ENVIRONMENTAL APPEALS BOARD
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C.

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

NOTICE OF EXCEPTIONS BY
BAYER CROPSCIENCE LP AND NICHINO AMERICA, INC.

Bayer CropScience LP and Nichino America, Inc. (collectively, "Registrants" or "Appellants") file this Notice of Exceptions, including proposed findings of fact, conclusions of law, and orders, pursuant to 40 C.F.R. § 164.101(a) and the June 9, 2016 Order of the Environmental Appeals Board ("EAB"), and request that the EAB review and reverse the orders and decisions issued by the Administrative Law Judge ("ALJ") identified below. Pursuant to 40 C.F.R. § 164.101(a) and the June 9, 2016 EAB order, Appellants are filing a separate Appeal Brief in support of this Notice of Exceptions.

I. STATEMENT OF EXCEPTIONS

Appellants hereby take exception to and appeal:

(1) the ALJ's April 25, 2016 Order denying Appellants' Motion for Accelerated Decision and finding that the conditions of registration the United States Environmental Protection Agency ("EPA" or "Appellee") imposed on Appellants' flubendiamide registrations requiring forced "voluntary" cancellation were lawful and that EPA's determination to cancel flubendiamide registrations based on an unreasonable adverse effects determination could proceed through a hearing under

FIFRA § 6(e), 7 U.S.C. § 136d(e), rather than under the procedure established at FIFRA § 6(b), 7 U.S.C. §136d(b) for such determinations (ALJ Dkt. #24);

(2) the ALJ's May 3, 2016 Order granting Appellee's Motion to Limit Scope of Testimony and finding that "whether [Appellants'] flubendiamide pesticides have an unreasonable adverse effect on the environment is not an issue for hearing," and finding all risk-benefit "evidence in regard thereto . . . not admissible at hearing" (ALJ Dkt. #27); and

(3) the June 3, 2016 Corrected Initial Decision finding untimely Appellants' objections to cancellation based on EPA's failure to engage in open, measured scientific dialogue before demanding cancellation as required under the multi-step "voluntary" cancellation provisions; finding that EPA satisfied the preconditions for demanding "voluntary" cancellation and that Appellants did not comply with the "voluntary" cancellation demand; and finding that EPA's existing stocks determination allowing use of existing stocks in the hands of end-users but prohibiting further sale and distribution was consistent with FIFRA (ALJ Dkt. #39).

II. PROPOSED FINDINGS OF FACT

Based on the record evidence and for the reasons stated in the Appeal Brief, the EAB should make the following findings of fact:

A. Registration of Flubendiamide

1. In granting the initial flubendiamide registrations after review of the required health and safety data, EPA determined, as required, that conditional registration of flubendiamide met the FIFRA Registration Standard and was in the public interest. PBNX 7; PBNX 9; PBNX 21 at PBN0106, 110; PBNX 116 at 3:1-22; FIFRA § 3(c)(7)(C), 7 U.S.C. § 136a(c)(7)(C).

2. EPA refused to issue the flubendiamide registrations without conditions of registration devised to allow EPA to bypass the statutory cancellation process and demand "voluntary" cancellation within one week. PBNX 7 at PBN0002, PBN0006; PBNX 8 at PBN0018-20; PBNX 116 at 7:9-8:6; Corrected Hearing Tr. ("Tr.") 111:7-22.

3. Having invested more than $125 million in discovery, data, and development costs in support of flubendiamide pesticide products, and with EPA registration required to market their innovative flubendiamide products, Registrants had no realistic choice but to accept the unlawful "voluntary" cancellation conditions of registration that EPA demanded; the alternative was to forgo registration of the flubendiamide products at a substantial loss to Registrants, agriculture, and the environment. PBNX 116 at 7:22-8:6; PBNX 117 at 3:14-22; PBNX 118 at 2:17-23; Tr. 111:7-22, 112:4-6, 144:11-145:3, 146:4-14.

B. Implementation of the "Voluntary" Cancellation Provisions

4. The flubendiamide Preliminary Acceptance Letter provides that EPA must "complete its review" of the required data and any other data Registrants submit and "engage in dialogue about the data and the Agency's conclusions" before demanding voluntary cancellation; the parties agree that these provisions required measured scientific dialogue. PBNX 8 at PBN0019; Tr. 43:1-44:7, 51:16-21, 105:9-14; RE 4 at 200036.

