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 CHARLOTTE SANSON
ON BEHALF OF BAYER CROPSCIENCE LP AND NICHINO AMERICA, INC.

TABLE OF CONTENTS

Page

I. BACKGROUND AND EXPERIENCE

Q: Please state your name and business address.

A: My name is Charlotte Sanson. My business address is 2 T.W. Alexander Drive, Research Triangle Park, North Carolina.

Q: Please identify your current employer.

A: I currently work for Bayer CropScience LP ("Bayer") at its U.S. business headquarters in Research Triangle Park, North Carolina.

Q: Please identify and describe your current position at Bayer.

A: I currently serve as Bayer's Director of Registrations. In this capacity I manage a team responsible for all of Bayer's federal and state registrations of crop protection pesticide products, including all products that contain the active ingredient flubendiamide.

Q: Please describe your educational background.

A: I earned a Bachelor of Science in Medical Technology from the University of Dayton in 1981 and a Master of Science in Occupational and Environmental Health from Wayne State University in 1989.

Q: Please provide additional information about your employment history.

A: I have worked in the chemicals and pesticides industries since 1986 in technical, marketing, and regulatory positions.

I joined Bayer from BASF Corporation ("BASF") in 2014. At BASF I was responsible for state or federal pesticide registrations from 1989 to 2014.

Q: Please identify any professional organizations in which you participate or have held office.

A: I was an active participant in CropLife America's Registration Committee from 2010 to 2014. CropLife America is the leading trade association in the United States for crop protection

pesticide registrants and distributors. The Registration Committee is comprised of regulatory affairs professionals of the member companies and regularly meets with EPA to discuss matters of general importance to EPA and the regulated community. I served as the CropLife America Registration Committee Vice Chair from 2013 to 2014.

I also have served in the North America Free Trade Agreement ("NAFTA") Industry Working Group continuously since 2004. This is a group formed by CropLife America to comment on implementation of regulatory processes for NAFTA countries from industry's perspective and to meet with national governments and other stakeholders to discuss matters of general importance to the governments and industry in implementing NAFTA.

Q: Please describe your involvement in the flubendiamide activities that give rise to this proceeding.

A: I participated in nearly all the recent discussions with the United States Environmental Protection Agency ("EPA") leading up to this proceeding. As part of my responsibilities in general and for those discussions, I familiarized myself with the regulatory history of flubendiamide.

II. REGULATORY HISTORY OF FLUBENDIAMIDE

A. Conditional Registration of Flubendiamide

Q: Please describe the regulatory history of flubendiamide.

A: After eight years of research and development by the two registrants, and after contracting for or generating the extensive data required by FIFRA for pesticide registrations, in 2006, Bayer began submitting to EPA the data necessary for EPA to evaluate flubendiamide for registration. The data package spanned human toxicology, environmental, and non-target data. It included more than 200 studies.

A: After evaluating the data, EPA registered flubendiamide in 2008 under FIFRA § 3(c)(7)(C). This is the provision of FIFRA that allows EPA to grant a conditional registration for a new active ingredient. EPA's conditional registration included requirements to generate additional data, as identified in EPA's July 31, 2008 preliminary acceptance letter. PBNX 8 at 1, 3.

Q: What standard was EPA required to apply under FIFRA, if you know?

A: EPA was required to and did apply FIFRA's risk-benefit standard for registration.

Q: What is your understanding of what that standard is?

A: "Risk-benefit" is the shorthand for the lengthier and more detailed term used in FIFRA: "unreasonable adverse effects on the environment." Unreasonable adverse effects on the environment is in turn defined in FIFRA as: "any unreasonable adverse risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." This definition is found in FIFRA § 2(bb).

Q: What types of EPA findings were required for EPA to make its determination in 2008, if you know?

