UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

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

OFFER OF PROOF BY
BAYER CROPSCIENCE LP AND NICHINO AMERICA, INC.

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I. INTRODUCTION

Pursuant to the Tribunal's May 3, 2016 Order on Respondent's Motion to Limit Scope of Testimony, and the directions Judge Biro provided at the May 10, 2016 hearing, Petitioners Bayer CropScience LP ("Bayer") and Nichino America, Inc. ("Nichino") submit the following written Offer of Proof with respect to testimonial and documentary evidence that was excluded from the proceeding.

II. TESTIMONIAL AND DOCUMENTARY EVIDENCE REGARDING FLUBENDIAMIDE'S RISKS AND BENEFITS

The May 3, 2016 Order granted Respondent's Motion to Limit Scope of Testimony and excluded from the hearing evidence and testimony regarding "whether the Petitioners' flubendiamide pesticides have an unreasonable adverse effect on the environment" on the grounds that such evidence is not "relevant to a material issue in dispute in the proceeding" and because of "the need to more tightly control evidence admitted at hearing . . . due to the extremely limited time-frame of 75 days in which the matter must proceed to – and through – administrative hearing and any appeal." May 3, 2016 Order at 10.

This evidence is relevant for at least two reasons. At a minimum, it is relevant to the existing stocks provision, which under EPA's own Existing Stocks Policy should take into account risks and benefits in determining whether to allow sale, distribution and use of existing stocks of a product for which the Agency "has identified particular risk concerns." PBNX 52 at PBN1553. In addition, it is relevant to the remedy requested by Petitioners at the outset of this hearing, that is, an order that EPA must follow the FIFRA § 6(b) cancellation process if it wishes to cancel the flubendiamide registrations for failure to meet the FIFRA registration standard and cannot shield its unreasonable adverse effects determination from substantive review.

The evidence excluded by the May 3, 2016 Order includes:

- Petitioners' Exhibits 37-51, 80-115, and 119-122.

- Other regulatory exhibits, including Petitioners' Exhibits 9 & 21-36 and Respondent's Exhibits 1 & 5, that were admitted as they relate to the regulatory process, communications, and actions by Bayer and EPA leading up to EPA's cancellation determination and demand, but not on the substantive question of whether flubendiamide products pose unreasonable adverse effects.

- Portions of the testimony of Charlotte Sanson, Bayer CropScience's Director of Registrations (PBNX 116):
    - Page 9 (lines 3-9)
    - Page 12 (line 18 starting at "The levels of detection . . ." – line 19)
    - Page 13 (lines 1-16)
    - Pages 15-17 (this testimony was excluded on the issue of the substantive merits of EPA's cancellation decision and the risks and benefits of flubendiamide, but was admitted as to the regulatory process, communications, and actions by Bayer and EPA leading up to EPA's cancellation determination and demand)
    - Page 22 (lines 17-22)

- Portions of the testimony of Lee Hall, Bayer CropScience's Industry Relations Lead and former Product Manager for Broad Acre Insecticides and Nematicides, including flubendiamide products (PBNX 117):
    - Page 4 (lines 20-24)
    - Page 5 (lines 1-3)
    - Page 5 (lines 4-21) (this testimony was excluded on the issue of the substantive merits of EPA's cancellation decision and the risks and benefits of flubendiamide, but was admitted as to the regulatory process, communications, and actions by Bayer and EPA leading up to EPA's cancellation determination and demand)
    - Page 6 through Page 13 (line 7)

- Portions of the testimony of Jeffrey Johnson, President of Nichino America (PBNX 118):
    - Page 3 (line 21 starting at "Given the modeling . . .") through Page 4 (line 2)

- The testimony of Dr. Bernard Engel, an expert witness who provided opinions on the concentrations of flubendiamide and its degradate des-iodo in water bodies and EPA's modeling and assessment of such concentrations (PBNX 119).

- The testimony of Dr. Dwayne Moore, an expert witness who provided opinions on the potential chronic risk of flubendiamide and its degradate des-iodo to benthic aquatic invertebrates and EPA's determinations with respect to toxicity (PBNX 120).

- The testimony of Dr. Ames Herbert, an expert witness who provided opinions on flubendiamide's attributes and benefits, including benefits to soybean, cotton, and peanut growers in Virginia, EPA's benefits assessment, and the consequences of cancellation (PBNX 121).

