

Verified Written Statement Of
Charlotte Sanson, Bayer CropScience LP
(Fact Witness)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of:

Bayer CropScience LP and
Nichino America, Inc.,

Petitioners.

)
)
)
)
)
)

FIFRA-HQ-2016-0001

**VERIFIED WRITTEN STATEMENT OF CHARLOTTE SANSON
ON BEHALF OF BAYER CROPSCIENCE LP AND NICHINO AMERICA, INC.**

TABLE OF CONTENTS

	<u>Page</u>
I. BACKGROUND AND EXPERIENCE	1
II. REGULATORY HISTORY OF FLUBENDIAMIDE	2
A. Conditional Registration of Flubendiamide	2
B. Data Submission, Evaluation, and Registration Extensions	9
C. Change in EPA’s Toxicity Endpoint	15
III. EPA’S DETERMINATION THAT FLUBENDIAMIDE DOES NOT MEET THE FIFRA STANDARD	18
IV. EPA’S NOTICE OF INTENT TO CANCEL	19
V. EPA’S PROPOSED EXISTING STOCKS PROVISIONS	20
VI. EXHIBITS	23

1 **I. BACKGROUND AND EXPERIENCE**

2 **Q: Please state your name and business address.**

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

5 **Q: Please identify your current employer.**

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

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

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

12 **Q: Please describe your educational background.**

13 A: I earned a Bachelor of Science in Medical Technology from the University of Dayton in
14 1981 and a Master of Science in Occupational and Environmental Health from Wayne State
15 University in 1989.

16 **Q: Please provide additional information about your employment history.**

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

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

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

23 A: I was an active participant in CropLife America’s Registration Committee from 2010 to
24 2014. CropLife America is the leading trade association in the United States for crop protection

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

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

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

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

16 **II. REGULATORY HISTORY OF FLUBENDIAMIDE**

17 **A. Conditional Registration of Flubendiamide**

18 **Q: Please describe the regulatory history of flubendiamide.**

19 A: After eight years of research and development by the two registrants, and after
20 contracting for or generating the extensive data required by FIFRA for pesticide registrations, in
21 2006, Bayer began submitting to EPA the data necessary for EPA to evaluate flubendiamide for
22 registration. The data package spanned human toxicology, environmental, and non-target data.
23 It included more than 200 studies.

1 A: After evaluating the data, EPA registered flubendiamide in 2008 under FIFRA
2 § 3(c)(7)(C). This is the provision of FIFRA that allows EPA to grant a conditional registration
3 for a new active ingredient. EPA's conditional registration included requirements to generate
4 additional data, as identified in EPA's July 31, 2008 preliminary acceptance letter. PBNX 8 at 1,
5 3.

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

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

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

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

14 **Q: What types of EPA findings were required for EPA to make its determination in**
15 **2008, if you know?**

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

1 additional data to address potential persistence and potential for risk to sediment-dwelling
2 organisms, consistent with FIFRA § 3(c)(7)(C). PBNX 8 at 1 (July 31, 2008 Preliminary
3 Acceptance Letter), PBNX 7 at 2 (Aug. 1, 2008 Notices of Registration referring to July 31,
4 2008 letter). The additional data included a vegetative buffer strip study to measure the
5 effectiveness of buffers at reducing runoff of flubendiamide and its degradate, des-iodo. EPA
6 also indicated that based on the results of that study, it may require a water monitoring program
7 to measure concentrations of flubendiamide and des-iodo over time in water bodies near fields
8 treated with flubendiamide at sites that EPA approved up front as vulnerable to runoff. PBNX 8.

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

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

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

3 **Q: Please describe flubendiamide’s safety profile.**

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

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

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

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

1 **extraordinarily worse-case scenario, post-application exposure to flubendiamide does not**
2 **pose a risk to occupational workers.”**

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

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

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

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

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

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

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

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

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

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

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

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

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

1 A: No.

2 **Q: Why not?**

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

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

8 A: Yes.

9 **Q: Why do you say that?**

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

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

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

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

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

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

10 **B. Data Submission, Evaluation, and Registration Extensions**

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

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

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

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

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

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

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

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

3 **Q: You mentioned the original timeframe for the registrations was five years starting in**
4 **2008. How is it that the registrations are still in force?**

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

21 **Q: Is this unusual in your experience?**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 **Q: What are the relevant facts?**

2 A: For methoxyfenozide, EPA chose to rely on the actual monitoring data showing no levels
3 of concern rather than its modeling which predicted much higher exposures that exceeded levels
4 of concern. EPA's risk assessment for methoxyfenozide explained that the modeling results
5 "likely overestimate concentrations in streams and various other kinds of water bodies" for a
6 number of reasons, including "washout, dispersion, burial of sediment and other dissipative
7 processes that aren't simulated." PBNX 49 at 21 (Preliminary Environmental Fate and
8 Ecological Risk Assessment for Methoxyfenozide (Sept. 16, 2015)). EPA also determined that
9 methoxyfenozide concentrations in flowing water bodies are not expected "to accumulate at such
10 a high concentration[] from year to year because of downstream advective removal." *Id.*

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

17 **Q: What happened next with EPA and flubendiamide?**

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

1 On December 8, 2015, EPA extended the December 10 expiration date to December 18,
2 2015 “to provide additional time for BCS [Bayer CropScience] and EPA to discuss areas of
3 uncertainties.” PBNX 13 (Dec. 8, 2015 EPA Letter re Extension of Flubendiamide Registrations
4 to Dec. 18, 2015). At a high level meeting on December 15, 2015 involving the Assistant
5 Administrator of EPA responsible for all pesticides and the CEOs of both Bayer and Nichino, the
6 Assistant Administrator described his view of flubendiamide. In contrast to the risk-benefit
7 FIFRA standard, he repeatedly used “precautionary” language (a different regulatory standard
8 used elsewhere in the world but not under FIFRA), contending that flubendiamide should be
9 cancelled based on its persistence alone to eliminate any possibility of future harm, even though
10 no harm had been identified through the extensive testing EPA had required. This directly
11 contradicted the risk-benefit approach required by FIFRA.

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

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

1 **C. Change in EPA’s Toxicity Endpoint.**

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

4 A: Yes.

5 **Q: What does it mean?**

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

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

11 A: No. Up to this point, the open scientific question concerned whether the modeling and
12 monitoring data suggested that flubendiamide or the des-iodo metabolite might accumulate to a
13 level of concern based on the toxicity data. These data include a 2010 spiked sediment study
14 conducted specifically to focus on the area of EPA’s concern: the level of toxicity to sediment-
15 dwelling aquatic invertebrates in pore water and sediment. As EPA confirmed in its May 21,
16 2008 review of a spiked water study submitted in 2006, the Agency prefers the spiked sediment
17 methodology for this purpose. PBNX 33 at 2 (Des-iodo Spiked Water Study Data Evaluation
18 Record (May 21, 2008)).

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

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

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

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

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

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

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

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

16 **Q: What happened at the January 6 meeting?**

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

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

7 **Q: What happened next?**

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

12 **III. EPA’S DETERMINATION THAT FLUBENDIAMIDE DOES NOT MEET THE**
13 **FIFRA STANDARD**

14 **Q: What happened next?**

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

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

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

3 **IV. EPA’S NOTICE OF INTENT TO CANCEL**

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

6 A: Yes. On March 1, 2016, EPA provided its Notice of Intent to Cancel the flubendiamide
7 registrations (“NOIC”)to Bayer and Nichino. The NOIC was dated February 29, 2016, and was
8 published in the Federal Register on March 4, 2016. PBNX 20 (81 Fed. Reg. 11,558 (Mar. 4,
9 2016)).

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

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

19 A: No, not to my knowledge. On the one hand EPA was announcing to the public and all
20 stakeholders for the first time that it had made a scientific and regulatory determination and was
21 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).

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

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

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

14 **V. EPA'S PROPOSED EXISTING STOCKS PROVISIONS**

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

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

19 **Q: Could you tell us what existing stocks are?**

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

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

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

5 A: Yes.

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

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

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

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

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

16 A: EPA published a policy on existing stocks in 1991. It is provided in our exhibit PBNX
17 52.

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

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

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

22 A: Yes.

23 **Q: What have you concluded?**

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

2 **Q: Why do you say that?**

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

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

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

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

1 VI. EXHIBITS

2 Q: Ms. Sanson, in your testimony you referenced the following exhibits: PBNX 7-21,
3 26, 33, 49, and 52, all of which previously were produced as attachments to Bayer and
4 Nichino's Motion for Accelerated Decision. Are these exhibits true and correct copies of
5 the documents you referenced?