5. Open scientific dialogue between EPA and the Registrants stopped abruptly in the Fall of 2015 when the Agency shifted its focus from its previously announced plan to extend the registrations for three more years (with additional study requirements agreed to by the Registrants) to cancellation. PBNX 116 at 13:17-14:15; Tr. 125:17-126:16, 173:19-174:14, 189:4-10.

6. At a December 15, 2015 meeting, the EPA Assistant Administrator made clear his personal view that flubendiamide should not have been registered and should not be registered;

after the meeting, EPA asked Registrants to prepare a final mitigation proposal for EPA's consideration; EPA did not disclose that the Agency had decided to revert to a toxicity endpoint 70 times lower than the endpoint that had served as the basis of the parties' ongoing discussions. PBNX 116 at 14:4-22; PBNX 14; Tr. 126:7-16.

7. On December 16, 2015, EPA scientists briefed the Assistant Administrator on their position supporting cancellation using the lower toxicity endpoint and new analysis they had not disclosed to Registrants using the new endpoint, among other factors. PBNX 116 at 16:1-9 (admitted only as to the regulatory process); PBNX 14.

8. Registrants objected to the reversion to the lower endpoint and the lack of transparency, and at a January 6, 2016 meeting between EPA and Registrants, the Agency admitted that the timing of this change was "unfortunate" and tried to explain why its activities "had not been visible to the registrants or any other stakeholders." PBNX 116 at 17:16-23 (admitted only as to the regulatory process); PBNX 14.

9. On January 29, 2016, EPA issued its Decision Memorandum providing the Agency's unreasonable adverse effects determination, along with an Ecological Risk Assessment Addendum dated January 28, 2016 and other new documents that contained new analyses, modeling, and conclusions not previously disclosed to Registrants, including using the new endpoint in a way not previously disclosed; EPA provided no opportunity for Registrants to discuss this determination with the Agency or to provide written comments and instead issued its demand that Registrants voluntarily cancel their registrations the very same day. PBNX 30-32; PBNX 17; PBNX 116 at 18:15-20.

10. In a February 5, 2016 letter declining EPA's cancellation demand, Registrants again objected to EPA's sudden reversion to the lower toxicity endpoint and offered to "address

the science in a transparent and methodical way"; EPA rejected Registrants' offer by announcing its Notice of Intent to Cancel on March 1, 2016 without discussion. PBNX 18; PBNX 19; PBNX 116 at 18:21-19:17.

C. EPA's Proposed Cancellation of Flubendiamide

11. EPA seeks to cancel the flubendiamide registrations based on a determination that continued registration and use of flubendiamide products would "result in unreasonable adverse effects on the environment." PBNX 17 at PBN0097; PBNX 19; PBNX 30 at PBN0852.

12. EPA has not followed the FIFRA § 6(b) process for cancellations based on an "unreasonable adverse effects" determination; among other things, EPA did not provide its determination and the reasons therefor to the Scientific Advisory Panel ("SAP") for scientific peer review; did not provide any opportunity for the United States Department of Agriculture ("USDA") to provide input on the benefits and importance of flubendiamide products; and refused to provide Registrants the right to request a full administrative hearing on the merits of its cancellation determination. PBNX 116 at 19:18-20:4; PBNX 20; PBNX 26.

13. EPA has not found that further use of flubendiamide products poses an "imminent hazard" and has not sought to suspend the flubendiamide registrations under FIFRA § 6(c), 7 U.S.C. § 136d(c). PBNX 20.

14. In a recent administrative cancellation proceeding, EPA asserted to the ALJ that "the provisions governing risk-based cancellations and suspensions" are found in §§ 6(b) & (c), and that "products cancelled pursuant to section 6(b) have been determined to pose unreasonable risks to man or the environment that require that they be removed from commerce," while "a section 6(e) cancellation is about the *registrant's* failure to meet its obligations, and not about a problem with *the pesticide product itself*." *See* EPA's Conditional Opposition to CropLife America's Motion to File Amicus Brief at4 n.2 & 5, Dkt. #24, *In re Reckitt Benckiser*, FIFRA

Dkt. #661 (May 6, 2013) (excerpted at PBNX 126) (available in public docket, excluded from hearing as irrelevant) (emphasis in original).

15. Documents that Registrants sought to introduce as cross-examination exhibits that the ALJ excluded as irrelevant confirm that six of the twelve registrations EPA sought to cancel under FIFRA § 6(b) in the *Reckitt Benckiser* case were conditional registrations issued under FIFRA § 3(c)(7), 7 U.S.C. § 136a(c)(7). PBNX 124-125.

