UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

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

VERIFIED WRITTEN STATEMENT OF LEE HALL
ON BEHALF OF BAYER CROPSCIENCE LP AND NICHINO AMERICA, INC.

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I. BACKGROUND AND EXPERIENCE

Q: Please state your name and business address.

A: My name is Lee Hall. My business address is 2 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Q: Please identify your current employer.

A: I work for Bayer CropScience LP ("Bayer"). Bayer's U.S. business headquarters is located in Research Triangle Park, North Carolina.

Q: Please describe Bayer's focus and mission as a company.

A: Bayer is a world-leading innovator in the development of newer, more effective, and more sustainable crop protection products. Bayer's mission is "Science for a Better Life," which means the company is dedicated to providing products that help farmers feed a growing population and foster healthy environments. This mission is supported by the discovery, development, registration, marketing, and stewardship of safe, effective, and environmentally responsible plant protection technologies.

Q: Please identify your current position at Bayer.

A: I currently serve as Industry Relations Lead. In that role I work with stakeholders in various commodity, grower, trade organizations and other stakeholder groups.

Q: What position did you hold at Bayer prior to Industry Relations Lead?

A: I served as a Product Manager for eight years before transitioning to my current position. As Product Manager I was responsible for Broad Acre Insecticides and Nematicides.

Q: Did your responsibilities as Product Manager include flubendiamide products?

A: Yes. I was responsible for Bayer's flubendiamide products from their launch in 2008 until April of 2015.

Q: What involvement do you have with flubendiamide products in your current position?

A: I continue to be involved in flubendiamide, focusing on growers' needs and product usage issues in my current role as Industry Relations Lead.

Q: Prior to your joining Bayer, what was your professional experience?

A: I have worked in the pesticides industry for nearly 32 years. I joined Union Carbide Agricultural Products Company (a legacy company of Bayer) in May 1984. My experiences at Bayer have included 26 years in various roles in R&D including Discovery Research, Field Research, Technical Service, and Product Development.

II. DEVELOPMENT OF FLUBENDIAMIDE

Q: Please generally describe flubendiamide and its use as an insecticide.

A: Flubendiamide is the first pesticide in its class of chemistry, known as phthalic acid diamides, to be registered by the Environmental Protection Agency ("EPA") under the Federal Insecticide, Fungicide, and Rodenticide Act. Flubendiamide is approved for use on over 200 crops and provides excellent, targeted control of larval lepidopteran pests (caterpillars).

Q: Who invented flubendiamide?

A: Flubendiamide was invented by Nihon Nohyaku Co., Ltd. ("NNC").

Q: Does Bayer have a business relationship with NNC?

A: Yes. Bayer has a licensing, product development, and marketing agreement with NNC and its wholly owned subsidiary, Nichino America, Inc. ("Nichino"), pursuant to which Bayer serves as Nichino's regulatory agent for flubendiamide.

Q: What are Bayer's responsibilities as Nichino's regulatory agent?

A: As regulatory agent, Bayer took the lead on engaging in discussions with EPA and generating data required to support the flubendiamide registrations.

Q: Who sells flubendiamide products in the United States?

A: Bayer sells flubendiamide products under the Belt® brand name and Nichino sells flubendiamide products under the Vetica® and Tourismo® brand names.

Q: Who holds the registrations for the products subject to EPA's proposed cancellation?

A: Bayer and Nichino ("Registrants") are the original and current holders of the flubendiamide registrations that are the subject of EPA's proposed cancellation.

Bayer holds the registration for the Belt® SC Insecticide end-use product (EPA Reg. No. 264-1025). Nichino holds the registration for the Flubendiamide Technical product (EPA Reg. No. 71711-26), which consists of nearly pure flubendiamide and is used to manufacture end-use products, and the Vetica® Insecticide and Tourismo® Insecticide end-use product registrations (EPA Reg. Nos. 71711-32 and 71711-33), which combine flubendiamide with buprofezin, another insecticide.

Q: What resources, if any, does Bayer commit to secure and support pesticide registrations under FIFRA?

A: Bayer invests heavily in the expertise needed to design and conduct the complex health and environmental tests and analyses necessary to obtain and support EPA pesticide approvals.

Q: What resources has Bayer expended on the flubendiamide registrations?

A: Bayer has made significant investments to obtain, maintain, and expand the flubendiamide registrations. Bayer spent more than $60 million in data and development costs to obtain the initial flubendiamide registrations and to support the expansion and continuation of the registrations.