A: First of all, we were asking EPA to register not only new products but new products that contained an active ingredient that EPA would be registering for the first time in any product. Because EPA planned to issue the registration on the condition that more data would be generated, EPA was required to and did make an affirmative finding that registration of flubendiamide was in the public interest. PBNX 21 at 1, 5 (BEAD Public Interest Finding For Flubendiamide (Apr. 15, 2008) ("EPA's Public Interest Finding")). This public interest finding is required for conditional registrations of a new active ingredient under FIFRA § 3(c)(7)(C). EPA granted the registrations for five years to allow the registrants time to generate and submit

additional data to address potential persistence and potential for risk to sediment-dwelling organisms, consistent with FIFRA § 3(c)(7)(C). PBNX 8 at 1 (July 31, 2008 Preliminary Acceptance Letter), PBNX 7 at 2 (Aug. 1, 2008 Notices of Registration referring to July 31, 2008 letter). The additional data included a vegetative buffer strip study to measure the effectiveness of buffers at reducing runoff of flubendiamide and its degradate, des-iodo. EPA also indicated that based on the results of that study, it may require a water monitoring program to measure concentrations of flubendiamide and des-iodo over time in water bodies near fields treated with flubendiamide at sites that EPA approved up front as vulnerable to runoff. PBNX 8.

Second, EPA was required to and did establish "permanent tolerances" for flubendiamide under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301-399) ("FFDCA"). A tolerance is the limit of residues allowed on food or feed crops. These tolerances were established through a formal notice and comment rulemaking process required by the FFDCA using a safety standard. EPA may only establish a tolerance if the use is "safe". To determine safety, EPA must determine that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This standard is found in FFDCA § 408(b)(2)(A)(i) and the definition is in FFDCA § 408(b)(2)(A)(ii). Over the years, EPA established numerous additional permanent tolerances through rulemakings under the FFDCA as new crops have been registered and added to the flubendiamide labels.

The tolerance-setting process is primarily focused on human health impacts through the diet. Given flubendiamide's very favorable human health profile, EPA has not proposed any changes to flubendiamide's tolerances and none is warranted. The human health profile of a compound is also a very important part of evaluating whether any pesticide, including

flubendiamide, meets FIFRA's risk-benefit standard for registration and so is supposed to be taken into account in that analysis too.

Q: Please describe flubendiamide's safety profile.

A: Flubendiamide has an excellent safety profile. EPA has concluded that flubendiamide poses no risk of concern to humans (either through diet or worker exposure), fish, mammals, crustaceans, mollusks, beneficial insects, and plants. It is impressive to have a pesticide, which after all is intended to kill an insect pest, with such a strong safety profile. We can see EPA's evaluation for instance in PBNX 9 at 2-8 (un-numbered original) (EPA Flubendiamide Pesticide Fact Sheet (Aug. 1, 2008) ("EPA Fact Sheet")).

For instance, on page 5 (unnumbered) of EPA's Fact Sheet, under dietary exposure, EPA stated in bold lettering its conclusions about acute and chronic risks. For acute dietary risk, it stated that "**the maximum exposure estimate is less than 8% of the aPAD for the most highly exposed population subgroup, children 1-2 years old. These analyses indicate that there are no acute dietary exposure considerations that would preclude registration of flubendiamide for the requested uses**."

Similarly, also on page 5 (unnumbered), EPA stated for chronic dietary risk that "**the maximum exposure estimate is less than 15% of the cPAD for the most highly exposed population subgroup, children 1-2 years old. These analyses indicate that there are no chronic dietary exposure considerations that would preclude registration of flubendiamide for the requested uses.**"

On page 7 (unnumbered) of EPA's Fact Sheet, as to occupational exposure, EPA made another strongly favorable statement in bold lettering: "**Therefore, even when assuming an**

extraordinarily worse-case scenario, post-application exposure to flubendiamide does not pose a risk to occupational workers."

In EPA's Public Interest Finding, EPA concluded by emphasizing that "the low toxicity to insect predators and honey bees should make flubendiamide an important component in integrated pest management programs." PBNX 21 at 5.

Both documents (PBNX 9 and 21) outline the many additional positive attributes of flubendiamide for the public as well. The only potential risk of concern identified by EPA was that flubendiamide and its degradate, des-iodo, may persist and accumulate over time in farm ponds surrounded by treated fields, potentially to a level that may impact freshwater benthic (sediment dwelling) invertebrates. PBNX 9 at 8-9 (un-numbered). EPA issued the flubendiamide registrations while requiring the registrants to develop data to better understand this potential. *Id.* at 10 (un-numbered).