16. The evidence does not support EPA's determination that continued use of flubendiamide will cause unreasonable adverse effects on the environment. PBNX 116 at 9:3-9, 12:18-19, 15:1-17:23, 22:17-22 (excluded as irrelevant); PBNX 117 at 4:20-5:3, 6:1-13:7 (excluded as irrelevant); PBNX 118 at 3:20-4:2 (excluded as irrelevant); PBNX 119-122 (excluded as irrelevant).

17. EPA's cancellation determination provides no scientific justification for or explanation of its use of a toxicity endpoint that is 70 times lower than supported by the relevant data and EPA's prior statements. PBNX 30; PBNX 116 at 16:1-23 (admitted only as to regulatory process); PBNX 120 at 27:3-28:9 (excluded as irrelevant).

18. Monitoring studies conducted at the Agency's direction and other real-world data arising from more than seven years of flubendiamide use show that the exposure modeling EPA relies on for its cancellation determination is wrong and that flubendiamide and its degradate des-iodo are not accumulating to levels of concern, even based on EPA's scientifically unsupported lower endpoint. PBNX 119 at 7:12-8:11, 10:1-17:13, 30:11-32:22 (excluded as irrelevant).

19. EPA's cancellation determination improperly discounts or ignores the significant agricultural and environmental benefits of flubendiamide, including its excellent, selective

(targeted) control of lepidopteran pests, its compatibility with and furtherance of Insect Resistance Management and Integrated Pest Management, its relatively low toxicity to beneficial insects and most other taxa, its cost-effectiveness, and its excellent human health safety profile. PBNX 30; PBNX 22 at PBN0125-30; PBNX 117 at 4:21-5:3, 6:1-9:15 (excluded as irrelevant); PBNX 121 at 9:21-13:3, 14:7-11, 14:15-15:3, 16:6-17:2 (excluded as irrelevant); PBNX 122 at 6:20-11:14 (excluded as irrelevant).

D. Exclusion of Registrants' Expert Testimony and Exhibits

20. Registrants offered testimony from three fact witnesses and four expert witnesses to address the most significant aspects of EPA's cancellation and existing stocks determinations and the risks and benefits of flubendiamide. PBNX 116-118 (excluded in part as irrelevant); PBNX 119-122 (excluded as irrelevant).

21. The ALJ's May 3, 2016 Order excluded Registrants' expert testimony and exhibits in their entirety, excluded portions of Registrants' fact witness testimony related to the risks and benefits of flubendiamide, and admitted certain of Registrants' exhibits and other portions of Registrants' fact witness testimony on issues other than the substantive risks and benefits of flubendiamide. Order on Mot. to Limit at 10.

22. Registrants' proposed testimony and evidence on the merits of EPA's cancellation decision and the risks and benefits of flubendiamide would have easily fit within the hearing schedule established by the ALJ; written direct testimony and exhibits were submitted in the prehearing exchange, leaving only cross-examination and potential re-direct for the live oral hearing; the hearing was concluded midafternoon on the first of the four days scheduled for completion of the hearing. Order Scheduling Hearing and Prehearing Procedures (ALJ Dkt. #7) at 2; Registrants' Prehearing Exchange (ALJ Dkt. #22) at 1-2; Tr. 195:13-14.

23. EPA elected not to "present any factual testimony on risk-benefit issues" in this proceeding; the Agency also pledged that, regardless of the ALJ's decision on EPA's motion to exclude all risk-benefit evidence, it would not contest any risk-benefit evidence offered by Registrants. Mot. to Limit (ALJ Dkt. #18) at 4-5.

E. EPA's Existing Stocks Determination

24. EPA issued an existing stocks determination which permitted use of existing stocks in the hands of end-users, but prohibited any further sale or distribution of flubendiamide, whether by Registrants, distributors, or retailers. PBNX 20 at PBN0104.

25. The provisions cited by EPA in support of its determination are found in Part III.A.2 of the 1991 Existing Stocks Policy, which applies to cancellations "where the Agency does not have significant risk concerns with respect to the cancelled pesticide." PBNX 20 at PBN0104; PBNX 52 at PBN1554.

26. Part III.A.1 of the 1991 Existing Stocks Policy applies to cancellations "where the Agency has identified particular risk concerns" and requires the Agency to make a "case-by-case" determination on the risks and benefits of sale, distribution, and use of existing stocks; EPA has not made any such determination. PBNX 52 at PBN1553; PBNX 20.