III. FLUBENDIAMIDE USE AND BENEFITS

A. Product Use

Q: Generally speaking, how does flubendiamide work?

A: Flubendiamide provides excellent, targeted control of larval lepidopteran pests (caterpillars) by affecting certain receptors in the targeted species, stopping feeding within minutes.

Q: Where in the United States is flubendiamide primarily used?

A: Flubendiamide products are sold by Bayer and Nichino throughout the country, with their primary use running across the South and up the West Coast (south of the Mason-Dixon line and from Virginia through California).

Q: Please identify the crops EPA has approved for use with flubendiamide.

A: Flubendiamide was originally labeled for use on broad acre crops (e.g., corn and cotton), pome fruit, tree nuts, vines, and some vegetables. Over time, EPA has expanded the approved uses to cover more than 200 crops.

Q: During what seasons do growers use flubendiamide products?

A: Growers use flubendiamide on a wide range of crops throughout the year. It is used on winter vegetables in Arizona and Florida from January through March, on tree fruits and nuts in California from March through June, on soybeans, cotton, and alfalfa from June through August, and on fall vegetables from September through December.

B. Benefits of Flubendiamide

Q: Please summarize the main benefits of flubendiamide products.

A: Flubendiamide is not a high volume use product, but where it is used the qualitative benefits are significant. Flubendiamide selectively targets lepidopteran pests with minimal impacts on beneficial insects. It is an important tool for managing resistance because it can be

rotated with other pesticides with different modes of action. Flubendiamide also has an excellent human health safety profile and low ecological risk profile. It is competitively priced compared to its competitors.

Q: Mr. Hall, are you familiar with the document that has been identified as PBNX 22?

A: Yes, this is the Benefits Document Bayer submitted to EPA in May of 2015. It is a comprehensive summary of flubendiamide's human health, environmental, safety, and pest management benefits across fifteen representative crops. The benefits information is supported by citations to articles published in scientific journals, field study results, and crop-specific testimonials from growers, grower organizations, and experts in the field of entomology. This submission included over 300 pages of comparative health and safety information, use information, and third party data, articles, and letters of support demonstrating flubendiamide's current use and benefits and its important current and future role for IPM and resistance management.

Q: Did Bayer submit any other benefits-related documents to EPA?

A: Yes, in June 2015 Bayer supplemented its May 2015 submission with a white paper, PBNX 24, that further outlines flubendiamide's benefits and provides an aquatic risk assessment summary.

Q: Did EPA provide a response to Bayer's benefits documents?

A: Yes. In its July 2015 review memo, EPA's Biological and Economics Analysis Division ("BEAD") provided its assessment of Bayer's benefits submissions. The BEAD benefits review is PBNX 23.

1. Minimal Impact on Beneficial Insects

Q: You indicated that one benefit of flubendiamide that it is "selective," correct?

A: Yes, that's right.

Q: Has EPA acknowledged flubendiamide's selective properties?

A: Yes. In EPA's review of Bayer's benefits submissions, the Agency noted that flubendiamide has minimal impact on many beneficial insects, including parasitic and predatory species such as parasitoid wasps, ladybird beetles, soldier beetles, and predatory mites. PBNX 23 at 4.

Q: Why is this important?

A: Flubendiamide's selective nature encourages natural or biological pest control, and makes flubendiamide an important tool for modern Integrated Pest Management ("IPM") approaches.

Q: What is IPM?

A: IPM is an ecosystem-based strategy that focuses on long-term prevention using a range of practices to minimize negative impacts and resistance issues.

Q: Are you familiar with the document identified as PBNX 21?

A: Yes, this is the Agency's April 15, 2008 Public Interest Finding for flubendiamide.

Q: What, if anything, did EPA say about flubendiamide's selectivity in its Public Interest Finding?

A: In the Public Interest Finding, EPA concludes that flubendiamide is "highly selective," with a "better toxicity profile than most insecticides currently targeted to control lepidopterous pests in the target crops." PBNX 21 at 5. On the same page, EPA concludes that flubendiamide provides "Lepidoptera control equivalent or superior to the insecticides currently being used for

pest control," with "low toxicity to insect predators and honey bees [that] should make flubendiamide an important component in integrated pest management programs." *Id.* Flubendiamide's selectivity encourages natural or biological pest control, which, as EPA acknowledged, makes flubendiamide "a valuable tool" in the development of IPM programs. *Id.*

Q: Have flubendiamide products become an important tool for IPM practices as BEAD predicted?