6 A: Yes.

7 Q: Thank you, Ms. Sanson.

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

9

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

11 Executed on this 21st day of April, 2016.

12

13

14


Charlotte Sanson

Verified Written Statement Of
Lee Hall, Bayer CropScience LP
(Fact Witness)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of:

Bayer CropScience LP and
Nichino America, Inc.,

Petitioners.

)
)
)
)
)
)

FIFRA-HQ-2016-0001

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

TABLE OF CONTENTS

	<u>Page</u>
I. BACKGROUND AND EXPERIENCE	1
II. DEVELOPMENT OF FLUBENDIAMIDE	2
III. FLUBENDIAMIDE USE AND BENEFITS	4
A. Product Use	4
B. Benefits of Flubendiamide	4
1. Minimal Impact on Beneficial Insects	6
2. Managing Resistance	8
3. Safety and Risk Profiles	9
4. Commercial Benefits	10
5. Overall Benefits	12
IV. IMPACT OF EPA’S PROPOSED EXISTING STOCKS PROVISIONS	13

1 **I. BACKGROUND AND EXPERIENCE**

2 **Q: Please state your name and business address.**

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

5 **Q: Please identify your current employer.**

6 A: I work for Bayer CropScience LP (“Bayer”). Bayer’s U.S. business headquarters is
7 located in Research Triangle Park, North Carolina.

8 **Q: Please describe Bayer’s focus and mission as a company.**

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

15 **Q: Please identify your current position at Bayer.**

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

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

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

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

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

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

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

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

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

10 **II. DEVELOPMENT OF FLUBENDIAMIDE**

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

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

16 **Q: Who invented flubendiamide?**

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

18 **Q: Does Bayer have a business relationship with NNC?**

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

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

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

1 **Q: Who sells flubendiamide products in the United States?**

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

4 **Q: Who holds the registrations for the products subject to EPA’s proposed**
5 **cancellation?**

6 A: Bayer and Nichino (“Registrants”) are the original and current holders of the
7 flubendiamide registrations that are the subject of EPA’s proposed cancellation.

8 Bayer holds the registration for the Belt® SC Insecticide end-use product (EPA Reg. No.
9 264-1025). Nichino holds the registration for the Flubendiamide Technical product (EPA Reg.
10 No. 71711-26), which consists of nearly pure flubendiamide and is used to manufacture end-use
11 products, and the Vetica® Insecticide and Turismo® Insecticide end-use product registrations
12 (EPA Reg. Nos. 71711-32 and 71711-33), which combine flubendiamide with buprofezin,
13 another insecticide.

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

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

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

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

1 **III. FLUBENDIAMIDE USE AND BENEFITS**

2 **A. Product Use**

3 **Q: Generally speaking, how does flubendiamide work?**

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

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

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

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

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

15 **Q: During what seasons do growers use flubendiamide products?**

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

20 **B. Benefits of Flubendiamide**

21 **Q: Please summarize the main benefits of flubendiamide products.**

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

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

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

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

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

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

18 **Q: Did EPA provide a response to Bayer’s benefits documents?**

19 A: Yes. In its July 2015 review memo, EPA’s Biological and Economics Analysis Division
20 (“BEAD”) provided its assessment of Bayer’s benefits submissions. The BEAD benefits review
21 is PBNX 23.

1 **1. Minimal Impact on Beneficial Insects**

2 **Q: You indicated that one benefit of flubendiamide that it is “selective,” correct?**

3 A: Yes, that’s right.

4 **Q: Has EPA acknowledged flubendiamide’s selective properties?**

5 A: Yes. In EPA’s review of Bayer’s benefits submissions, the Agency noted that
6 flubendiamide has minimal impact on many beneficial insects, including parasitic and predatory
7 species such as parasitoid wasps, ladybird beetles, soldier beetles, and predatory mites. PBNX
8 23 at 4.

9 **Q: Why is this important?**

10 A: Flubendiamide’s selective nature encourages natural or biological pest control, and
11 makes flubendiamide an important tool for modern Integrated Pest Management (“IPM”)
12 approaches.

13 **Q: What is IPM?**

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

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

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

18 **Q: What, if anything, did EPA say about flubendiamide’s selectivity in its Public
19 Interest Finding?**

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

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

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

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

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

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

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

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

1 **Q: Has EPA acknowledged this benefit of flubendiamide?**

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

4 **2. Managing Resistance**

5 **Q: What other benefits are associated with flubendiamide?**

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

10 **Q: How does flubendiamide’s mode of action manage resistance?**

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

15 **Q: Has EPA acknowledged flubendiamide’s resistance management properties?**

16 A: Yes. In its July 2015 review of Bayer’s benefits submissions, BEAD agrees that
17 cancellation of flubendiamide would “reduce[] the ability to manage” insecticide resistance and
18 that likely alternatives including pyrethroids “do not fit well with most IPM practices.” PBNX
19 23 at 8.

20 **Q: How else does flubendiamide manage resistance?**

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

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

4 **3. Safety and Risk Profiles**

5 **Q: What other benefits are associated with flubendiamide?**

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

9 **Q: Has EPA commented on flubendiamide’s safety and ecological risk profile?**

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

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

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

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

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

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

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

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

20 **4. Commercial Benefits**

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

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

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

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

19 **Q: How will cost considerations impact growers’ choice of alternative products if Belt is**
20 **cancelled?**

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

1 **Q: What other commercial benefits are associated with flubendiamide?**

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

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

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

12 **Q: Has EPA noted flubendiamide's commercial benefits?**

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

19 **5. Overall Benefits**

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

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

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

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

8 **IV. IMPACT OF EPA'S PROPOSED EXISTING STOCKS PROVISIONS**

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

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

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

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

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

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

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

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

19 **Q: Is there a less disruptive alternative?**

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

1 Bayer has produced flubendiamide for 2016 according to its normal schedule. Bayer
2 placed its last order for flubendiamide technical product in February 2016 and will not order any
3 more technical product for 2016. Given this limited supply, if permitted to distribute existing
4 stocks, Bayer could supply flubendiamide products to the distribution channel in calendar year
5 2016 totaling, at most, somewhat less than the amount of flubendiamide products Bayer sold in
6 2015. I understand that Mr. Johnson will testify that Nichino has stopped production for the year
7 and produced less this year than last year. The amount of existing stocks that will be in the
8 hands of Bayer, Nichino, and distributors if a cancellation order is issued will depend on the
9 timing of the order and the timing of grower demand.

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

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

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

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

3

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

8 A. Yes.

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

10

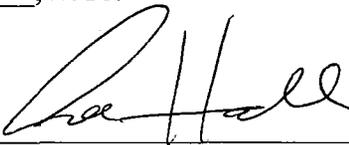
11 I declare under penalty of perjury that the foregoing is true and correct.

12 Executed on this 21st day of April, 2016.

13

14

15



Lee Hall

16

Verified Written Statement Of
Jeffrey Johnson, Nichino America, Inc.
(Fact Witness)

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 JEFFREY JOHNSON
ON BEHALF OF BAYER CROPSCIENCE LP AND NICHINO AMERICA, INC.**

TABLE OF CONTENTS

	<u>Page</u>
I. BACKGROUND AND EXPERIENCE	1
II. NICHINO AND NIHON NOHYAKU CO., LTD.....	2
III. INVENTION AND DEVELOPMENT OF FLUBENDIAMIDE	2
IV. EPA'S PROPOSED EXISTING STOCKS PROVISIONS.....	3

1 **I. BACKGROUND AND EXPERIENCE**

2 **Q: Please state your name and business address.**

3 A: My name is Jeffrey R. Johnson and my business address is 4550 New Linden Hill Road,
4 Suite 501, Wilmington, Delaware 19808.

5 **Q: Please identify your current employer.**

6 A: Nichino America, Inc. or Nichino for shorthand.

7 **Q: Please identify and describe your current position at Nichino.**

8 A: I am the President of Nichino and have served in that position since December 2002. In
9 this capacity I direct and manage the organization's strategic, financial and operational
10 objectives through a management team consisting of a Vice-President and five Directors.
11 Additionally, I establish current and long range plans and policies, subject to approval by the
12 Board of Directors of Nichino America.