27. EPA's Post-Hearing Brief acknowledges that the Agency's existing stocks determination "differs from the Policy" because it would prohibit third-party sale and distribution of flubendiamide products already in the stream of commerce. EPA's Post-Hearing Brief (ALJ Dkt. #35) at 11.

28. EPA made its existing stocks determination without any information, which it could easily have requested of Registrants, on their production or sales amounts and timing, or the volume of current or potential future existing stocks of flubendiamide in the hands of Registrants, distributors, retailers, or growers. Tr. 52:12-53:13.

29. Nichino ceased production in September 2015 and Bayer placed one final order in February 2016; the Registrants have not produced and will not produce any more flubendiamide in 2016 than they did in 2015. PBNX 118 at 3:20-21; PBNX 117 at 15:1-6; Tr. 173:16-174:14.

30. Nichino's flubendiamide formulation is not registered in any other jurisdiction, and all existing stocks would need to be disposed of without any beneficial use. PBNX 118 at 3:13-19; Tr. 173:8-15, 174:15-175:6.

31. EPA's existing stocks determination was not based on any consideration of the economic impact on distributors, retailers, or growers, and, if implemented, will cut off supply to growers at the very stage of the growing season when flubendiamide use is most critical. PBNX 117 at 13:16-14:18; PBNX 121 at 18:6-19 (excluded as irrelevant); Tr. 54:2-9.

32. Registrants' challenge in this proceeding to a unique and unprecedented condition of registration is made in good faith to prevent EPA from cancelling a beneficial product through an unlawful process, not to delay cancellation to prolong sales of flubendiamide. PBNX 116 at 7:9-9:2; PBNX 117 at 15:1-9; PBNX 118 at 3:20-21; Tr. 133:22-135:7; 162:17-163:4.

III. PROPOSED CONCLUSIONS OF LAW

Based on the record evidence and for the reasons stated in the Appeal Brief, the EAB should state the following conclusions of law:

1. Congress "establish[ed] a detailed, multi-step process that EPA *must* follow when it wants to cancel or suspend a registration." *Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34, 42 (D.D.C. 2011) (emphasis in original).

2. FIFRA § 6 requires that if EPA wishes to cancel any existing pesticide registration, whether unconditional or conditional, based on a determination that use of the registration "generally causes unreasonable adverse effects on the environment," the Agency must issue a notice of intent to cancel ("NOIC"), provide the right to request a hearing under

FIFRA §§ 6(b) & (d), and comply with all related process, including consulting with USDA and the Secretary of Health and Human Services, if applicable, before issuing the NOIC, and submitting its determination for review by the SAP; FIFRA § 6(b) is not limited to unconditional registrations.

3. FIFRA precludes EPA from inventing alternative cancellation mechanisms to circumvent the statutory process; *see Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131, 1136 (D.C. Cir. 2010) (remanding for determination whether EPA can "bypass[] cancellation" through misbranding scheme); *Reckitt Benckiser*, 762 F. Supp. 2d at 43 (confirming that EPA's misbranding enforcement authority cannot be used to circumvent "the rigorous cancellation process Congress provided for in the statute").

4. Because EPA seeks to cancel flubendiamide based on its substantive determination that use of flubendiamide will cause "unreasonable adverse effects," its issuance of a Notice of Intent to Cancel pursuant to FIFRA § 6(e) and attempt to cancel flubendiamide through the streamlined § 6(e) process and avoid the requirements of § 6(b) is unlawful.

5. If EPA determines it is necessary to remove flubendiamide products from the market during the cancellation process, the Agency must make an "imminent hazard" determination and follow the statutory process for suspension under FIFRA § 6(c).

6. The "voluntary" cancellation provisions in the flubendiamide registrations would allow EPA to evade FIFRA's statutory cancellation obligations, and EPA's refusal to issue the registrations without the "voluntary" cancellation provisions was an abuse of discretion and unlawful.

7. Even if the "voluntary" cancellation provisions were lawful, they do not provide EPA the right to demand "voluntary" cancellation because EPA did not engage in good-faith,

open scientific dialogue on the data and its conclusions as required under the provisions before demanding cancellation; instead, the Agency thwarted such discussion by deliberately withholding its change in position on the endpoint and producing its new analysis, modeling, and conclusions on the same day as its cancellation demand.

8. Evidence regarding (1) the soundness of EPA's risk-based cancellation of flubendiamide, (2) flubendiamide's risks and benefits to agriculture and the environment, and (3) whether a prohibition of the sale or distribution of the existing stocks of flubendiamide would be disruptive and harmful to agriculture is relevant both to Registrants' challenge to the lawfulness of the "voluntary" cancellation provisions and to the soundness of EPA's determination to prohibit the distribution and sale of existing stocks of flubendiamide and should not have been excluded.