- The testimony of Dr. John Palumbo, an expert witness who provided opinions on flubendiamide's attributes and benefits, including benefits to growers of leafy vegetables and melons, EPA's benefits assessment, and the consequences of cancellation (PBNX 122).

The excluded testimony and exhibits were included in the written testimony and exhibits exchanged by the parties and provided to the Tribunal as part of the April 22, 2016 Prehearing Exchange. Taken as a whole, the excluded evidence and testimony on the risks and benefits[1] of flubendiamide are relevant to the substantive merits of EPA's cancellation decision and whether it is consistent with FIFRA's unreasonable adverse effects Registration Standard, and the merits of EPA's existing stocks determination and whether it is consistent with FIFRA and EPA's Existing Stocks Policy (PBNX 52); provide important factual background for judging the lawfulness of EPA's forced "voluntary" cancellation condition and EPA's purpose and intent in seeking to shield the substantive merits of its cancellation decision from review; provide information on the consequences of EPA's cancellation determination and existing stocks provision; and provide a response to statements made by EPA throughout the record regarding the toxicity, persistence, and benefits of flubendiamide products.

[1] The excluded testimony and evidence regarding flubendiamide's benefits to agriculture and the environment corroborates and expands upon the benefits information provided in the Amicus Curiae Brief of the Growers in Support of Objections to EPA's Notice of Cancellation that was jointly submitted by 35 grower associations, food processors, and food retailers from across the country. Dkt. No. 8.

A. Charlotte Sanson Testimony and Related Exhibits

The excluded portions of Ms. Sanson's testimony and related exhibits cited in her testimony[2] provide important scientific and regulatory facts regarding the substantive merits of EPA's assessment of flubendiamide's toxicity and substantive basis for EPA's scientific and regulatory decision to cancel flubendiamide as reflected in EPA's January 29, 2016 Decision Memorandum (PBNX 30) and Cancellation Demand Letter (PBNX 17) and the March 4, 2016 NOIC (PBNX 20).

Ms. Sanson would have testified that the levels of detection from the real-world monitoring studies that EPA required Bayer to conduct as a condition of registration to address uncertainty as to whether flubendiamide and its degradate would accumulate in the environment to levels of concern were all below levels of concern identified by EPA. PBNX 116 at 12:18-19.

Ms. Sanson would have testified that EPA was treating flubendiamide differently from methoxyfenozide, a product with a persistence and toxicity profile similar to flubendiamide's. For methoxyfenozide, "EPA properly focused on the higher-tier, real world monitoring data rather than overly conservative modeling," and recognized that the modeling results "'likely overestimate concentrations in streams and various other kinds of water bodies' for a number of reasons, including 'washout, dispersion, burial of sediment and other dissipative processes that aren't simulated.'" PBNX 116 at 13:1-16; PBNX 49 at PBN1484.

Ms. Sanson would have testified to the differences between a spiked water and a spiked sediment study, and would have testified that EPA indicated it "prefers" the use of a spiked sediment study to measure the toxicological endpoint of concern for flubendiamide and that the 19.5 parts per billion ("ppb") endpoint from the 2010 spiked sediment study was the appropriate

[2] Ms. Sanson cited PBNX 49, which was excluded, and PBNX 9, 21, 26, and 33, which were admitted, but not for purposes of addressing substantive risk-benefit issues.

endpoint from a regulatory and scientific standpoint instead of the 0.28 ppb endpoint from the 2008 spiked water study which EPA suddenly reverted to in December 2015. PBNX 116 at 15:6-16:23.

Ms. Sanson would have testified, based on almost 30 years of experience with pesticide registration issues, her knowledge of flubendiamide's scientific and regulatory record, and her review of the expert testimony of Dr. Engel, Dr. Moore, Dr. Herbert, and Dr. Palumbo that EPA's cancellation determination "is not warranted" and that, if cancellation was allowed, existing stocks should be allowed to clear the channels of trade because "the risks do not outweigh the benefits." *Id.* at 22:17-22.