13 **Q: Please provide additional information about your employment history.**

14 A: From January 2001 to November 2002, I served as the Vice President of Nichino. Before
15 that, I was a Commercial Development Manager for Nichino from July 1997 to December 2000.
16 Prior to Nichino, I joined Nor-Am Chemical Company in 1984 (the US subsidiary of Schering
17 AG, which later merged with Hoechst to become AgrEvo in 1994). While at Nor-Am/AgrEvo
18 from 1984 to 1997, I held various positions including Sales Representative, Business
19 Development Manager, Marketing Manager and Market Project Leader. My previous
20 employment over the course of more than 32 years has been focused on development,
21 registration, and sales of pesticides.

22 **Q: Please describe your educational background.**

23 A: I have a BS in Entomology/Plant Pathology from the University of Delaware.

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

3 A: I have been a Member of the Board of Directors of CropLife America since 2012.
4 CropLife America is the leading trade association in the United States for crop protection
5 registrants and distributors.

6 **II. NICHINO AND NIHON NOHYAKU CO., LTD**

7 **Q: Please describe Nichino and its corporate family.**

8 A: Nichino is a wholly owned subsidiary of Nihon Nohyaku Co., Ltd. or NNC for short.
9 NNC was established in 1928 and is a basic researcher and manufacturer of plant protection
10 products based in Tokyo, Japan.

11 **Q: Please describe NNC's mission.**

12 A: NNC's mission is to meet current needs in global crop protection markets by introducing
13 innovative agrochemicals that can contribute to healthy food production while protecting the
14 environment. NNC has conducted insecticide discovery research at its Research Center near
15 Osaka, Japan since 1990.

16 **III. INVENTION AND DEVELOPMENT OF FLUBENDIAMIDE**

17 **Q: What role, if any, did NNC play in the invention or development of flubendiamide?**

18 A: NNC invented flubendiamide. In the course of its research, in 1993, it discovered a lead
19 compound for a new insecticide from the class of phthalic acid diamides. It synthesized two
20 thousand derivatives from this initial discovery and conducted many studies to improve activity
21 before it finally discovered flubendiamide in 1998. NNC and Nichino have spent more than \$65
22 million on the initial discovery, data, and development costs to obtain the US registrations and to
23 bring flubendiamide to the US market.

24 **Q: Please describe the relationship between NNC and Bayer on flubendiamide?**

1 A: NNC has a licensing, product development, and marketing agreement with Bayer
2 CropScience LP, under which Bayer serves as Nichino's regulatory agent for flubendiamide and
3 sells flubendiamide products under the Belt[®] brand name. Nichino sells flubendiamide products
4 under the Vetica[®] and Turismo[®] brand names.

5 **IV. EPA'S PROPOSED EXISTING STOCKS PROVISIONS**

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

8 A: Yes.

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

10 A: EPA has proposed that immediately upon cancellation, all distribution or sale of existing
11 stocks should be prohibited, except for return of products for disposal or export. Product in the
12 hands of a user could be used as allowed by the current label.

13 **Q: What do the registrants believe are appropriate existing stocks provisions, if there is**
14 **a cancellation decision?**

15 A: We believe it is more appropriate to allow the existing stocks to clear the channels of
16 trade. In this way, the stocks that are already produced and released for shipment, using EPA's
17 standard language, could be sold, distributed and used in the normal way, without additional
18 transportation to ship them back to the registrant and without any additional impact to the
19 environment by disposal without any beneficial use.

20 We have already stopped production, and the amount we produced this year is less than
21 last year. Given the modeling and endpoint analyses I understand that Dr. Engel and Dr. Moore
22 will be providing in combination with the benefits information in the grower declarations,
23 described by IR-4, and that I understand Dr. Herbert and Dr. Palumbo will provide, we do not
24 believe cancellation is warranted at all. Even if EPA's cancellation is allowed without peer

1 review at this time, the risks do not outweigh the benefits for a normal year's production – and
2 here – less than a normal year's production, to be allowed to clear the channels of trade.

3

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

5 Executed on this 21st day of April, 2016.

6

7

8

9



Jeffrey Johnson

Verified Written Statement Of
Bernard Engel, Ph.D.
(Expert Witness)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of:

Bayer CropScience LP and
Nichino America, Inc.,

Petitioners.

)
)
)
)
)
)

FIFRA-HQ-2016-0001

**VERIFIED WRITTEN STATEMENT OF BERNARD ENGEL, PH.D.
ON BEHALF OF BAYER CROPSCIENCE LP AND NICHINO AMERICA, INC.**

TABLE OF CONTENTS

	<u>Page</u>
I. BACKGROUND AND EXPERIENCE	1
II. SCOPE OF TESTIMONY	3
III. SUMMARY OF CONCLUSIONS.....	4
IV. OPINIONS AND ANALYSIS	5
A. Basic Hydrologic Principles and Movement of Compounds.....	5
B. The Bayer Monitoring Studies Do Not Show Long-Term Accumulation of Flubendiamide or Des-Iodo.	7
1. Study Design and Conduct.....	7
2. The Monitoring Data Confirm Movement of Flubendiamide and Des Iodo Through the Watershed.....	8
3. The Pond Monitoring Data Do Not Show That Long-Term Accumulation Is Occurring or Will Occur.	10
4. The Stream Monitoring Data Confirm Movement Through the Watershed and Do Not Show Accumulation.	15
C. The USGS Data Do Not Show That Flubendiamide or Des-Iodo Are Ubiquitous or Accumulating.....	17
D. EPA Takes Contradictory Positions on the Effect of Buffers on Flubendiamide and Des-Iodo Runoff.....	21
E. EPA’s Modeling Does Not Perform in Predicting Flubendiamide and Des-Iodo Concentrations.	22
1. EPA Relies on Unsupported Assertions That Its Modeling Performs Well.....	22
2. Statistical Analysis Shows That EFED’s Model Does Not Perform Well.....	24
F. EFED’s Models Should Be Improved as a Long-Term Objective.	29
G. Monitoring Results Show That Flubendiamide and Des-Iodo Have Not Accumulated to Levels of Concern.....	30
H. Monitoring of Flubendiamide and Des-Iodo Concentrations Should Continue. ...	32
V. EXHIBITS	33

1 **I. BACKGROUND AND EXPERIENCE**

2 **Q: Please state your name, and where you are employed.**

3 A: My name is Dr. Bernard Engel, and I am employed in the Department of Agricultural &
4 Biological Engineering at Purdue University.

5 **Q: Please describe your education background and professional training.**

6 A: I am educated and trained as an agricultural engineer with a focus on agricultural
7 hydrology, water quality, and soil and water conservation. I hold Bachelor's of Science and
8 Master's of Science degrees in Agricultural Engineering from the University of Illinois at
9 Urbana-Champaign and a Doctor of Philosophy degree in Agricultural Engineering from Purdue
10 University. I hold a Professional Engineering (PE) license in Indiana.

11 **Q: Please summarize your occupational history.**

12 A: For the past 31 years, I have taught undergraduate and graduate level courses and
13 conducted research in hydrology, water quality, hydrologic/water quality modeling,
14 environmental decision support systems, and soil and water conservation at Purdue University.
15 During this time, I have held titles of Assistant Professor and Associate Professor, and currently I
16 am Professor and Head of the Department of Agricultural and Biological Engineering. I have
17 served as mentor and primary research advisor for 45 graduate students completing Master's of
18 Science and Doctor of Philosophy degrees and on the research advisory committees for an
19 additional 115 graduate students in the fields noted above.

20 PBNX 50 is a copy of my curriculum vitae further describing my qualifications,
21 experience, and publications.

22 **Q: Please describe your research and professional accomplishments.**

23 A: My research accomplishments in hydrology, water quality, hydrologic/water quality
24 modeling, environmental decision support systems, and soil and water conservation are widely

1 recognized for their quality and impact. I was named the outstanding young researcher in my
2 professional society (American Society of Agricultural Engineers – now called American
3 Society of Agricultural and Biological Engineers) in 1999. I received the outstanding research
4 award from the Purdue University College of Agriculture in 1998 for my research. I was
5 recognized as the outstanding graduate educator by the Purdue University College of Agriculture
6 in 2006 based on research conducted by graduate students I mentor. I was recognized as a
7 Fellow of my professional society (American Society of Agricultural and Biological Engineers)
8 based on career contributions in research, teaching, and leadership.