Q: Please describe the additional, post-registration data development and assessment process.

A: EPA's July 31, 2008 letter included a schedule for the registrants to submit proposed protocols for the required data, so that EPA could review the study designs and plans and request modifications as appropriate. PBNX 8 at 1. EPA also committed to review the data generated and submitted by the registrants, and to engage in discussion with the registrants about the data and EPA's conclusions. *Id*. at 3.

Q: What were the possible outcomes of the data development and assessment process?

A: EPA's letter outlined three potential outcomes, including: (1) EPA would issue an unconditional registration; (2) EPA and the registrants would agree on a path forward, revising

or providing additional data under a conditional registration; or (3) EPA would accept voluntary cancellation of the flubendiamide registrations. *Id*.

EPA also stated in the July 31, 2008 letter: "No cancellation shall occur if EPA determines, after review of the data, that the flubendiamide [technical and end-use] product registrations could meet the standards for registration set forth in section 3(c)(5) of FIFRA" and Bayer and Nichino agree "to comply with any conditions (including, but not limited to, revised label language, use deletions or conditions of registration) that EPA finds necessary in order to make the registration determination." PBNX 8 at 3, 4 (unnumbered).

Q: What provision other than data development, if any, did EPA insist on before granting the flubendiamide registrations?

A: EPA refused to issue the registrations unless the applicants "concur[red]" that if in the future EPA made an affirmative finding that "further registration of the flubendiamide . . . products will result in unreasonable adverse effects on the environment," the companies would immediately, within seven days, request "voluntary" cancellation of the registrations. *Id*. EPA threatened that, absent this provision, it would not grant the registrations, even though it already had determined months earlier that the registrations were in the public interest.

Q: In your 27 years of experience with registration matters, have you ever seen a provision like this before?

A: No. I am not aware of another provision, as EPA seems to be interpreting this one now, allowing EPA to make an unreasonable adverse effects finding based on an evaluation that no one could comment on or challenge.

Q: Based on your experience, do you believe that EPA presented an actual choice to the applicants about whether to "concur" in this provision?

A: No.

Q: Why not?

A: The companies had invested years of effort and many millions of dollars to demonstrate the safety profile and efficacy of the compound. They had no choice but to accept EPA's ultimatum. Faced with EPA's "take it or leave it" approach, the companies had no practical or rational alternative but to "concur."

Q: To your knowledge, did Bayer intend to honor this provision?

A: Yes.

Q: Why do you say that?

A: Bayer is a science-driven company. Bayer trusted that EPA would act based on the science. We were and are prepared to do so. EPA's conditions included a real world, water monitoring study. We understood that, if generated, the real world data would be relied upon. That is not how EPA proceeded here. In any event, from a practical standpoint, Bayer had no choice but to accept the provision, or it would have had to forfeit registrations it believed could and should properly be issued under the FIFRA standard, and to lose a very promising product in which it had invested years of work and many millions of dollars.

Q: Could you be more specific about what you mean when you say Bayer was and is prepared to act based on the science?

A: If the science had demonstrated a risk, which we do not believe it does, that was not outweighed by the benefits as provided by FIFRA, which we also do not believe it does, we would have pursued voluntary cancellation. This is part of our corporate culture. If new findings show that it is not safe to use a particular compound as is, we take steps to mitigate the

risk, which can include revising application methods or amounts, removing uses from the label, or cancelling products.

Q: Before we move to the next topic, would you elaborate on your comment a moment ago about flubendiamide's risk profile?

A: Yes. The real world monitoring data – and now I am referring to both the data in the Registrants' monitoring study and the thousands of analyses conducted by the United States Geological Service at the request of EPA – show concentrations below any toxicity endpoints, including the 0.28 ppb value (the endpoint of concern for des-iodo flubendiamide) used by EPA in its final analysis.

B. <u>Data Submission, Evaluation, and Registration Extensions</u>

Q: Let's go back to fill in more of the history. Did the registrants generate the required data?

A: Yes. Consistent with the July 31, 2008 letter, the registrants generated the required data. There is no dispute about that. EPA has repeatedly confirmed it. For instance, this is shown in PBNX 10, 12, 13, 15 and 16.

Q: What involvement, if any, did EPA have in the design of the studies?

