIC") based on an unreasonable adverse effects determination, including submitting EPA's January 29, 2016 determination for review by the Scientific Advisory Panel and United States Department of Agriculture, have not been met, which means that a valid NOIC has not been issued and this Tribunal lacks the jurisdiction to proceed. *See, e.g.*, Reply in Support of Mot. for Accelerated Decision at 1. EPA has not claimed and cannot claim that this Tribunal lacks the authority and obligation to confirm its jurisdiction before issuing a ruling.

The Registrants' testimony and exhibits bear on the question of how and why EPA adopted this approach, why it does not comport with statutory cancellation process and requirements, what rights the Registrants and other stakeholders would be denied if EPA is permitted to proceed, and what the real-world cost of an unlawful cancellation would be. The Registrants' evidence will demonstrate that the "voluntary" cancellation condition unlawfully

bypasses the FIFRA § 6(b) cancellation process,[4] that it serves no valid regulatory purpose, and that it was forced upon Registrants by EPA.[5] It will demonstrate that EPA has adopted this unlawful practice to shield from review an unreasonable adverse effects determination that is scientifically unsound,[6] and that the unlawful cancellation would deprive growers of a crop protection tool that is extremely beneficial and important.[7] A refusal to permit Registrants to present this evidence at the hearing would deprive Registrants of their only administrative opportunity to contest EPA's cancellation decision. The Registrants have a right to present their case and cross-examine EPA's witness on these issues.

Finally, the question of whether a condition is lawful cannot and should not be separated from the question of whether it has been satisfied. It would be illogical and inefficient to hold a hearing on whether a condition has been satisfied without considering and resolving whether the condition is valid in the first place.

B. A Determination of Whether the Conditions of Registration Have Been Satisfied Is Within the Scope of this Hearing.

Even if the Tribunal were to determine that the voluntary cancellation condition is valid, Registrants have a right to challenge whether EPA made a valid scientific finding triggering Registrants' obligation to voluntarily cancel. The "voluntary" cancellation condition requires EPA to make a determination that further registration would cause unreasonable adverse effects. If the Tribunal agrees with Registrants that EPA's adverse effects finding was invalid, then

[4] *See, e.g.*, Verified Written Statement of Charlotte Sanson ("Sanson Statement") at 19:18-20:13.
[5] *See, e.g.*, Sanson Statement at 7:9-8:6.
[6] *See, e.g.*, Moore Statement at 18:10-31:3; Verified Written Statement of Bernard Engel ("Engel Statement").
[7] *See, e.g.*, Hall Statement; Herbert Statement; Palumbo Statement.

Registrants were under no obligation to voluntarily cancel their registrations and have complied with all conditions of their registrations.[8]

The fact and expert testimony and documentary evidence submitted by Registrants in today's prehearing exchange will establish (1) that EPA did not undertake the multi-step process required under FIFRA to make a determination that a registration no longer meets the Registration Standard,[9] (2) that EPA's assessment of flubendiamide's environmental risks was scientifically unsound,[10] (3) that EPA improperly discounted or outright ignored flubendiamide's benefits to growers, agriculture, and the environment,[11] and (4) that, as a result, the voluntary cancellation condition was never properly triggered. A refusal to permit this testimony and evidence at the hearing would deny Registrants their statutory right to contest whether the conditions of their registration have been satisfied.

C. A Consideration of the Risks and Benefits of Permitting Existing Stocks to Clear the Channels of Trade Is Within the Scope of This Hearing.

Registrants' challenge to EPA's existing stocks proposal is detailed in their Request for Hearing and Statement of Objections. Request for Hearing and Statement of Objections ¶¶ 196-215. EPA has since filed a Motion to Limit Scope of Testimony, in which it seeks to exclude Registrants' witness testimony and documentary evidence regarding the risk and benefits of existing stocks. Registrants' opposition to that motion, which is due on April 26, will more fully explain the legal and factual bases for why that motion should be denied. Here, Registrants provide a brief summary of their arguments.

First, EPA cannot contend that the risks and benefits of allowing use of existing stocks are irrelevant to an existing stocks provision. EPA concedes that the Agency itself considered

[8] *See, e.g.*, Sanson Statement at 9:11-10:20.
[9] *See, e.g.*, Sanson Statement at 19:18-20:13.
[10] *See* Sanson Statement; Moore Statement; Engel Statement.
[11] *See* Hall Statement; Herbert Statement; Palumbo Statement.

those factors in deciding to allow use by growers. Motion to Limit at 3. EPA claims these considerations were irrelevant because it chose not to allow sale and distribution of existing stocks for the punitive purpose of ensuring that registrants are not "financially reward[ed]." *Id.* Yet, in reaching this decision, EPA must have concluded that serving this purpose outweighed the potential benefits of sale and distribution of existing stocks, which would allow more use by growers that EPA had found beneficial.

Second, EPA's existing stocks proposal is inconsistent with the Agency's own FIFRA policy on existing stocks and should therefore be revised. Request for Hearing and Statement of Objections ¶¶ 205-10; Sanson Statement at 21:15-22:22. EPA acknowledges that its proposal to prohibit further sale or distribution of flubendiamide is purely punitive and is in no way based on flubendiamide's risks or benefits. Motion to Limit at 3. EPA's existing stocks policy expressly provides that where cancellation is related to an unreasonable adverse effects finding, EPA must take into account the risks and benefits of the continued sale and use of the product in its existing stocks proposal. PBNX 52 at 29,364.

EPA complains in the Motion to Limit that there is not sufficient time for the parties to present testimony and evidence on the risks and benefits of its existing stocks proposal and for the Tribunal to weigh that evidence in a § 6(e) hearing, but this is one of the enumerated purposes of such a hearing. Registrants have already undertaken the substantial work to prepare fact and expert witness testimony challenging the alleged environmental risks of flubendiamide and demonstrating its many benefits to growers, agriculture, and the environment. EPA could

similarly have prepared and submitted testimony and exhibits on the subject; instead, the Agency made a calculated decision not to do so[12] and must now live with that choice.

EPA's own reasoning and express policy provide that risks and benefits must be taken into account in determining the existing stocks provision for flubendiamide. As a result of EPA's choice not to develop evidence on this issue, the only way for the Tribunal to determine how existing stocks should be handled is to consider the evidence that Registrants have marshalled refuting flubendiamide's alleged risks,[13] demonstrating its many benefits, and explaining how these factors support the continued distribution, sale, and use of existing stocks until they are exhausted.[14] For this reason, the scope of the hearing must allow for the presentation of evidence on flubendiamide's risks and benefits.

V. MATTERS OF OFFICIAL NOTICE

Petitioners are not aware of any matters for which official notice should be taken.

VI. TRANSLATION SERVICES

Petitioners do not request any translation services.

[12] Motion to Limit at 3-4 ("Respondent did not base the existing stocks determination in the Notice of Intent to Cancel on risk-benefit or scientific issues, and will not be offering any testimony in this proceeding on whether the sale and distribution of existing stocks would cause unreasonable adverse effects on the environment. If the Presiding Officer and Environmental Appeals Board do not agree with Respondent that it is consistent with FIFRA that registrants should not benefit from unlawfully refusing to comply with conditions of their registrations, EPA will not make any further arguments with respect to the sale and distribution of existing stocks.").

[13] *See, e.g.*, Sanson Statement; Moore Statement; Engel Statement.

[14] *See, e.g.*, Hall Statement at 13:8-16:2; Herbert Statement at 17:5-22:16; Palumbo Statement at 21:11-23:11.

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Respectfully Submitted,

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