9 **Q: How has your research affected the development of hydrologic and water quality**
10 **models?**

11 A: I am globally recognized as a leading researcher in nonpoint source pollution modeling
12 based on the impact of my research in peer reviewed journal papers published in this area over
13 the past 20 years. I have developed and improved multiple hydrologic/water quality models,
14 including the Soil and Water Assessment Tool (SWAT), Groundwater Loading Effects of
15 Agricultural Management Systems (GLEAMS), and Agricultural Non-Point Sources (AGNPS)
16 model. These efforts are documented in peer reviewed journal papers.

17 **Q: Please describe your professional publications.**

18 A: I have authored more than 165 peer reviewed journal papers, 8 book chapters, and more
19 than 250 papers published in conference proceedings and papers distributed at national and
20 international meetings focused on hydrology, water quality monitoring and modeling,
21 environmental decision support systems, and soil and water conservation.

1 **Q: Have you ever served on a FIFRA Scientific Advisory Panel (“SAP”)?**

2 A: Yes, I have served on numerous Scientific Advisory Panels and Boards for the U.S.
3 government as an expert in the areas identified above, including FIFRA SAPs on Development
4 of a Spatial Aquatic Model (SAM) for Pesticide Risk Assessment in 2015, Problem Formulation
5 for the Reassessment of Ecological Risks from the Use of Atrazine in 2012, and Two-
6 dimensional Exposure Rainfall-Runoff Assessment (TERRA) Watershed Model and its Use in
7 the FIFRA Ecological Risk Assessment for Antimicrobial Uses of Copper in 2011, among
8 others.

9 **Q: Please describe your areas of expertise.**

10 A: I am an expert in, among other things, hydrology, water quality, hydrologic/water quality
11 modeling, water quality monitoring, soil and water conservation, and environmental decision
12 support systems. My research, teaching, and consulting activities in these areas include
13 pesticides, nutrients, and soil erosion/sediment.

14 **II. SCOPE OF TESTIMONY**

15 **Q: Please describe the scope of testimony that you have been asked to provide.**

16 A: I was engaged by Bayer CropScience LP (Bayer) to review and evaluate the United
17 States Environmental Protection Agency’s (EPA’s) assessment of current and predicted future
18 concentrations of flubendiamide and its primary environmental degradate, des-iodo
19 flubendiamide (hereafter referred to as des-iodo), that will occur in water bodies from the use of
20 flubendiamide products in agriculture. More specifically, I was asked to (a) review the available
21 monitoring and sampling data, related reports and studies, modeling, and risk assessments related
22 to current and potential future environmental exposure to flubendiamide and des-iodo in water
23 bodies, (b) determine whether EPA had properly evaluated the available data, (c) evaluate EPA’s
24 use of modeling to predict current and potential future flubendiamide and des-iodo

1 concentrations, and (d) determine whether EPA’s proposed cancellation of flubendiamide
2 products based on a conclusion that concentrations have exceeded or will exceed Agency-
3 identified levels of concern is based on sound science.

4 In my analysis, I considered EPA documents regarding flubendiamide available on
5 EPA’s flubendiamide cancellation website, additional EPA documents and Bayer documents and
6 data provided by Bayer, including the data and results from the Bayer monitoring studies as of
7 March 17, 2015 that were provided to EPA, more recent information and results from the
8 ongoing monitoring studies provided by Bayer, flubendiamide and des-iodo flubendiamide data
9 from the USGS website, and journal articles and other materials cited in this Written Statement.

10 **Q: Bayer and Nichino offer Dr. Engel as an expert in the areas of hydrology; water**
11 **quality; hydrologic/water quality modeling; water quality monitoring; and soil and water**
12 **conservation.**

13 **III. SUMMARY OF CONCLUSIONS**

14 **Q: Please provide a summary of the conclusions you reached in your analysis.**

15 A: Based on my review and analysis of materials and data provided and other materials
16 described in this Written Statement, it is my opinion that EPA’s assessment of current and future
17 environmental exposure to flubendiamide and des-iodo from the use of flubendiamide products
18 is flawed and incorrect, and that the data and information on environmental exposures and
19 concentrations do not support EPA’s proposed cancellation decision.

20 More specifically, based on my review and analysis I conclude that:

- 21 • Basic hydrologic principles suggest flubendiamide and des-iodo will not accumulate in
22 the environment to concentrations of regulatory concern.
- 23 • The registrants’ monitoring data offer useful insight into the seasonal and annual trends
24 of residue concentrations, showing clear signs of chemical inputs and subsequent declines
25 that are either missed or ignored by EPA’s Environmental Fate and Effects Division
26 (EFED).

- 1 • EFED does not interpret the effects of buffers and grassed waterways in a consistent
2 manner in their analyses, stating at times they do not impact chemical transport and at
3 other times minimizing the regulatory value of the Georgia test site due to the presence of
4 a grassed waterway.
- 5 • EFED modeling that EPA uses to predict current and future residue concentrations in
6 farm ponds is wrong and erroneously over predicts environmental
7 concentrations. Predictions of future concentrations under the modeling become
8 irrational.
- 9 • EFED modeling neither fits the existing field data nor is there a statistical basis to suggest
10 it has power to predict future trends.
- 11 • Statistical analysis of the EFED modeling indicates that the model has unacceptable
12 predictive value. The mean of the observed monitoring data provides a better estimate of
13 environmental concentrations than does the model.
- 14 • In light of the quantitative analysis confirming the unacceptable performance of the
15 EFED modeling approach, regulatory decisions should be made based on monitoring
16 results, not EFED’s modeling.
- 17 • After almost five years of monitoring, the registrants’ monitoring data show no
18 exceedances of the toxicological endpoints identified by EPA, and no evidence that
19 concentrations are accumulating or will accumulate to levels of concern.
- 20 • The USGS data do not show “widespread” detection or accumulation of flubendiamide
21 and des-iodo.
- 22 • Continued monitoring is justified in this case.

23 **IV. OPINIONS AND ANALYSIS**

24 **A. Basic Hydrologic Principles and Movement of Compounds**

25 **Q: Please provide an overview of the hydrologic cycle and the movement of compounds**
26 **through watersheds.**

27 A: In evaluating EPA’s conclusions with respect to environmental exposures to
28 flubendiamide and des-iodo, it is important to understand how materials that are slow to degrade
29 (such as flubendiamide and des-iodo) or that do not degrade (such as heavy metals or
30 phosphorus) move through the environment. Examining the hydrologic cycle provides a basis
31 for much of the movement of constituents that move primarily with water flow as does

1 flubendiamide. Materials move through watersheds at varying rates depending on factors
2 including precipitation, constituent properties, and characteristics of the watershed such as soils,
3 slopes, and land uses. These materials would typically be moved through primary pathways of
4 runoff and associated with soil particles that are eroded and moved by the runoff. Flubendiamide
5 and des-iodo would move primarily in surface runoff and associated eroded soil particles or
6 sediment carried in the runoff.

7 As materials are transported through a watershed, they may be temporarily delayed. Soil
8 initially eroded from the watershed landscape may be deposited in small channels, streams, or
9 rivers before later being scoured and moved further through the stream and river network. Ponds
10 and small lakes may also be sources of delays.

11 Ultimately, materials that move through the watershed will reach large water bodies
12 (large lakes and oceans) where accumulation at very low levels may occur. Given the large
13 volumes of water and masses of sediments in these systems and the comparatively small masses
14 of the materials, observed concentrations will typically be very low, even if some accumulation
15 occurs. Factors such as degradation and burying of sediment will also limit accumulation in
16 large water bodies.

17 **Q: How do the processes you just described relate to metals and nutrients?**

18 A: The above processes would be similar for metals and even for a nutrient such as
19 phosphorus, for which there is a significant body of scientific literature. Phosphorus transport is
20 particularly relevant to this case because, like flubendiamide and des-iodo, its equilibrium state
21 favors relatively insoluble mineral forms that favor binding to sediment or precipitation out of
22 the water column. Yet, phosphorus concentrations do not accumulate to infinitely large values in
23 small water bodies and lakes, but rather phosphorus concentrations reach some plateau and

1 fluctuate around that level depending on continued loading to the water body. *Masses* may
2 continue to increase in the water body, including its sediment, as the materials are covered by
3 new incoming sediment, but *concentrations* would not continue to increase unbounded.