A: Yes, they have. In the past seven years we have seen growers relying on flubendiamide as part of an IPM approach to control the lepidopteran pests that flubendiamide targets. Dr. Herbert and Dr. Palumbo will provide testimony regarding the importance of flubendiamide as an IPM tool within their areas of expertise.

Q: How does flubendiamide differ from alternatives that are not selective?

A: Broader-spectrum alternatives like pyrethroids, organophosphates, and carbamates affect a much wider range of insects, including beneficial species.

Q: What is the significance of a compound having a broader spectrum of activity on its use for pest management?

A: Broad-spectrum pesticides can cause flare-ups when populations of fast-reproducing species, such as aphids and mites, recover and grow unchecked in the absence of slower-reproducing insect predators. These flare-ups can create new pest problems that require additional pesticide applications with additional environmental impacts and increased costs to the growers. Flubendiamide's selectivity and minimal impact on predatory insects help avoid these problems.

Q: Has EPA acknowledged this benefit of flubendiamide?

A: Yes. BEAD agreed in its Public Interest Finding that use of flubendiamide "should not result in the flaring of secondary pest populations." PBNX 21 at 5.

2. <u>Managing Resistance</u>

Q: What other benefits are associated with flubendiamide?

A: Flubendiamide products are also an important tool for growers in managing pest resistance. They can be rotated (i.e., alternated) with other pesticides with different modes of action as part of a resistance management program to avoid resistance issues that can arise from the overuse of a single mode of action.

Q: How does flubendiamide's mode of action manage resistance?

A: As a member of the diamide class of chemistry, flubendiamide has a different mode of action from the longstanding pyrethroid, carbamate, and organophosphate products and is effective at controlling insect populations that have developed resistance to those classes of chemistry.

Q: Has EPA acknowledged flubendiamide's resistance management properties?

A: Yes. In its July 2015 review of Bayer's benefits submissions, BEAD agrees that cancellation of flubendiamide would "reduce[] the ability to manage" insecticide resistance and that likely alternatives including pyrethroids "do not fit well with most IPM practices." PBNX 23 at 8.

Q: How else does flubendiamide manage resistance?

A: Unlike chlorantraniliprole, its main IPM-friendly alternative, flubendiamide is non-systemic. This is significant because prolonged pest exposure to systemic insecticides, which can expose multiple generations of pests, can lead to the development of resistance by some

insects to those products. Flubendiamide provides residual control for two weeks on average, which provides benefits to growers but may avoid some of the resistance issues associated with longer lasting systemic insecticides.

3. Safety and Risk Profiles

Q: What other benefits are associated with flubendiamide?

A: Flubendiamide has an excellent safety profile, both with respect to human health and ecological risk, and as compared to alternatives such as organophosphates, carbamates, and pyrethroids.

Q: Has EPA commented on flubendiamide's safety and ecological risk profile?

A: Yes. For example, EPA issued a Flubendiamide Pesticide Fact Sheet in August 2008 when the original flubendiamide registrations were granted, which is PBNX 9. In the Fact Sheet, EPA acknowledges that flubendiamide poses no risk of concern to humans (either through diet or worker exposure), fish, mammals, crustaceans, mollusks, beneficial insects, and plants. PBNX 9 at 2-8. EPA has reached similar conclusions in the human health and ecological risk assessments the Agency has conducted since 2008.

Q: To your knowledge, is this important to growers?

A: Yes. Growers prefer pesticides that they can be confident do not pose any health or safety risk to themselves or their employees, and they prefer to use insecticides with minimal ecological risks and impacts. We hear this frequently from our customers.

The importance of safety is also reflected in the grower statements and letters attached to the amicus brief filed by the growers in this action. As the growers put it, growers are on the "front lines when it comes to the safety of pesticides." Grower's Amicus Brief at 24. For example, Cliff Keel, a tobacco farmer who has used flubendiamide for approximately seven

years, noted in his declaration that tobacco is a very "labor-intensive, hands-on crop," which creates opportunities for direct exposure to treated plants. This makes safety of the insecticides he uses very important, to protect the health of his workers, including his son who is involved in spraying and harvesting. Growers' Amicus Brief, Exhibit 7 ¶ 3.

Similarly, Dr. Hannah Burrack, an Associate Professor and Extension Specialist at North Carolina State University, recommends Belt for tobacco not only because of its effectiveness, but also because it raises "fewer concerns about worker exposure" compared to the previous standard Orthene (which contains the organophosphate acephate). *Id.*, Exhibit 11. Dr. Burrack provided data from grower surveys showing increased use of Belt leading to reductions in use of Orthene and Tracer (spinosad, a broad-spectrum insecticide). *Id.*

Q: Does flubendiamide have other benefits associated with its low risk profile?