B. Lee Hall Testimony and Related Exhibits

The excluded portions of Lee Hall's testimony and related exhibits cited in his testimony[3] provide important information regarding flubendiamide's benefits based on Mr. Hall's understanding as Industry Relations Lead and former Product Manager for flubendiamide. Mr. Hall would have testified that although flubendiamide "is not a high volume use product, . . . where it is used the qualitative benefits are significant," including flubendiamide's selective activity, its "minimal impact on beneficial insects," its importance as a tool for managing pest resistance, its "excellent human health safety profile and low ecological risk profile," and its competitive pricing compared to competitors. PBNX 117 at 4:21-5:3. Mr. Hall would have testified that flubendiamide fits Bayer's mission of "developing and supporting products that are safer, more effective, and more environmentally responsible than existing alternatives" and that "cancellation of flubendiamide would be a step backward." *Id*. at 12:21-13:7.

[3] Mr. Hall cited PBNX 9 and 21-24, which were admitted, but not for purposes of addressing substantive risk-benefit issues.

Mr. Hall would have testified regarding flubendiamide's selective nature and minimal impacts on beneficial insects, which encourages natural or biological pest control and makes flubendiamide an important tool for Integrated Pest Management ("IPM"), and the benefits of flubendiamide's selective action compared to broader spectrum alternatives such as pyrethroids, organophosphates, and carbamates. *Id.* at 6:1-8:3.

Mr. Hall would have testified that flubendiamide is an important tool for managing pest resistance because it can be rotated with pesticides with different modes of action and can control pests that have developed resistance to other classes of chemistry, and EPA's Biological and Economic Analysis Division recognized that cancellation of flubendiamide would reduce growers' ability to manage resistance. *Id*. at 8:4-9:3; PBNX 23 at PBN0424.

Mr. Hall would have testified that flubendiamide has an excellent safety profile with respect to human health and ecological risk as compared to its alternatives, that growers prefer to use pesticides "that they can be confident do not pose any health or safety risk to themselves or their employees" and that have "minimal ecological risks and impacts," and that flubendiamide's low risk profile allows for "fewer restrictions on timing of application" and reentry into treated fields, which are beneficial to farmers. PBNX 117 at 9:4-10:19.

Mr. Hall would have testified to the commercial benefits of flubendiamide, including the fact that for certain crops it is significantly less expensive than other IPM-friendly alternatives such as chlorantraniliprole (e.g., 35% less expensive than Altacor brand chlorantraniliprole for nut and pome crops and 70% less expensive than Coragen brand chlorantraniliprole for leafy vegetables), and that growers find Bayer's Belt flubendiamide products "economical, effective and safe" and that Belt "provides quicker results" and "'outstanding' residual activity," typically requires only one application, and "costs less than other options." *Id.* at 10:20-12:18.

C. Jeffrey Johnson Testimony

The excluded portions of Jeffrey Johnson's testimony relate to EPA's decision to cancel flubendiamide and its existing stocks determination. Mr. Johnson would have testified that based upon Dr. Engel's and Dr. Moore's analysis of EPA's modeling and choice of endpoint, and the extensive benefits evidence in the grower declarations, the IR-4 letter (PBNX 26), and the testimony of Dr. Herbert and Dr. Palumbo, cancellation of flubendiamide is not warranted. Mr. Johnson would have further testified with respect to existing stocks that "the risks do not outweigh the benefits for . . . less than a normal year's production, to be allowed to clear the channels of trade." PBNX 118 at 3:21-4:2.

D. Dr. Bernard Engel Testimony and Related Exhibits

The excluded expert testimony of Dr. Bernard Engel (PBNX 119) and related exhibits cited in his testimony[4] address the evidence regarding the concentrations of flubendiamide and des-iodo in water bodies and EPA's modeling of aquatic concentrations, and provide a response to statements by EPA that are in the record through the testimony of Susan Lewis, the Decision Memorandum (PBNX 30), the Cancellation Demand Letter (PBNX 17), the Press Release Announcing Cancellation (PBNX 19), the NOIC (PBNX 20), the Ecological Risk Assessment Addendum (PBNX 31), and other related exhibits contending that flubendiamide and des-iodo have accumulated or will accumulate to levels of concern.

Dr. Engel is a professor at Purdue University with more than 30 years of experience in the fields of agricultural hydrology, water quality, water quality monitoring, and soil and water conservation. He has served as an expert on numerous Scientific Advisory Panels ("SAPs") convened by EPA. PBNX 119 at 1:1-14, 3:1-13.

[4] Dr. Engel cited PBNX 50-51 and 80-84, which were excluded, and PBNX 25, 30-31, and 35-36, which were admitted, but not for purposes of addressing substantive risk-benefit issues.