4 **Q: Would you expect flubendiamide and des-iodo concentrations in water bodies to**
5 **behave in a similar fashion?**

6 A: The expectations for flubendiamide and des-iodo would be similar because the small
7 masses that reach ponds or small lakes would be buried in the sediment or otherwise flow with
8 the water exiting the pond and watershed. Contrary to this, the EFED projections and
9 interpretation of flubendiamide and des-iodo data and model results for small ponds suggest
10 continued increases in flubendiamide and des-iodo concentrations without bounds, which is
11 unreasonable and seemingly impossible.

12 **B. The Bayer Monitoring Studies Do Not Show Long-Term Accumulation of**
13 **Flubendiamide or Des-Iodo.**

14 **1. Study Design and Conduct**

15 **Q: What is your understanding of the monitoring studies that Bayer has conducted?**

16 A: Bayer has conducted almost five years of monitoring for flubendiamide and des-iodo at
17 two sites in North Carolina and Georgia. These studies were conducted as required by EPA.
18 EFED reviewed and approved the monitoring sites, study design, and supporting protocols prior
19 to initiation of the monitoring studies.

20 **Q: Please describe how these studies are conducted.**

21 A: Each site includes intermittent and perennial streams and a farm pond that receives
22 drainage from an adjacent treated field. The field sites have the approximate properties of
23 EFED's "farm pond scenario," where a small pond receives its entire runoff loading from an
24 adjacent, treated field approximately 10 times larger than the pond. EFED defines this 10:1

1 drainage-to-pond ratio as the reasonable worst case for exposure assessment, and results derived
2 from these studies are intended to be protective of the greater agricultural environment.

3 Flubendiamide and des-iodo concentrations in all sampling locations at these sites have
4 been determined approximately once per month for these constituents in the sediment, water
5 column, and sediment pore water. Bayer has conducted monitoring at these sites for almost five
6 years. The monitoring is ongoing.

7 **Q: What monitoring data were provided to you for your analysis?**

8 A: For this analysis I was provided and reviewed monitoring data available through March
9 17, 2015, which I understand were finalized and submitted to EPA. In addition, at my request
10 Bayer provided information and results from the ongoing monitoring studies through October
11 2015, that are reflected in the Figures and discussions below.

12 **2. The Monitoring Data Confirm Movement of Flubendiamide and Des**
13 **Iodo Through the Watershed.**

14 **Q: What do the monitoring data show, if anything, with respect to the movement of**
15 **flubendiamide and des-iodo through the watershed?**

16 A: The observed data from both of these sites show trends that are consistent with delayed
17 movement through an agricultural watershed as described above. Monitoring data at the North
18 Carolina and Georgia pond sites show declines in flubendiamide and des-iodo each year as these
19 constituents move out of the ponds via water flowing through the ponds. This was confirmed at
20 both study sites by photographs showing water flowing into an overflow pipe or over the
21 spillway of the pond during the study period.

1 **Q: Did the monitoring data indicate accumulation of flubendiamide or des-iodo in up-**
2 **and downstream sampling locations?**

3 A: No. Data collected by Bayer at the Georgia and North Carolina study sites indicate
4 flubendiamide and des-iodo do not accumulate in the up- and downstream sampling locations.
5 In discussing the Georgia flowing water sites, EFED agrees that flubendiamide and des-iodo will
6 not accumulate to a substantial degree, stating that “EFED does not anticipate continuous
7 accumulation at these flowing-water sites because any accumulation is continuously (water) or
8 periodically (sediment) flushed downstream.”¹

9 **Q: What is your opinion on the potential long-term accumulation of flubendiamide and**
10 **des-iodo in the environment?**

11 A: Under the hydrologic principles described above, flubendiamide and des-iodo will move
12 through the watershed and ultimately reach large water bodies (large lakes and oceans). Given
13 the small masses of flubendiamide applied in the landscape, and its degradation processes,
14 accumulation of flubendiamide and des-iodo to levels of concern will not occur in these water
15 bodies. A degradation pathway via photolysis for des-iodo has been identified by Bayer which
16 provides sufficient reactivity to ensure long-term accumulation in the environment should not
17 take place.²

¹ PBNX 25 at 8 (EFED Response to Bayer CropScience LP White Paper (July 15, 2015)).

² L.L. McConnell, Bayer CropScience, [Phthalic acid ring-UL-14C]Flubendiamide-desiodo Phototransformation in Aqueous pH 7 Buffer, Final Report, Report No. MEAMN004 (2016).

1 **3. The Pond Monitoring Data Do Not Show That Long-Term**
2 **Accumulation Is Occurring or Will Occur.**

3 **Q: Do any of the observed concentrations of flubendiamide or des-iodo from the North**
4 **Carolina and Georgia ponds exceed levels of concern identified by EPA?**

5 A: The observed flubendiamide and des-iodo concentrations in the North Carolina and
6 Georgia sites show no accumulations above levels of concern nor do they suggest that
7 accumulations will occur reaching levels of concern, since the study has now extended to the
8 point where the concentration plateaus for both locations are being reached or will be in the near
9 future.

10 **Q: What is your understanding of EPA’s position on the flubendiamide and des-iodo**
11 **monitoring data and what they show with respect to accumulation?**

12 A: EPA contends that the monitoring data show that flubendiamide and des-iodo are
13 accumulating and will continue to accumulate.

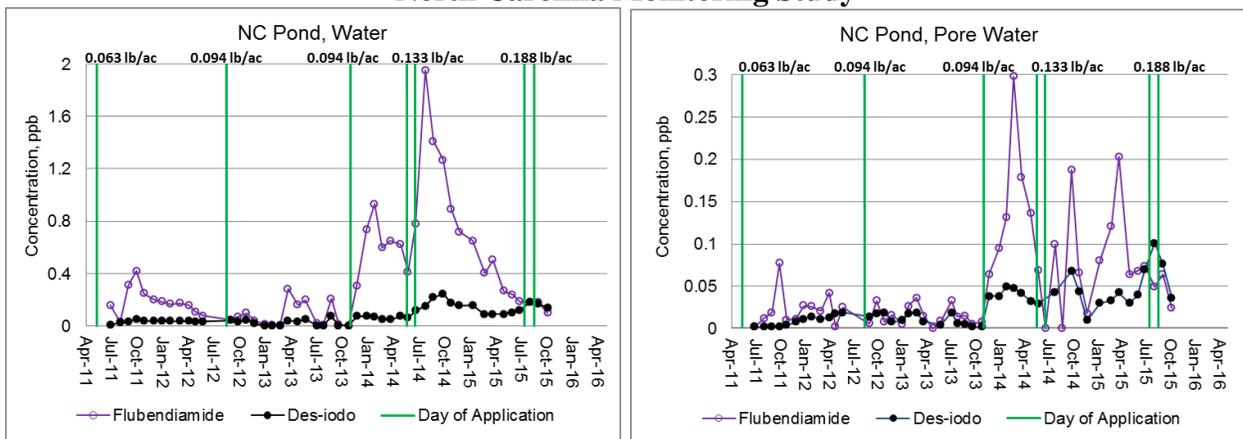
14 **Q: What is your opinion on this position?**

15 A: EPA’s assumption that flubendiamide and des-iodo are accumulating based on the
16 observed data in the North Carolina and Georgia monitoring sites is unfounded. As described
17 below, variability in observations in North Carolina is explained by variability in flubendiamide
18 application rates, conditions, and timing. EPA wrongly discounts the Georgia data because of
19 the presence of grassed waterways at that site. Further, based on the sediment sampling
20 approach to obtain pore water concentrations, until flubendiamide is present in the top 5 cm of
21 pond sediment, the concentrations of constituents may increase, but then would be expected to
22 plateau. The EFED modeling does not account for any of these conditions. Likewise, EFED’s
23 use of and interpretation of trend lines fit to the observed data are incorrect for failing to account
24 for any of these factors.