A: It reviewed and commented on the study protocols and conduct. This was important to be sure the studies were conducted in the way EPA required and, in the case of the water monitoring study, that it was conducted in what EPA considered to be vulnerable locations.

Q: What occurred after the studies were generated and submitted to EPA?

A: EPA and Bayer communicated about study reports and interpretation of the study results.

Q: What, if any, additional regulatory actions did the registrants request and did EPA take during these years of data generation and scientific discussions, if you know?

A: While the data generation and evaluation were ongoing, EPA approved expansion of flubendiamide's registrations to over 200 crops.

Q: You mentioned the original timeframe for the registrations was five years starting in 2008. How is it that the registrations are still in force?

A: EPA repeatedly extended the original September 1, 2013 "expiration" date, including an initial extension of the deadline for an additional two years to allow for further data generation and review, and a flurry of more recent extensions until the issuance of its January 29, 2016 Decision Memorandum and demand for voluntary cancellation. During its ongoing review and discussion of the submitted data and continued monitoring, EPA repeatedly confirmed that the registrants had satisfied the conditional registration requirements and agreed to extend the registrations. In a July 18, 2013 letter extending the registrations to August 31, 2015, EPA confirmed that "[a] s of July 31, 2012, [the registrants] . . . ha[ve] submitted all data required by the original conditions of registration for flubendiamide." PBNX 10 (July 18, 2013 EPA Letter re Extension of Flubendiamide Registrations to Aug. 31, 2015). On August 26, 2015, EPA again extended the registrations to December 10, 2015 to "provide time for [the registrants] and the EPA to discuss whether potential additional data requirements and label amendments are necessary to address areas of uncertainty" and again confirmed that "[a]s of July 31, 2012, [the registrants] ha[ve] submitted all data required by the original conditions of registration for flubendiamide." PBNX 12 (Aug. 26, 2015 EPA Letter re Extension of Flubendiamide Registrations to Dec. 10, 2015).

Q: Is this unusual in your experience?

A: No. This is common. It is a mechanism that allows EPA to keep focused attention on the data generation and evaluation process and also on discussions on potential mitigation.

More generally, it also is common for EPA to use its authority to request additional data to refine its risk assessments and to identify risk mitigation consistent with FIFRA. This is true for both conditional registrations and unconditional registrations. EPA often communicates with registrants to evaluate potential mitigation options and implement them. Sometimes this is done while data are being generated that can inform the mitigation, for instance, by allowing the mitigation to be refined, removed, or a substitution for such measures to be made in the future.

Q: What in your experience was the utility of this process here?

A: In light of flubendiamide's favorable human health (both dietary and occupational) and non-target organisms safety profile and its value to agriculture, and the substantial amount of scientific data supporting its registration, it is consistent with EPA's fulfillment of its responsibilities under FIFRA that right up until the end of 2015 EPA repeatedly expressed its intention to adopt further risk mitigation measures and extend the registrations to allow the generation of additional data.

In discussions with the registrants in July and August 2015, EPA presented a plan for continuing the registrations for all crop uses that involved reducing exposure by eliminating aerial applications, limiting use to a single application per growing season for all crops, and conducting additional studies. PBNX 11 at 2 (Aug. 4, 2015 email from C. Rodia to N. Delaney). EPA provided a specific list of proposed additional studies, including an expanded stream and pond monitoring program and toxicity studies on additional aquatic species. *Id*. EPA proposed a three-year extension of the registrations (to 2018) to allow the data to be generated and reviewed. *Id*.

Q: What was the registrants' reaction to the EPA plan?

A: We discussed it with EPA and worked through some revisions.

The registrants agreed to conduct additional studies identified by EPA, including the additional ecotoxicity studies and the expansion and continuation of the monitoring program, which was anticipated to cost millions of dollars. We undertook the necessary work to develop and deliver for EPA's review protocols and scoping documents for the studies.

The registrants also committed to working with EPA to refine limitations on use rates and applications to reduce aquatic exposure while meeting commercial needs. EPA continued to indicate that it planned to extend the registrations for three years (to 2018) while the registrants generated the additional data. EPA extended the expiration date to December 10 while we worked on the final details. PBNX 12.