A: Yes. In addition to its safety benefits, flubendiamide's lower risk profile allows for more flexible use because of fewer restrictions on timing of application (e.g., shorter pre-harvest intervals and restricted entry intervals for workers). The pre-harvest interval determines how close to the expected harvest date an insecticide can be used, and the restricted entry interval determines how soon after application of the insecticide workers can enter the field. Among other things, the greater flexibility afforded by shorter pre-harvest and restricted entry intervals increases the ability of growers to respond to pest issues if and when they arise, which can lower overall insecticide use.

4. <u>Commercial Benefits</u>

Q: What other benefits are associated with the use of flubendiamide?

A: Flubendiamide is a competitively priced "IPM friendly" insecticide, and for certain crops is less than half the cost of chlorantraniliprole, its major phthalic diamide competitor. Bayer has

a single commercially available brand of flubendiamide, BELT® SC, with unsegmented pricing. There are three separate brands of chlorantraniliprole, Altacor®, Coragen®, and Prevathon®, and each is segmented by price and crop. For instance, BELT brand flubendiamide is ~35% less expensive (or 2/3 the cost) as compared to Altacor brand chlorantraniliprole which is labeled for nut and pome crops. On leafy vegetables, BELT is ~ 70% less expensive (or 1/3 the cost) as compared to Coragen brand chlorantraniliprole. Cost is an important factor for growers trying to operate their businesses at a profit.

Growers recognize the cost benefits of flubendiamide. For example, Mike Sturdivant, a soybean, cotton, and corn farmer in Mississippi, explained that "[a]vailable alternatives are much more expensive than Belt" and that "no other tools in my arsenal . . . are as effective as Belt, especially from a cost standpoint." Growers' Amicus Brief, Exhibit 14. Ed Greer, a soybean, cotton, corn, rice, wheat, and grain sorghum farmer in Louisiana, notes that Belt "has become one of our anchor products because it is economical, effective and safe," and that loss of Belt will force them to use a "more costly alternative that has not been proven in the field." *Id.*, Exhibit 8. Chris Ward, a crop protection consultant, reports that he recommends Belt for soybean growers because it is "safe and effective," has "outstanding" residual activity, typically requiring only one application, "provides quicker results," and "costs less than other options." *Id.*, Exhibit 24.

Q: How will cost considerations impact growers' choice of alternative products if Belt is cancelled?

A: If growers do not have Belt as an affordable IPM option, many will opt instead for pyrethroids and organophosphates due to cost concerns.

Q: What other commercial benefits are associated with flubendiamide?

A: Unlike many of the other products commonly used to control lepidopteran insects, flubendiamide products are rainfast once spray deposits have dried, providing control for up to two weeks. Flubendiamide's residual effectiveness period can reduce the need for multiple applications, lowering costs and environmental impacts. For example, Stanley Winslow, an agronomist in North Carolina, notes that use of flubendiamide has eliminated the need for a second treatment, which costs farmers $8 to $9 dollars per acre. *Id.*, Exhibit 22.

Q: How would elimination of Belt affect the market for IPM-friendly insecticides?

A: Having more than one choice in insecticide options not only provides more options for IRM, but it also increases competition among products. Thus, removal of Belt will lead to less competition, which could cause prices for the remaining IPM-friendly alternatives to rise.

Q: Has EPA noted flubendiamide's commercial benefits?

A: Yes. EPA has acknowledged flubendiamide's competitive pricing compared to IPM alternatives such as chlorantraniliprole, and that growers that currently use flubendiamide may have to choose between reverting to more disruptively, IPM-unfriendly options or incurring higher costs for IPM-friendly alternatives. PBNX 23 at 6. However, EPA's Decision Memorandum that provides the explanation for EPA's cancellation decision ignores the cost benefits of flubendiamide entirely.

5. <u>Overall Benefits</u>

Q: How does flubendiamide fit within Bayer's overall mission?

A: As I have explained, Bayer's mission is "Science for a Better Life," which means we are focused on providing the next generation of crop protection products with a focus on developing and supporting products that are safer, more effective, and more environmentally responsible

than existing alternatives. Flubendiamide fits that profile and our mission. It has no human health safety concerns, has proven extremely effective at controlling targeted pests with minimal impacts on beneficial insects, and with an ecological profile that is equal to or better than alternatives. As Dr. Moore and Dr. Engel will testify, despite EPA's stated concerns, the science does not support EPA's position that use of flubendiamide is causing or will cause harm to benthic aquatic invertebrates, the one area of potential concern identified by EPA.