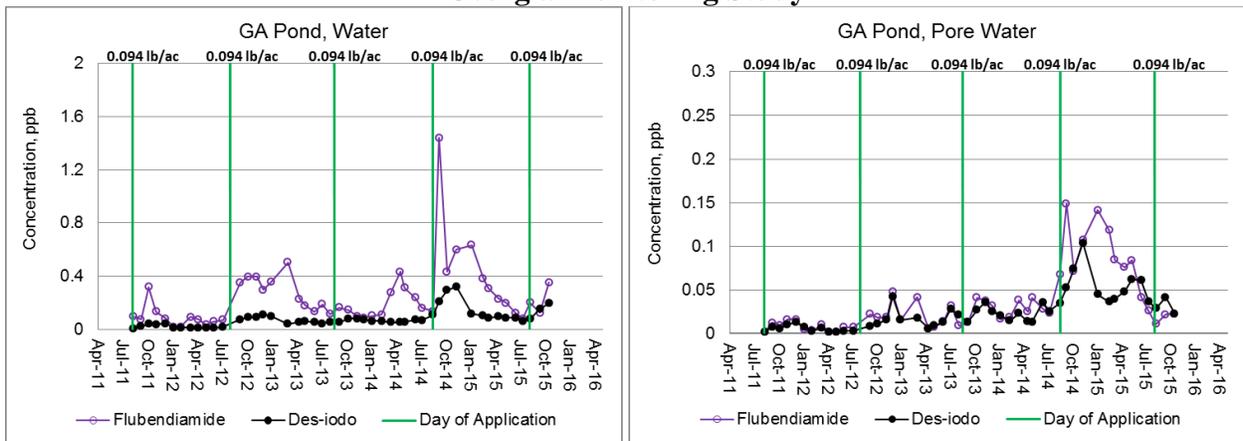
1 **Q: Have you reviewed any recently updated data regarding the concentrations of**
2 **flubendiamide and des-iodo in the ponds at the two monitoring sites?**

3 **A: Yes.** At my direction, Bayer updated previously produced figures showing the behavior
4 of flubendiamide and des-iodo over time in the water column and pore water for the North
5 Carolina and Georgia monitoring sites to include additional data through October 2015. These
6 updated figures are provided below as Figure 1. A copy of Figure 1 is included at PBNX 80.

7 **North Carolina Monitoring Study**



8
9
10 **Georgia Monitoring Study**



11
12
13 **Figure 1.** Monitoring results of flubendiamide and des-iodo in water column (left side) and pore
14 water (right side) from North Carolina (top) and Georgia (bottom) ponds.

1 The charts in Figure 1 show measured concentrations of flubendiamide (in purple) and des-iodo
2 (in black). The timing of Belt® (flubendiamide) applications to the pond watershed is shown by
3 vertical lines, with the amount applied shown at the top of the chart.

4 **Q: Based on your examination of the updated pond monitoring data, what conclusions**
5 **have you drawn about flubendiamide's and des-iodo's attributes?**

6 A: Examination of the observed data shows several important attributes of flubendiamide
7 and des-iodo behavior. Examining the water column and pore water data for both flubendiamide
8 and des-iodo shows observed concentrations increasing following flubendiamide application in
9 the watershed (as would be expected), reaching a peak, and then declining prior to the next
10 year's application. These observed declines at both the North Carolina and Georgia monitoring
11 sites are largely counter to the EFED model that at best predicts only trivial declines due to pond
12 outflow.

13 **Q: Are the observed concentrations at the North Carolina site indicative of long-term**
14 **accumulation?**

15 A: No, the observed concentrations at the North Carolina site are not evidence of a trend
16 toward long-term accumulation as EPA suggests. Instead, the change in application rates and
17 timing, rainfall timing and magnitude, and conditions for flubendiamide application at the North
18 Carolina site explain much of the trend in the observed data at this site.

19 **Q: Please elaborate on the effect of application rates on the North Carolina observed**
20 **data.**

21 A: For compounds such as flubendiamide, movement of the material in runoff and with
22 sediment is proportional to application rate, meaning that doubling of the application rate will
23 result in doubling of its movement in runoff and sediment (assuming similar rainfall patterns).

1 At the North Carolina site, the 2012 flubendiamide application rate was 1.5 times the rate for
2 2011. The application rate for 2014 was more than double that of 2011. The application in 2013
3 occurred under unusual circumstances that are not typical (applied in November to the ground
4 without an actively growing crop) and represent conditions of high potential for movement of the
5 material with runoff and sediment. Timing and magnitude of rainfall following field application
6 of flubendiamide further explain magnitudes of movement with runoff and sediment to the pond
7 as well as declines in concentrations in the water column as water flows through the pond. The
8 parameterization of the EFED model in the manner in which it was applied at the North Carolina
9 site does not appropriately account for these factors.

10 **Q: In your opinion, are the observed concentrations of flubendiamide and des-iodo at**
11 **the North Carolina site evidence of long-term accumulation?**

12 A: No. The concentrations of flubendiamide and des-iodo would be expected to increase at
13 the North Carolina monitoring site based on the factors discussed above, rather than their
14 chemical properties. Thus, EFED's conclusion that the data show long-term accumulation as
15 predicted by EPA's model has no basis; the increased concentrations observed are explained by
16 increased application rates, field conditions at the time of the 2013 application, and rainfall
17 magnitude and timing. Further, as described below in the section on statistical analysis of the
18 model, the suggestion that the EFED model matches observed data at the North Carolina site is
19 incorrect.

20 **Q: How do the Georgia pond monitoring data compare to the North Carolina pond**
21 **data?**

22 A: The Georgia monitoring data also show increases in flubendiamide and des-iodo
23 concentrations in the water column and in sediment pore water following field application. The

1 concentrations reach a peak and then decline until an application in the following year. The
2 variability from year to year is much less at the Georgia site than at the North Carolina site. The
3 flubendiamide application rate and timing each year are consistent for the Georgia site, while
4 these were not consistent for the North Carolina site as discussed above.

5 **Q: How does EPA assess the Georgia monitoring data?**

6 A: EFED discounts use of the Georgia data throughout their analysis as the magnitude of
7 these data remain more uniform over time and significantly below the EFED model predictions.
8 EFED attempts to attribute this to the presence of grassed waterways, suggesting the grassed
9 waterways are preventing flubendiamide and des-iodo from reaching the pond, even though
10 EFED elsewhere states that grassed buffers are not effective mitigation measures for
11 flubendiamide and des-iodo (see discussion of EPA's inconsistent position on buffers below).
12 Grassed waterways and buffers cannot capture all runoff constituents for conditions such as
13 those in Georgia. The magnitude of flubendiamide reaching the Georgia pond would be reduced
14 by the grassed waterway, but the presence of grassed waterways would not prevent observation
15 of a trend should one exist. In summary, the Georgia pond experiment informs the exposure
16 assessment by again confirming the constituents decline seasonally with trends that cannot be
17 captured by the EFED model.

18 **Q: Are there any other factors that could affect the concentrations of flubendiamide
19 and des-iodo in the ponds at the two monitoring sites?**

20 A: Yes. Any observed increases in pore water flubendiamide and des-iodo concentrations in
21 the monitored data at the Bayer monitoring sites to date can also be explained by the sediment
22 pore water sampling methodology. Pore water is sampled from the top 5 cm of sediment. A 5
23 cm depth of sediment in these ponds would represent sediment reaching the pond over some

1 period of time, likely several years or more. Thus, as new sediment containing flubendiamide
2 and des-iodo is deposited in a pond, the pore water concentration of these constituents would be
3 expected to increase until 5 cm of sediment was deposited that contained these constituents.
4 Beyond this period, pore water concentrations would plateau and fluctuate around the plateau
5 value based on amounts of constituents represented in the most recent 5 cm of sediment (recall
6 the phosphorus trends discussed above).