Dr. Engel would have testified regarding basic hydrological principles related to the movement of compounds through watersheds, that these principles, ignored by EPA, indicate that flubendiamide and des-iodo will not accumulate to levels of concern as predicted by EPA, and that the monitoring data confirm that flubendiamide and des-iodo are moving through the watershed and will degrade through photolysis. PBNX 119 at 5:24-7:11, 8:12-9:17, 15:15-16:12.

Dr. Engel would have testified that five years of monitoring conducted by Bayer at EPA's requirement and direction at two sites selected to be roughly equivalent to the "farm pond" scenario modeled by EPA show that flubendiamide is not accumulating as EPA's models predict; that the measured concentrations show seasonal decline in concentrations after application; that variations in concentration measured in the studies can be explained by varying use rates, weather patterns, and sediment layering effects; that the measured concentrations are below all levels of concern identified by EPA and the Registrants; that EPA should rely on the monitoring data as the best evidence of environmental concentrations of flubendiamide and des-iodo; and that the monitoring should continue. *Id.* at 7:12-8:11, 10:1-15:14, 30:11-32:22.

Dr. Engel would have testified that EPA's "characterization of the USGS data is misleading" and that the USGS data show "limited, low-level detections consistent with areas of product use" and do not support EPA's conclusions that flubendiamide and des-iodo are "widespread" and "accumulating." *Id*. at 17:1-21:2.

Dr. Engel would have testified that EPA's claims that its modeling "performs quite well" in predicting flubendiamide and des-iodo concentrations are incorrect; that statistical analysis shows that the modeling performs "very poorly," does not meet standard measures for acceptable performance, and greatly overpredicts flubendiamide and des-iodo concentrations even after EPA's refinements to account for water flow through the ponds; that simply taking the mean of

the observed data is a better predictor of the observed data than the model; and that EPA's models should be significantly improved. *Id.* at 22:13-30:10.

Dr. Engel would have testified that EPA's cancellation determination relies on conflicting positions with respect to the effects of buffers on flubendiamide and des-iodo concentrations. *Id.* at 21:3-22:12.

Dr. Engel would have testified that EPA's determination that flubendiamide is causing or will cause unreasonable adverse effects lacks merit because EPA's modeling is not accurate or useful, and the real-world data from Bayer's monitoring studies and the USGS, "including more than 1,000 overlying and pore water pond samples, do not show any concentrations indicating accumulation to or near identified toxicity endpoints." *Id.* at 30:11-32:8.

E. Dr. Dwayne Moore Testimony and Related Exhibits

The excluded expert testimony of Dwayne Moore (PBNX 120) and related exhibits cited in his testimony[5] address the available studies and data and EPA's ecological risk assessments and conclusions on the toxicity of flubendiamide and des-iodo, particularly with respect to concerns regarding chronic toxicity to benthic aquatic invertebrates which are the basis for EPA's cancellation determination, and provide a response to statements by EPA that are in the record through the testimony of Susan Lewis, the Decision Memorandum (PBNX 30), the Cancellation Demand Letter (PBNX 17), the Press Release Announcing Cancellation (PBNX 19), the NOIC (PBNX 20), the Ecological Risk Assessment Addendum (PBNX 31), and other related exhibits contending that flubendiamide and des-iodo cause or will cause unreasonable adverse effects on the environment based on a 0.28 ppb level of concern for benthic aquatic invertebrates.

[5] Dr. Moore cited PBNX 43-38, which were excluded, and PBNX 27-34, which were admitted, but not for purposes of addressing substantive risk-benefit issues.

Dr. Moore has a B.S. degree in Plant Sciences from the University of Western Ontario and an M.S. and Ph.D. in Community Ecology from the University of Ottawa, has 25 years of experience as an ecological risk assessor, including 7 years with Environment Canada (the Canadian equivalent to EPA), and 17 years of experience leading and conducting ecological risk assessments for private firms and government agencies, including EPA. He has served as an expert on three "SAPs" convened by EPA. PBNX 120 at 1:6-3:2.