On December 1, 2015, Bayer and Nichino met with EPA to discuss the path forward and to reiterate the registrants' commitment to generate the additional scientific data EPA had identified and to work together on mitigation.

Q: What, if any, additional analyses did the registrants provide to EPA during this time?

A: The registrants provided a comparative assessment with a competitive pesticide, methoxyfenozide, that has nearly the same persistence and risk profile to benthic aquatic invertebrates as flubendiamide. EPA required similar real world water monitoring studies for that compound as a condition of registration. The levels of detection, like those for flubendiamide, were below levels of concern at all of the monitoring sites tested.

Q: What was the reason for providing this assessment to EPA, if you know?

A: We wanted to point out the way that EPA recently analyzed the monitoring versus modeling data for that compound and to ask that EPA approach the flubendiamide analysis the same way.

Q: What are the relevant facts?

A: For methoxyfenozide, EPA chose to rely on the actual monitoring data showing no levels of concern rather than its modeling which predicted much higher exposures that exceeded levels of concern. EPA's risk assessment for methoxyfenozide explained 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 49 at 21 (Preliminary Environmental Fate and Ecological Risk Assessment for Methoxyfenozide (Sept. 16, 2015)). EPA also determined that methoxyfenozide concentrations in flowing water bodies are not expected "to accumulate at such a high concentration[] from year to year because of downstream advective removal." *Id*.

For methoxyfenozide, EPA properly focused on the higher-tier, real world monitoring data rather than overly conservative modeling, and has not taken steps to cancel the methoxyfenozide registrations. We wanted to point out that singling out flubendiamide for different, extreme treatment is not consistent with FIFRA nor is it fair in light of how EPA is approaching its overall risk-benefit regulation of pesticides, including its very recent analysis for methoxyfenozide.

Q: What happened next with EPA and flubendiamide?

A: Up until early December 2015, EPA was consistent in discussing with the registrants EPA's plan to extend the flubendiamide registrations for three years until 2018 and to require additional data. EPA and the registrants also continued to discuss potential mitigation. The registrants proposed mitigation through changes to the product label and conducted calculations to confirm that the mitigated label would pass EPA's risk assessment, even using a methodology the registrants believe to be more conservative than required.

On December 8, 2015, EPA extended the December 10 expiration date to December 18, 2015 "to provide additional time for BCS [Bayer CropScience] and EPA to discuss areas of uncertainties." PBNX 13 (Dec. 8, 2015 EPA Letter re Extension of Flubendiamide Registrations to Dec. 18, 2015). At a high level meeting on December 15, 2015 involving the Assistant Administrator of EPA responsible for all pesticides and the CEOs of both Bayer and Nichino, the Assistant Administrator described his view of flubendiamide. In contrast to the risk-benefit FIFRA standard, he repeatedly used "precautionary" language (a different regulatory standard used elsewhere in the world but not under FIFRA), contending that flubendiamide should be cancelled based on its persistence alone to eliminate any possibility of future harm, even though no harm had been identified through the extensive testing EPA had required. This directly contradicted the risk-benefit approach required by FIFRA.

The Assistant Administrator also contended that, absent any action by EPA beforehand, the registrations would expire on December 18, 2015. He indicated that EPA would consider whether to take action and would inform the registrants of its decision by the end of the day on December 18, 2015.

The registrants raised the practical difficulties of that timing and requested that EPA extend the December 18, 2015 date to help ensure an orderly process and that EPA advise the registrants promptly when a decision had been made. EPA committed to respond on the extension and suggested that the registrants submit the best, final mitigation proposal they could develop, as promptly as possible, in light of an internal briefing of the EPA Assistant Administrator the following day. The registrants quickly convened their experts and prepared and submitted a further mitigation proposal later the same day.

C. Change in EPA's Toxicity Endpoint.

Q: Are you familiar with the term "toxicity endpoint" as it has been used in the context of the flubendiamide ecological assessments under FIFRA?

A: Yes.

Q: What does it mean?

A: The toxicity endpoint as discussed in this context is a numerical value that establishes a threshold level of a compound below which adverse effects are not seen. In particular here, the toxicity endpoint is a NOEC or No Observed Effect Concentration or as EPA sometimes states it the NOAEC or No Observed Adverse Effect Concentration.