9. The provisions of FIFRA § 6(e) requiring that EPA's existing stocks determinations (1) be consistent with the purposes of FIFRA, and (2) not cause unreasonable adverse effects on the environment and granting Registrants the right to a hearing on those issues apply equally to determinations to permit or to prohibit the distribution, sale, or use of existing stocks. FIFRA § 6(e)(1)-(2), 7 U.S.C. § 136d(e)(1)-(2).

10. EPA's refusal to conduct a risk-benefit analysis in reaching its existing stocks determination is a departure from the Agency's long-standing Existing Stocks Policy and is inconsistent with FIFRA; EPA's failure to request or consider information regarding Registrants' existing stocks of flubendiamide was arbitrary, capricious, and an abuse of discretion; and the Agency's existing stocks determination to prohibit the sale or distribution of existing stocks by Registrants, distributors, or third parties is therefore unlawful.

IV. PROPOSED FINAL ORDER

Registrants respectfully request that, after review of the April 25, 2016 Order, the May 3, 2016 Order, the June 3, 2016 Corrected Initial Decision, the Registrants' Appeal Brief, and the pertinent testimony and exhibits, the EAB issue a Final Order containing the findings of fact and conclusions of law outlined above and ruling that:

1. The ALJ's May 3, 2016 Order excluding Registrants' testimony and exhibits related to the risks and benefits of flubendiamide as irrelevant and the ALJ's ruling during the May 10, 2016 hearing excluding certain exhibits and cross-examination related to the Reckitt Benckiser proceeding and cancellation of conditional registrations under FIFRA § 6(b) are overruled; such evidence is relevant to the soundness of EPA's cancellation determination, the scope and applicability of FIFRA §§ 6(b) & (e), and the question of whether the Administrator's existing stocks determination is consistent with FIFRA.

2. The hearing is reopened for the purpose of admitting the written testimony of Registrants' four expert witnesses, Dr. Engel, Dr. Moore, Dr. Herbert, and Dr. Palumbo (PBNX 119-122), the previously excluded portions of the written testimony of Ms. Sanson, Mr. Hall, and Mr. Johnson (PBNX 116-118), and the exhibits previously excluded in their entirety (PBNX 37, 39-51, 80-115, 124-126) or admitted but excluded for substantive purposes (PBNX 9, 21-36).

3. If EPA wishes to cancel a registration, whether unconditional or conditional, based on a determination that continued registration would cause "unreasonable adverse effects on the environment," the Agency must follow the process and requirements set forth in FIFRA §§ 6(b), (c), & (d).

4. EPA cannot impose "voluntary" cancellation provisions to evade statutory due process and cancel registrations based on a subsequent unreasonable adverse effects determination without following the process Congress required under FIFRA §§ 6(b), (c), & (d)

and without subjecting its cancellation determination to independent scientific and administrative review as required by FIFRA.

5. The "voluntary" cancellation provisions EPA required Registrants to accept as a condition of the flubendiamide registrations are unlawful and invalid, and EPA's proposed cancellation of the flubendiamide registrations pursuant to those conditions and § 6(e) is therefore denied.

6. Should EPA wish to cancel the flubendiamide registrations based on its unreasonable adverse effects determination, the Agency must proceed under and comply with the terms of FIFRA §§ 6(b) & (d). Should EPA wish to suspend the flubendiamide registrations pending cancellation, the Agency must proceed under and comply with the terms of FIFRA § 6(c).

7. Even if the "voluntary" cancellation provisions were lawful, EPA's proposed cancellation pursuant to them is denied because EPA did not comply with the requirements under the provisions to engage in good-faith, scientific dialogue on the data and the Agency's conclusions before requesting voluntary cancellation.

8. EPA's proposed "punitive" existing stocks provision is an abuse of discretion and inconsistent with FIFRA, would cause significant and unwarranted disruption to agricultural production, and would pose unnecessary environmental risks associated with return and disposal of the products.

9. If this Final Order is overturned on subsequent appeal and the proposed cancellation of flubendiamide is upheld, the distribution, sale, and use of any existing stocks existing at the time of cancellation should be permitted.

Dated: June 13, 2016

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 13th day of June, 2016, a true and correct copy of the foregoing Notice of Exceptions by Bayer CropScience LP and Nichino America, Inc. was filed electronically using the EPA EAB eFiling System; and served in the following manner to the below addressees:

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