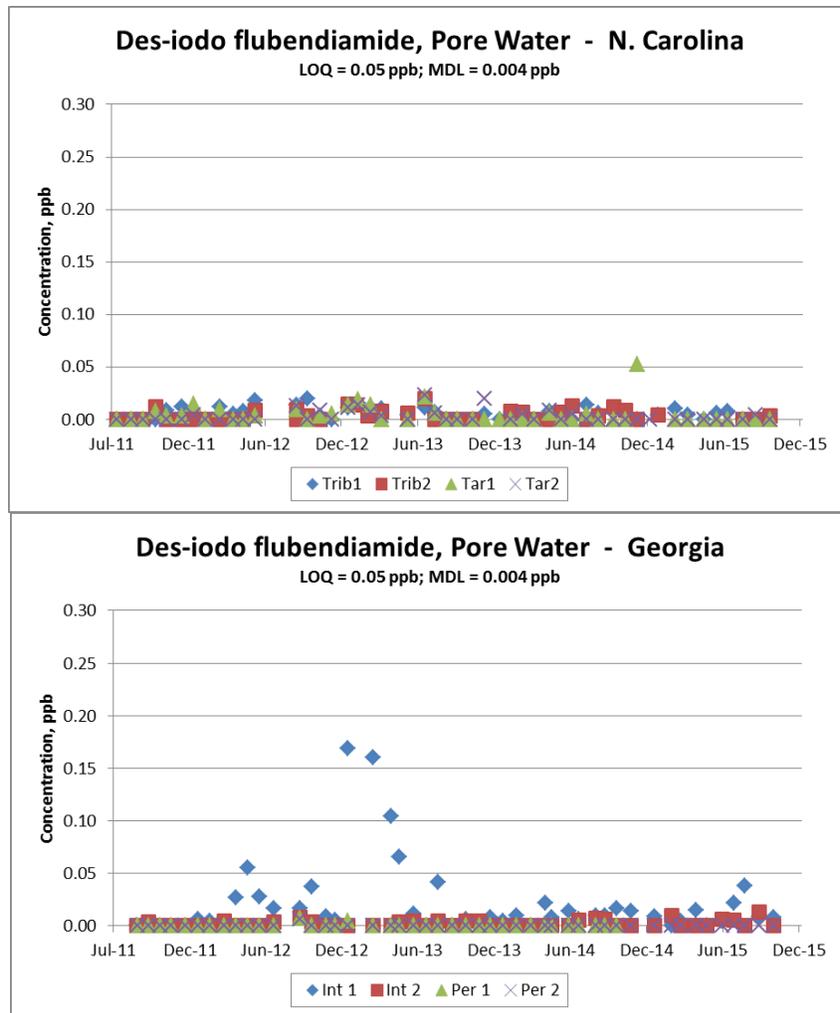
7 **Q: What effect would the sediment layering process have on sediment pore water**
8 **concentrations?**

9 A: This layering of constituents in the sediment will preclude the continued growth in
10 constituent concentrations in sediment pore water predicted by EFED's model. Constituents in
11 sediment below the top 5 cm of sediment will be buried and unavailable to contribute to
12 concentrations in the top 5 cm of sediment pore water. Ultimately, however, the pond sediment
13 and any materials in the pond sediment would be scoured and continue downstream, moving
14 through the watershed as described above.

15 **4. The Stream Monitoring Data Confirm Movement Through the**
16 **Watershed and Do Not Show Accumulation.**

17 **Q: Please describe the samples from other water bodies analyzed in Bayer's monitoring**
18 **studies.**

19 A: The Bayer monitoring studies also include samples from intermittent and perennial
20 streams, and provide samples of upstream water (control samples) prior to being influenced by
21 the test site and downstream water that is influenced by the test site to define exposures beyond
22 the farm pond. Figure 2 provides concentrations of des-iodo, which is the residue of greater
23 EFED concern, in the flowing water bodies in the monitoring study. A copy of Figure 2 is
24 included at PBNX 81.



1

2

3 **Figure 2.** Des-iodo concentrations in samples taken from upstream intermittent creeks
 4 (Trib 1 / Int 1), downstream intermittent creeks (Trib 2 / Int 2), upstream perennial
 5 creeks / rivers (Tar 1 / Per 1) and downstream perennial creeks / rivers (Tar 2 / Per 2).

6 **Q: In your opinion, what do the samples from the intermittent creeks and perennial**
 7 **creeks/rivers indicate?**

8 **A:** Samples taken before and after pond water flows into intermittent creeks or tributaries,
 9 and finally into larger perennial creeks and rivers confirm no evidence of accumulation; are well
 10 below any risk endpoint defined by EFED; and confirm my opinion that chemical residues will
 11 move from collection points, such as ponds, through the agricultural watershed in concentrations
 12 that do not challenge the environment.

1 **C. The USGS Data Do Not Show That Flubendiamide or Des-Iodo Are**
2 **Ubiquitous or Accumulating.**

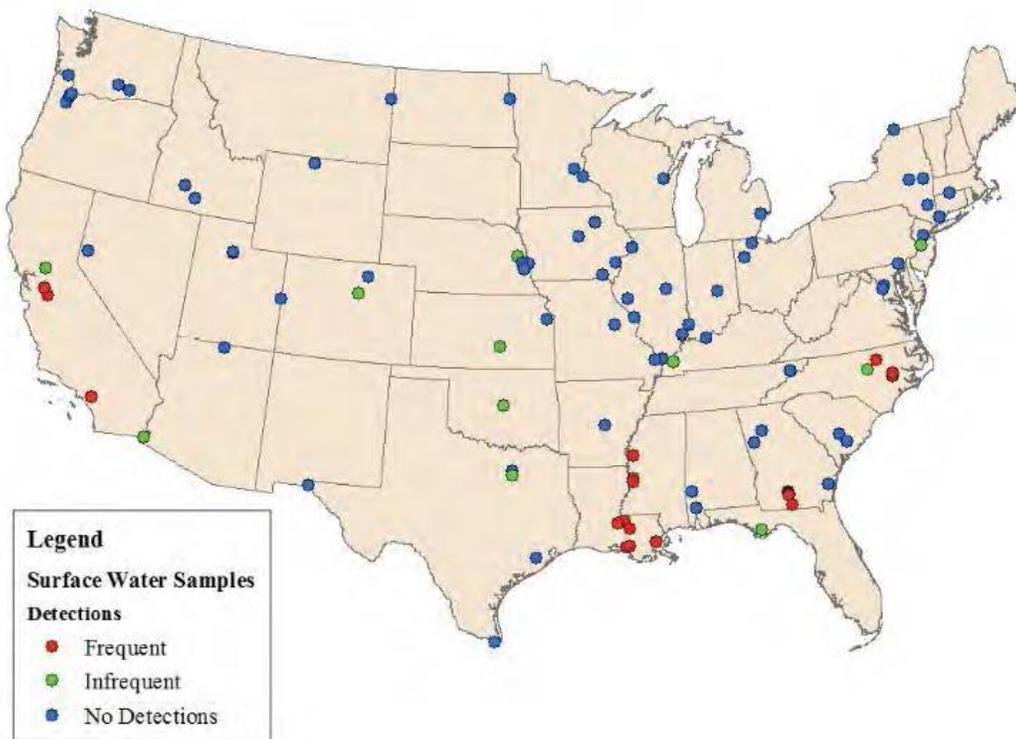
3 **Q: What is your understanding of the available United States Geological Service**
4 **(“USGS”) data for flubendiamide and des-iodo?**

5 A: At EPA’s request, the USGS has tested for flubendiamide and des-iodo as part of its
6 nationwide water monitoring program. As part of my review, I downloaded the flubendiamide
7 and des-iodo concentration data for rivers and streams from the USGS website on March 12,
8 2016. The USGS data include nearly four years of monthly observations for these constituents
9 from the fall of 2012 through the summer of 2015 for more than 90 stations, and include
10 additional stations with smaller numbers of observations. Analyses of 5,004 samples were
11 reported. Review of the USGS river and stream monitoring data do not suggest that
12 flubendiamide and des-iodo are ubiquitous or accumulating. Observed levels are well below the
13 “no effect” level.

14 **Q: Please describe EFED’s analysis of the USGS data.**

15 A: EFED previously analyzed USGS data for the period of fall 2012 to October 2014;
16 approximately one year of observations fewer than are currently available. Based on their
17 review of the USGS data, EFED indicated that “California, Georgia, North Carolina, Mississippi,
18 and Louisiana had multiple sites with frequent detections (Figure 1),” and referred to
19 “widespread, non-targeted, filtered USGS detections.”³ EPA’s figure showing these detections is
20 provided as Figure 3 below. A copy of Figure 3 is included at PBNX 82.

³ PBNX 31 at 16 (EFED Flubendiamide Ecological Risk Assessment Addendum (Jan. 28, 2016)).



1
2
3
4
5
6
7
8
9
10
11
12
13
14

Figure 3. Flubendiamide detections in surface water samples collected by the USGS and registrant (from EFED Ecological Risk Assessment Addendum (Jan. 28, 2016), PBNX 31 at 16).