Q: Was the relevant toxicity end-point here an open question?

A: No. Up to this point, the open scientific question concerned whether the modeling and monitoring data suggested that flubendiamide or the des-iodo metabolite might accumulate to a level of concern based on the toxicity data. These data include a 2010 spiked sediment study conducted specifically to focus on the area of EPA's concern: the level of toxicity to sediment-dwelling aquatic invertebrates in pore water and sediment. As EPA confirmed in its May 21, 2008 review of a spiked water study submitted in 2006, the Agency prefers the spiked sediment methodology for this purpose. PBNX 33 at 2 (Des-iodo Spiked Water Study Data Evaluation Record (May 21, 2008)).

In a spiked sediment study, the test compound is introduced into the sediment and the system is allowed to equilibrate. In a spiked water study, the chemical is introduced directly into the overlying water.

Q: What, if anything, occurred with regard to the toxicity endpoint here?

A: On December 16, 2015, EPA's Environmental Fate and Effects Division ("EFED") briefed the EPA Assistant Administrator as planned. In a new development, after years of discussion, the high level meeting the day before, and visibility of the registrants' submission of a "final" mitigation plan that passed even EFED's conservative, theoretical modeling approach, EFED stopped using the directly relevant toxicity endpoint from the des-iodo spiked sediment study that had been the basis of the many discussions, technical evaluations, and mitigation plans of the preceding months. It based the briefing on a different endpoint that appeared to be designed to ensure, after the fact, that the registrants' "final" mitigation proposal would fail.

The spiked sediment study specifically conducted to assess the potential toxicity of des-iodo to benthic aquatic invertebrates in pore water in sediment showed no observable adverse effects at any of the levels tested, supporting a toxicity endpoint for des-iodo of 19.5 parts per billion ("ppb") (as calculated by EPA using a time-weighted average approach) or 22 ppb (as calculated in the report based on measured concentrations). Although it is my understanding both from a regulatory standpoint (recall my comment above about EPA's 2008 Data Evaluation Record, PBNX 33 at 2) and based on Dr. Moore's anticipated expert testimony that this is the most appropriate study to measure toxicity from the potential route of exposure, EPA chose at the eleventh hour to ignore this study. Instead, it suddenly reverted to an endpoint derived from the less appropriate, earlier-conducted spiked water study, leading to a toxicity endpoint of 0.28 ppb, 70 times lower than supported by the more environmentally relevant data conducted using EPA's preferred methodology. This reversion seemed calculated to ensure that EPA could continue to "predict" exceedances of levels of concern even after making overdue and necessary corrections to its theoretical modeling.

Q: What was the registrants' reaction to this change in EPA's approach?

A: This dramatic change in the ground rules for an apparently preordained, political result was shocking to the registrants from a scientific standpoint and also given the chain of events that led up to it. Bayer wrote to the Assistant Administrator on December 16 to confirm whether he was aware of this sudden change in approach and lack of transparency, and to request the underlying science. PBNX 14 (Dec. 16, 2015 Bayer CropScience LP Email re Change in Flubendiamide Ecotoxicity Endpoint).

On December 18, 2015, EPA provided a letter "extending the expiration date of December 18, 2015 to January 15, 2016." PBNX 15 at 1. EPA also scheduled a meeting with the registrants for January 6, 2016 at which EPA EFED would present its evaluations.

The registrants intensively reviewed the information provided by EPA over the holidays. On January 5, 2016, we submitted two formal reports on environmental fate and ecotoxicology data whose conclusions had previously been reviewed with EPA. In particular, one of the studies showed that des-iodo, the flubendiamide metabolite whose potential toxicity forms the basis for EPA's proposed cancellation, degrades when exposed to sunlight.

Q: What happened at the January 6 meeting?

A: At the January 6 meeting, EPA presented its scientific position, relying on the lower toxicity endpoint and theoretical modeling to support its position that flubendiamide is accumulating or will accumulate in vulnerable water bodies above a level of concern. EPA acknowledged that things were "very dynamic" and the timing of its change was "unfortunate." It sought to explain what activities had taken place within the Agency at the end of the year that had not been visible to the registrants or any other stakeholders. EPA did not provide its ultimate finding at this time.