Dr. Moore would have testified that EPA's ecological risk assessments and cancellation determination are focused on potential chronic risks to benthic aquatic invertebrates, that EPA's reliance on a toxicological endpoint from a spiked water study assessing the impact of flubendiamide and des-iodo on the midge (*Chironomus riparius*) rather than "the subsequent, more relevant spiked sediment stud[y] is not scientifically justified," and that EPA's risk assessments therefore "provide no reliable scientific basis to conclude that benthic invertebrates are at significant risk from the continued registration and use of flubendiamide products." PBNX 120 at 8:1-13:21.

Dr. Moore would have testified regarding the differing design, purposes, and intended uses of spiked water and spiked sediment studies; the EPA statements and OECD guidance establishing that the spiked sediment study is the more relevant study to assess the potential impact of concern (accumulation of flubendiamide and des-iodo in sediment pore water over time from residues in agricultural runoff); that EPA previously identified the fact that the "[o]verlying water was spiked" as a "Major Guideline Deviation" in the spiked water study and stated that EPA "prefer[s] that the sediment is spiked"; that EPA's calculation of the 0.28 ppb No Observed Effect Concentration ("NOEC") for des-iodo in sediment pore water using the spiked water study relies on data that "was never intended to derive toxicity endpoints for sediment and

pore water" and is "not scientifically sound"; that use of the spiked sediment study, consistent with EPA's prior statements and guidance, results in an NOEC for des-iodo in sediment pore water of 19.5 or 22 ppb; and that EPA's use of the spiked water study NOEC "significantly overestimates the toxicity of des-iodo by measuring the wrong route of exposure, and results in an endpoint that is not relevant to the exposure that would occur in the real world." *Id.* at 14:1-21:18, 24:9-25:8, 26:14-19; PBNX 33 at PBN0912; PBNX 45-46.

Dr. Moore would have testified that the spiked water study has methodological flaws that further undermine its usefulness and are not shared by the spiked sediment study. PBNX 120 at 22:1-24:8, 25:9-26:13.

Dr. Moore would have testified that EPA's decision documents do not justify or explain EPA's decision to revert to the 0.28 ppb NOEC from the spiked water study and to use that endpoint as the basis for the cancellation determination, and that as a former regulator and scientist, he found EPA's lack of transparency on this critical decision "striking" and "troubling." *Id.* at 27:1-28:9.

Dr. Moore would have testified that EPA's efforts to redefine the scope of its concern and extrapolate risks to benthic aquatic invertebrates to invertebrates in the water column in the January 29, 2016 Addendum to Clarify Invertebrate Terminology (PBNX 32) did not make sense and were contrary to EPA's guidance. *Id.* at 28:10-29:20.

Dr. Moore would have testified that the exposure data, including observed data from five years of monitoring "in water bodies close to treated fields . . . do not come close to approaching a properly determined sediment pore water NOEC of 19.5 µg/L," that "[t]he observed levels of flubendiamide and des-iodo do not suggest any risks of concern that could provide a scientific

basis to justify a cancellation determination," and that "EPA has no scientific basis for canceling the flubendiamide registrations." *Id.* at 30:1-31:13.

F. Dr. Ames Herbert Testimony and Related Exhibits

The excluded expert testimony of Dr. Ames Herbert (PBNX 121) and related exhibits cited in his testimony[6] address and provide his opinions on: (1) Integrated Pest Management ("IPM") and Insect Resistance Management ("IRM") generally; (2) flubendiamide and the benefits that it provides soybean, cotton, and peanut growers in his area (Virginia and the surrounding region); (3) flubendiamide's role as an IPM and IRM tool; (4) EPA's assessment of flubendiamide's benefits; and (5) the consequences to Virginia's growers of flubendiamide's cancellation and EPA's existing stocks provision, and offered expert opinions on each subject. Dr. Herbert is an expert in the field of entomology with a specialty in IPM and IRM. In addition to conducting research to develop better pest control practices in order to improve productivity while protecting the environment, Dr. Herbert collaborates with growers to improve management of insect pests of soybean, peanut, cotton, and small grains that reduce reliance on pesticides while maintaining crop quality and profitability. Dr. Herbert's testimony and the exhibits relied upon for that testimony, had they been introduced into evidence, would have established the following.

Dr. Herbert would have testified that IPM and IRM are critical tools for growers seeking to optimize pest control while minimizing pesticide impacts on the environment and the development of insect resistance. The EPA and U.S. Department of Agriculture ("USDA") both recognize the importance of IPM and IRM and claim to promote their use by growers. *See, e.g.*, PBNX 41.