For all these reasons, cancellation of flubendiamide would be a step backward.

IV. IMPACT OF EPA'S PROPOSED EXISTING STOCKS PROVISIONS

Q: Mr. Hall, are you familiar with the existing stocks provisions EPA proposed in the Notice of Intent to Cancel?

A: Yes. I understand that EPA has taken the position that immediately upon cancellation, any further distribution or sale of any existing stocks of flubendiamide products should be prohibited, except for return of products for disposal or export. I also understand that EPA proposes to limit use of existing stocks at the time of cancellation only to product that is in the hands of "end users" at the time of cancellation.

Q: What would be the impact of this approach on growers?

A: A cancellation order that immediately banned any further distribution or sale of flubendiamide products could be very disruptive.

The end-users of pesticide products are generally either the growers themselves (if they purchase and apply the product) or applicators who are contracted to apply the product. Given its selective and targeted nature, and consistent with IPM practices, many growers wait to see if any caterpillar pest pressure develops for a given crop and season before making the decision to purchase and apply flubendiamide themselves or through an applicator. Thus, they typically do not have a supply of flubendiamide products on hand. Private applicators, almost without

exception will not warehouse product and will secure only the amount needed "per job." Retailers or dealerships with application services will warehouse, but are generally considered retailers or distributors first with application services as an added value, and thus it is not clear that they could apply any product under the proposed existing stocks provision. If a cancellation order suddenly cuts off all sales by distributors and retailers, growers may find themselves without the product they need when pest problems arrive.

A cancellation order that takes effect immediately in June or July would be particularly disruptive. Although the season and pest pressure can vary year to year, June through August is a time of heavy flubendiamide use and demand in most row crops, including soybeans, peanuts, alfalfa, and tobacco, as well as nut crops such as almonds. Bayer sales typically peak in May through July in order to provide products to distributors so that they can get it to retailers and growers when needed. The sudden unavailability of flubendiamide products during this heavy use season will be very disruptive. There will be shortages and delays as growers try to identify and find sources for alternate treatment strategies. The ban on distribution will make it impossible to get flubendiamide products to the areas that need them most, while other products may sit unused in growers' hands.

The disruption of the supply chain will punish growers in the form of higher costs, uncertainty, lower yields, and potential crop damage from uncontrolled pests.

Q: Is there a less disruptive alternative?

Yes. A more standard existing stocks provision that allowed Bayer and its distributors to sell existing stocks released for shipment at the time of cancellation would provide for a more orderly and controlled phase-out.

Bayer has produced flubendiamide for 2016 according to its normal schedule. Bayer placed its last order for flubendiamide technical product in February 2016 and will not order any more technical product for 2016. Given this limited supply, if permitted to distribute existing stocks, Bayer could supply flubendiamide products to the distribution channel in calendar year 2016 totaling, at most, somewhat less than the amount of flubendiamide products Bayer sold in 2015. I understand that Mr. Johnson will testify that Nichino has stopped production for the year and produced less this year than last year. The amount of existing stocks that will be in the hands of Bayer, Nichino, and distributors if a cancellation order is issued will depend on the timing of the order and the timing of grower demand.

As the limited remaining supply moves through the chain, it can be directed to areas where it is needed most. This will help avoid growers being caught without access to a product they were planning to use and will provide time for an orderly transition, including time for growers and agricultural experts to develop plans for adjusting their pest control strategies and determining how to best mitigate the loss of the valuable flubendiamide products.

EPA's proposed immediate ban on further sale or distribution for use as a means to punish the registrants is unnecessarily disruptive and could be most damaging to growers. Growers may not be able to get access to alternatives that are as effective, in a timely fashion, and at comparable cost, while at the same time some flubendiamide products will sit unused in the hands of end-users because they cannot transfer to others who need them.

A more standard existing stocks provision that barred further manufacture of flubendiamide products but allowed existing stocks held by registrants and distributors to move through the channel would allow for a more efficient and fairer phase-out, while providing

growers time to adapt their pest control strategies in light of the removal of an important pest-control tool.

Q: Mr. Hall, in your testimony you referenced the following exhibits: PBNX 9, 21-24. PBNX 9 and 21-24 were previously produced as attachments to Bayer and Nichino's Motion for Accelerated Decision. Are these exhibits true and correct copies of the documents you referenced?

A. Yes.

Bayer and Nichino move to enter PBNX 9, 21-24 into evidence.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 21st day of April, 2016.

Lee Hall