The registrants asked EPA to confirm, if EPA decided the flubendiamide registrations should not continue beyond the January 15, 2016 date, whether the Agency: (1) would pursue "automatic" expiration without further action, which we believed would be unlawful; (2) would seek to implement the forced "voluntary" cancellation condition, which we believe would be unlawful; or (3) would issue a proper notice of intent to cancel and follow the cancellation proceedings required by FIFRA § 6(b).

Q: What happened next?

A: EPA ultimately confirmed that if it determined that the registrations should not continue, it would demand "voluntary" cancellation and seek cancellation under FIFRA § 6(e) if Bayer and Nichino refused to request "voluntary" cancellation. On January 14, 2016, EPA again extended the conditional registration for flubendiamide, this time to January 29, 2016. PBNX 16.

III. EPA'S DETERMINATION THAT FLUBENDIAMIDE DOES NOT MEET THE FIFRA STANDARD

Q: What happened next?

A: On January 29, 2016, EPA issued a letter, formally notifying Bayer and Nichino that it had determined flubendiamide poses unreasonable adverse effects to the environment and requesting that Bayer and Nichino "voluntarily" cancel their registrations for flubendiamide within one week of the letter. PBNX 17 at 2. EPA further stated that the failure to submit the requested voluntary cancellation would cause EPA to initiate a cancellation proceeding consistent with FIFRA § 6(e). *Id.*

On February 5, 2016, Bayer and Nichino responded to EPA's request. The response stated: (1) that the "voluntary" cancellation condition was an unlawful condition of registration; (2) that if EPA determined flubendiamide poses unreasonable adverse effects to the environment, the proper procedure is to issue a Notice of Intent to Cancel pursuant to FIFRA § 6(b); and

(3) that the available evidence shows that flubendiamide does not pose unreasonable adverse effects to the environment. PBNX 18 at 1-2.

IV. EPA'S NOTICE OF INTENT TO CANCEL

Q: EPA has entered its Notice of Intent to Cancel into the record here. Are you familiar with it and, if so, could you briefly describe it?

A: Yes. On March 1, 2016, EPA provided its Notice of Intent to Cancel the flubendiamide registrations ("NOIC")to Bayer and Nichino. The NOIC was dated February 29, 2016, and was published in the Federal Register on March 4, 2016. PBNX 20 (81 Fed. Reg. 11,558 (Mar. 4, 2016)).

Also on March 1, 2016, EPA issued press releases and posted information on its website announcing that EPA was seeking cancellation because flubendiamide products "pose a risk to aquatic invertebrates that are important to the health of aquatic environments."[1] EPA asserted that "[r]equired studies showed flubendiamide breaks down into a more highly toxic material that is harmful to species that are [an] important part of aquatic food chains, especially for fish, and is persistent in the environment." EPA "concluded that continued use of the product would result in unreasonable adverse effects on the environment." EPA posted the NOIC and 11 other documents totaling 504 pages regarding the merits of its cancellation decision.[2]

Q: Are you aware of other examples similar to this?

A: No, not to my knowledge. On the one hand EPA was announcing to the public and all stakeholders for the first time that it had made a scientific and regulatory determination and was proposing to cancel pesticides based on that determination, but it was not allowing anyone to

[1] EPA Moves to Cancel the Insecticide Flubendiamide (Mar. 1, 2016) (PBNX 19).

[2] Flubendiamide – Notice of Intent to Cancel and Other Supporting Documents, https://www.epa.gov/ingredients-used-pesticide-products/flubendiamide-notice-intent-cancel-and-other-supporting (last visited April 20, 2016).

comment on the substance of its determination or its implications. Not the FIFRA Scientific Advisory Panel. Not the United States Department of Agriculture. Not the IR-4 Program which had invested over one million dollars and great effort to support minor uses of flubendiamide (PBNX 26). Not the growers. Not any members of the public. Not the registrants.

Q: You mentioned that EPA posted extensive substantive documents in connection with its press releases. You also mentioned that the real world monitoring data, both in the Registrants' study and the thousands of analyses conducted by the United States Geological Service at the request of EPA, show concentrations below any toxicity endpoints, including the 0.28 ppb value used by EPA in its final analysis. What, if anything, did EPA provide to the public in these documents comparing the real world monitoring data concentrations and the toxicity endpoints?