[6] Dr. Herbert cited PBNX 37, 39-42, and 100, which were excluded, and PBNX 21-23, 26, and 30, which were admitted, but not for purposes of addressing substantive risk-benefit issues.

Dr. Herbert would have testified that flubendiamide narrowly and effectively targets lepidopteran pests, which are some of the most destructive pests plaguing crops in the southeastern and mid-southeastern United States. Flubendiamide "fits perfectly with IPM programs, provides excellent control of lepidopteran pests while conserving natural enemies, and is non-toxic to pollinators—a 'smart bomb' that targets caterpillar pests with no collateral damage to important natural enemies or pollinators." PBNX 121 at 14:8-11. Flubendiamide's lack of toxicity to pollinators is a particularly important attribute, given both the USDA's and EPA's increasing concern regarding the potential impacts of pesticides on pollinators. *Id.* at 12:16-13:3

Dr. Herbert would have testified that flubendiamide "has a number of characteristics that make it an important tool in resistance management," including a "narrow spectrum of activity" and "optimal residual activity," which permit growers to rotate flubendiamide with other classes of pesticides to avoid the development of pest resistance. *Id.* at 14:17-15:3.

Dr. Herbert would have testified that EPA's Biological and Economic Analysis Division's ("BEAD's") analysis of Bayer's benefits submission, while acknowledging many of flubendiamide's proven benefits to growers and the environment, ignored much of the crop-specific data and analysis that Bayer presented. Even more egregiously, BEAD downplayed the significance of flubendiamide's benefits and the consequences of grower reversion to the use of IPM- and IRM-disruptive pyrethroids based solely on survey data regarding the amount of acreage on which flubendiamide is applied. Because flubendiamide is a very narrow-acting compound, the compound's benefits are better measured "by the particular attributes the product provides for growers (e.g. its highly-specific efficacy against caterpillar pests and lack of toxicity to bees and natural enemies of pests.)," when it is needed. *Id.* at 15:11-22. BEAD further

outright ignored the significance to agriculture, human health, and the environment of a shift back to pyrethroids, which pose significant human toxicity risks, are broadly toxic to beneficial insects and pollinators, must often be applied repeatedly to assure efficacy, and are already prone to the development of insect resistance.

Dr. Herbert would have testified that EPA's Decision Memorandum contained only a "cursory benefits summary" that "discounts the significance of many of flubendiamide's benefits while ignoring others entirely." *Id.* at 16:10-11. EPA acknowledges that the most likely replacement for flubendiamide will be pyrethroids, but ignores the significance of this shift away from IPM and IRM. Dr. Herbert identifies three problems with a reversion back to pyrethroids: "one, that resistance to pyrethroids has been confirmed for Corn earworm, Soybean looper, and other caterpillar pests; two, it has been proven that pyrethroids destroy non-target beneficial natural enemy species; and three, pyrethroids are toxic to pollinators and cannot be applied if crops are flowering and bees are actively foraging." *Id.* at 17:14-18. The other compounds identified by EPA as potential replacements for flubendiamide either do not share its targeted efficacy for lepidopteran pests or lack certain of flubendiamide's other attributes.

Dr. Herbert would have testified that EPA's existing stocks proposal "would be very disruptive to growers in Virginia." *Id.* at 18:8-9. Because of flubendiamide's particularly narrow use, growers do not store the product and instead purchase it on an as-needed basis when lepidopteran outbreaks occur. Growers will therefore suddenly need to identify and obtain a substitute for flubendiamide in "the height of caterpillar pest season," just as the product is most likely to be needed the most. *Id.* at 18:9-15.

G. Dr. John Palumbo Testimony and Related Exhibits

The excluded expert testimony of Dr. John Palumbo (PBNX 122) and related exhibits cited in his testimony[7] address: (1) IPM and IRM generally; (2) flubendiamide's attributes; (3) Leafy vegetable crops and the benefits that flubendiamide provides for growers; (4) the benefits that flubendiamide provides for melon growers; (5) EPA's assessment of flubendiamide's benefits; and (6) the consequences to southwestern growers of flubendiamide's cancellation and EPA's existing stocks provision. Dr. Palumbo is an expert in the field of entomology with a focus on the study of insect biology and ecology and the application of that knowledge to develop innovative IPM strategies in vegetable cropping systems in the Arizona and southern California growing region. Dr. Palumbo develops and directs an applied research and extension program to investigate the management of the key pests associated with Arizona vegetable production and provides empirically based information on the management of insect populations in vegetable and melon crops that can be directly applied by growers throughout the southwestern United States. Dr. Palumbo's testimony and the exhibits relied upon for that testimony, had they been introduced into evidence, would have demonstrated the following:

Dr. Palumbo would have testified that IPM is essential to efforts to implement innovative pest management strategies that reduce the industry's reliance on broadly toxic pesticides without sacrificing yield, quality, and profitability, and while minimizing dietary and environmental risks. The development of insecticide resistance is a threat to IPM and must be combatted with IRM.