A: We have not been able to find any such comparison in the documents presented to the public.

V. EPA'S PROPOSED EXISTING STOCKS PROVISIONS

Q: What familiarity, if any, do you have with the FIFRA regulatory term "existing stocks" and its use?

A: I am familiar with that term and its use. I also generally monitor how EPA handles our and our competitors' products on existing stocks.

Q: Could you tell us what existing stocks are?

A: Yes. EPA's standard definition includes any product that has been "released for shipment." A product is considered released for shipment when the producer has packaged and labeled it in the way it will be distributed or sold and stored it in an area where finished products are ordinarily held for shipment. This means that EPA can inspect the product to determine if

they are properly formulated, packaged and labeled. The released for shipment phrase is defined in EPA's regulations at 40 C.F.R. § 152.3.

Q: Are you familiar with the existing stocks provisions that EPA proposed in its Notice of Intent to Cancel?

A: Yes.

Q: Please describe the key features of EPA's proposal.

A: EPA has proposed that immediately upon cancellation all distribution or sale of existing stocks should be prohibited, except for return of products for disposal or export. As to product that already is in the hands of user, the product could be used.

Q: How does this compare to other existing stocks provisions with which you are familiar?

A: It is much more restrictive and, based on the way EPA phrased the notice and its written comments since, it apparently is intended to be punitive because the registrants are challenging EPA's science in this matter.

Q: What policies, if any, does EPA have on existing stocks?

A: EPA published a policy on existing stocks in 1991. It is provided in our exhibit PBNX 52.

Q: What familiarity, if any, do you have with this policy?

A: I am generally familiar with it as part of my normal responsibilities.

Q: Have you considered whether EPA's proposed existing stocks provisions here are consistent with the policy?

A: Yes.

Q: What have you concluded?

A: EPA's proposal is inconsistent with its own long-standing existing stocks policy.

Q: Why do you say that?

A: Because EPA identified a particular risk concern here. Under its own policy, it should have made a case-specific determination. The policy lays out the specific considerations, and EPA did not provide any analysis, findings, or conclusions with respect to these factors.

Q: What do the registrants believe would be an appropriate existing stocks provision, if there is a cancellation decision?

A: We believe it is appropriate to allow the existing stocks to clear the channels of trade. In other words, that the registrants should be allowed to sell and distribute existing stocks, distributors and retailers should be allowed to sell to their customers, and users should be allowed to use the remaining existing stocks. My understanding is that Mr. Johnson will testify that Nichino has stopped production. Bayer made its last order to purchase technical flubendiamide (the near pure active ingredient needed to manufacture end-use products) in February. We plan only to formulate end-use product from the amount already ordered. Based on this, we can confirm that we will produce no more this year than last year and actually less, if as we hope is not the case, the registrations are cancelled.

The modeling and end-point analyses that I understand Dr. Engel and Dr. Moore will testify to, taken in conjunction with the benefits information in the grower declarations, described by IR-4, and by Dr. Herbert and Dr. Palumbo demonstrate that in fact cancellation is not warranted. Even if EPA's proposed cancellation is allowed without peer review at this time, surely the risks do not outweigh the benefits for normal production to be allowed to clear the channels of trade.

VI. EXHIBITS

Q: Ms. Sanson, in your testimony you referenced the following exhibits: PBNX 7-21, 26, 33, 49, and 52, all of which previously were produced as attachments to Bayer and Nichino's Motion for Accelerated Decision. Are these exhibits true and correct copies of the documents you referenced?

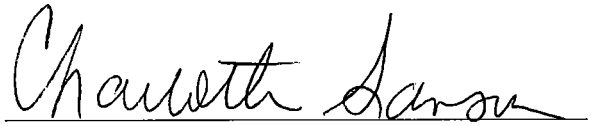
A: Yes.

Q: Thank you, Ms. Sanson.

Bayer and Nichino move to enter PBNX 7-21, 26, 33, 49, and 52 into evidence.

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

Executed on this 21st day of April, 2016.



Charlotte Sanson