Dr. Palumbo would have testified that flubendiamide narrowly targets Lepidopteran larval complex pests and is "one of the more efficacious and therefore valuable insecticide

[7] Dr. Palumbo cited PBNX 110-15, which were excluded, and PBNX 22-23 and 30, which were admitted, but not for purposes of addressing substantive risk-benefit issues.

alternatives presently available for managing Lepidopteran pests in Leafy vegetables, Brassica (Cole) Leafy vegetable crops and melons." PBNX 122 at 6:15-19.

Dr. Palumbo would have testified that flubendiamide's "selective efficacy, non-systemic activity, rainfastness, good residual activity, [] good human health and safety profile, low toxicity to beneficial insects, and cost effectiveness" make it well-suited for IPM. *Id.* at 6:21-23. Flubendiamide's "modest residual activity is an important attribute for IRM because it only remains efficacious long enough to expose a single generation[] of a Lepidopteran population to the active ingredient and control that pest, reducing selection pressure on flubendiamide to the population." *Id.* at 9:16-18. Flubendiamide's cost-effectiveness, particularly when compared to other IPM-friendly compounds such as chlorantraniliprole, is an important attribute. Cost is a major driver for grower decision-making regarding pesticides, and flubendiamide's competitive pricing permits growers to profitably adopt IPM and IRM practices.

Dr. Palumbo would have testified that flubendiamide is a particularly important tool for leafy vegetable crops in Arizona and southern California because of the threat lepidopteran pests pose to those crops. When growers apply flubendiamide, "no additional insecticides are required to achieve complete control." *Id.* at 13:10-11. Without effective control, "a significant acreage of the Arizona lettuce crop would be lost to larvae contamination and could not be harvested." *Id.* at 13:5-7. Flubendiamide has attributes that not even its diamide competitor, chlorantraniliprole, shares. Flubendiamide's more limited residual activity and its non-systemic function make it "a better fit for Leafy Vegetable IPM programs than [] a systemic compound such as chlorantraniliprole." *Id.* at 14:13-15. Flubendiamide's lack of toxicity to pollinators and to natural enemies makes it "an ideal compound [for] control of Lepidopteran pests (particularly cabbage looper and beet armyworms) on melons." *Id.* at 15:14-16.

Dr. Palumbo would have testified that EPA BEAD ignored entirely the portion of Bayer's benefits submission relating to flubendiamide's use on lettuce and watermelon. BEAD acknowledged flubendiamide's benefits to alfalfa growers, and admitted that growers would likely revert to IPM- and IRM-disruptive pyrethroids, organophosphates, and carbamates if flubendiamide is cancelled. BEAD improperly dismissed flubendiamide's significance to alfalfa based on the percentage of alfalfa acreage treated with the compound, ignoring flubendiamide's role as an important tool for alfalfa growers in Arizona and the disruption its cancellation would cause in IPM and IRM efforts in this region. *Id.* at 16:12-17:15. EPA's claim in its Decision Memorandum "that there are efficacious alternatives for flubendiamide" is both vague and oversimplified. *Id.* at 18:16-20. Flubendiamide's cancellation will drive growers away from the very IPM and IRM practices that EPA should be promoting and toward compounds such as pyrethroids and organophosphates that are toxic to pollinators and other beneficial insects and have a far less favorable human health profile. By canceling compounds such as flubendiamide, EPA threatens the sustainability of leafy vegetable production in Arizona and southern California and makes insect pest resistance more likely to develop.

Dr. Palumbo would have testified that EPA's existing stocks proposal, which did not take grower interests into account, will be disruptive for growers in Arizona and southern California because it "would effectively prevent growers from applying flubendiamide from the date of cancellation forward." *Id.* at 22:13-15. EPA's decision to permit end users to use flubendiamide already in their possession "would be a largely meaningless gesture." *Id.* at 22:11-13. When lepidopteran pest numbers hit their peak this fall, growers will no longer be able to have flubendiamide applied on fall lettuce crops. Growers will also be deprived of flubendiamide's use right in the middle of the monsoon season when it is needed most.

III. EVIDENCE AND CROSS-EXAMINATION RELATED TO THE RECKITT BENCKISER CANCELLATION PROCEEDING

At the May 10, 2016 hearing, a line of cross-examination and cross-examination exhibits that Petitioners intended to pose to EPA's sole witness Susan Lewis were excluded as irrelevant. The excluded cross-examination and exhibits related to a recent cancellation proceeding involving EPA's cancellation of certain rodenticide product registrations held by Reckitt Benckiser, which is the only contested pesticide cancellation proceeding to have occurred in at least twenty years and for which Ms. Lewis was designated as a witness.

The cross-examination and exhibits, if permitted, would have shown that EPA, after first attempting to effectively cancel certain rodenticide product registrations held by Reckitt Benckiser by deeming them "misbranded" as of a certain date and threatening civil and criminal enforcement action for further sales, an approach that was found unlawful,[8] proceeded to seek cancellation of the registrations through FIFRA § 6(b), which resulted in the commencement of an administrative hearing on the merits of EPA's cancellation determination. The cross-examination exhibits included EPA's Notice of Intent to Cancel published in the Federal Register on February 5, 2013 (PBNX 124) that identified the registration numbers for the relevant products; EPA's Conditional Opposition to CropLife America's Amicus Brief filed in that proceeding (PBNX 126) that likewise identified the registration numbers for the products at issue; and Notices of Registration for certain of the products at issue (PBNX 125). These excluded cross-examination exhibits establish that 6 of the 12 registrations that EPA sought to cancel were conditional registrations issued under FIFRA § 3(c)(7) that EPA sought to cancel under FIFRA § 6(b).

[8] *See Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131 (D.C. Cir. 2010); *Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34 (D.D.C. 2011).

If permitted, Petitioners would have cross-examined Ms. Lewis using these exhibits with respect to whether EPA's actions in seeking cancellation of Reckitt Benckiser's conditional registrations under § 6(b) were consistent with the position taken by the Center for Biological Diversity ("CBD") in an amicus brief filed in this proceeding that "use of the hearing procedures described in section 6(b) is not proper for 'registration[s] issued under section 3(c)(7) of [FIFRA],'" and that the flubendiamide registrations were issued under § 3(c)(7) and thus can be cancelled only under § 6(e). Amicus Curiae Brief of the Center for Biological Diversity (Dkt. No. 14) at 17 (citing *Woodstream Corp. v. Jackson*, 845 F. Supp. 2d 174, 177 (D.D.C 2012)).

Petitioners would have further cross-examined Ms. Lewis on whether these exhibits contradict the finding in the *Woodstream* decision relied on by CBD that the Woodstream cancellation circumstances "are entirely distinguishable" on the basis that "Reckitt Benckiser . . . had an existing, unconditioned registration." *Woodstream*, 845 F. Supp. 2d at 183 n.5.

Petitioners would have further cross-examined Ms. Lewis on whether EPA agreed with the CBD Amicus Brief on this issue, whether she was involved in EPA's decision not to file a response to the CBD Amicus Brief to correct its inaccurate statements, and whether EPA's actions in the Reckitt Benckiser proceeding confirm EPA's prior representations in its Conditional Opposition to CropLife America's Amicus Brief in the Reckitt Benckiser proceeding that "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*," that "[i]n contrast, the provisions governing risk-based cancellations" are in § 6(b), and that pesticides "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." PBNX 126 at 4 n.2 and 5 (emphasis in original).

Finally, if permitted, Petitioners would have cross-examined Ms. Lewis with respect to any testimony she may have offered on cross-examination to justify, explain, or distinguish the facts of Reckitt Benckiser and EPA's actions and representations in the Reckitt Benckiser cancellation proceeding.

Dated: May 19, 2016

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 19th day of May, 2016, a true and correct copy of the foregoing Offer of Proof by Bayer CropScience LP and Nichino America, Inc. was filed electronically using the EPA OALJ e-filing system; and served in the following manner to the below addressees:

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