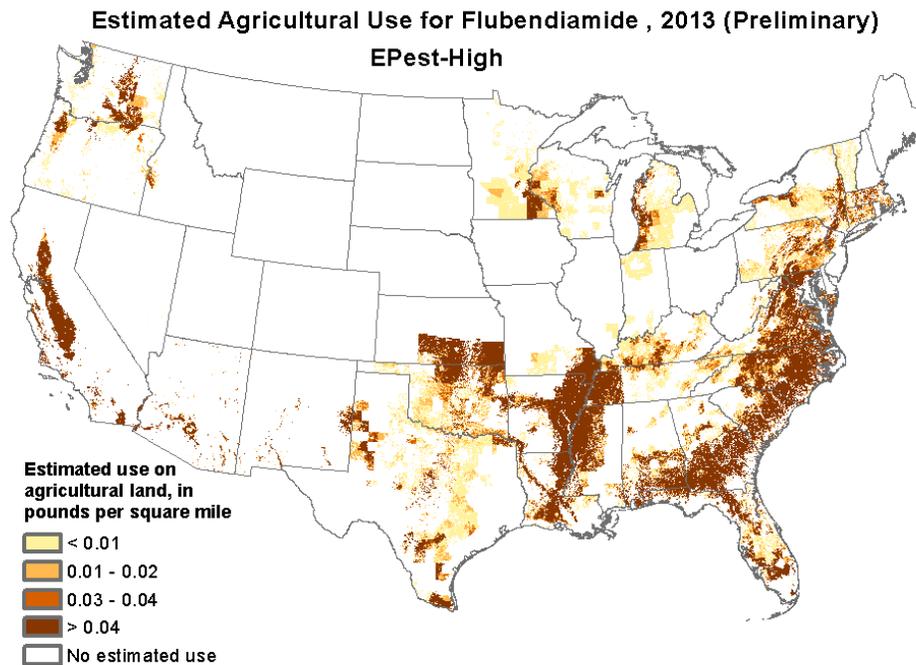
Q: What is your opinion on EFED’s characterization of the geographical distribution of flubendiamide detections in the USGS data?

A: While the sites with what EFED termed “frequent detections” are widespread geographically, characterizing this as “widespread detections” is misleading. The three North Carolina sites that are identified as having frequent detections include two tributaries to the Neuse River and a downstream Neuse River site. The sites in Louisiana include three locations on the Mississippi River and three sites on the Atchafalaya River. Two sites with frequent detections in Mississippi are on the Yazoo River and the third is on the Mississippi River. The sites labeled with frequent detections in Georgia are small streams sampled by Bayer as part of its monitoring study, and not USGS as the supporting EPA text for the figure suggests. For the

1 sites labeled as having infrequent detections, many of the detections were labeled by USGS as
2 “below the reporting level but at or above the detection level” or “below the detection level.”

3 **Q: How does the geographical distribution of flubendiamide detections compare to the**
4 **geographical use of flubendiamide products?**

5 A: Figure 4 below shows the estimated agricultural use of flubendiamide for 2013 (sourced
6 from the USGS website referenced in the figure caption). A copy of Figure 4 is included at
7 PBNX 82. Stream and river sites in Figure 3 characterized by EPA as having frequent detections
8 of flubendiamide occur in areas with the greatest flubendiamide application. Note also that not
9 all sites in areas of highest application on Figure 4 were characterized by EPA on Figure 3 as
10 having frequent detections.



11
12 **Figure 4.** Estimated flubendiamide application in 2013 (from
13 [http://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2013&ma](http://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2013&map=FLUBENDIAMIDE&hilo=H)
14 [p=FLUBENDIAMIDE&hilo=H](http://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2013&map=FLUBENDIAMIDE&hilo=H)).

1 **Q: Were the USGS samples filtered?**

2 A: Yes. EFED correctly describes the USGS samples as being filtered prior to analysis and
3 acknowledges this will attenuate the residue levels by removing sediment-bound residue. While
4 the extent of the residue attenuation due to filtering cannot be established, the reported USGS
5 results are similar to those reported by Bayer where filtering did not occur, suggesting the impact
6 of filtering is small.

7 **Q: Please describe EFED's conclusions from its analysis of the USGS data.**

8 A: EFED incorrectly concludes that the flubendiamide and des-iodo concentrations
9 measured in flowing water by USGS are evidence for upstream accumulation in lentic (non-
10 flowing) water bodies.⁴ This conclusion cannot be drawn from the USGS data, as one should
11 more reasonably assume the constituent detections in the USGS data illustrate the transport of
12 residues through the watersheds under the influence of hydrologic cycling previously described.
13 The more reasonable source of the residues is the treated fields in the watershed, not the lentic
14 water bodies as EFED concludes. While some fields on which flubendiamide is applied would
15 flow into ponds before the water from the ponds flows into streams, the majority of fields in
16 watersheds would typically flow into channels and small streams.

17 **Q: In your opinion, what conclusions can be drawn from a review of the USGS data?**

18 A: In summary, review of the USGS river and stream monitoring data show limited, low-
19 level detections consistent with areas of product use, but do not suggest that flubendiamide and
20 des-iodo are ubiquitous or accumulating. The data analyzed contain an additional year of data
21 beyond those available when EFED conducted an analysis of USGS data, providing further
22 evidence that flubendiamide and des-iodo are not accumulating and exceedances are not

⁴ PBNX 36 at 2 (EFED Response to Bayer CropScience LP Flubendiamide Aquatic Risk Email Submission (July 8, 2015)).

1 occurring. All values observed are below levels of regulatory concern. Further, EFED’s
2 characterization of the USGS data is misleading.

3 **D. EPA Takes Contradictory Positions on the Effect of Buffers on**
4 **Flubendiamide and Des-Iodo Runoff.**

5 **Q: Please describe EPA’s position on how buffers affect flubendiamide and des-iodo**
6 **runoff.**

7 A: EFED attempts to simultaneously take the position that buffers do not work in reducing
8 losses of flubendiamide to small ponds and that the grassed waterway works too well to consider
9 the Georgia pond data. It is not possible to logically adhere to both of these positions
10 simultaneously.

11 As discussed above, EFED largely discounts and ignores the data from the Georgia
12 monitoring site, where application rates each year are consistent and the resulting concentrations
13 of flubendiamide and des-iodo are more uniform, based on the presence of a grassed waterway
14 that was installed in the watershed.⁵

15 On the other hand, EFED has taken the position that buffers are not effective in
16 mitigating movement of flubendiamide off fields and out of watersheds. For example, one of
17 their “key findings” from the pond monitoring study was that “Vegetative Filter Strips (VFSs)
18 are ineffective in preventing this accumulation in downstream waterbodies.”⁶ If this is EFED’s
19 position, ignoring the results from the Georgia pond site is logically inconsistent. The grassed
20 waterway is a standard conservation practice in watersheds such as the study site in Georgia.
21 They are used to safely convey runoff that accumulates in concentrated flow areas. Grassed

⁵ See, e.g., PBNX 35 at 4-5, 13-14 (EFED Review of Water Monitoring Project (Feb. 20, 2015) (contending that the presence of grassed waterways would “reduce the accumulation of flubendiamide and des-iodo” and “confounded” the interpretation of the Georgia data).

⁶ PBNX 25 at 4.

1 waterways have some similarity to buffers in that both conservation practices are commonly
2 used in addressing runoff issues. If anything, a grassed waterway would be expected to be less
3 effective than a buffer in reducing flubendiamide reaching the pond, as grassed waterways are
4 primarily designed to safely convey runoff while preventing significant soil erosion in the
5 concentrated flow path or channel, thereby preventing gullies from forming.

6 Elsewhere, while largely ignoring the Georgia data, EPA asserts that “[b]ecause the
7 Agency’s modeling does not account for the effect of VFSs, but still largely matches the
8 monitoring data, we believe the effect of VFSs is not large enough to mitigate the ecological
9 risks posed by flubendiamide applications.”⁷ This contradicts EPA’s position that the grassed
10 waterway at the Georgia site precludes use and interpretation. Moreover, as discussed below,
11 EFED’s modeling does not “largely match” monitoring data at the Georgia or the North Carolina
12 site.

13 **E. EPA’s Modeling Does Not Perform in Predicting Flubendiamide and Des-**
14 **Iodo Concentrations.**

15 **1. EPA Relies on Unsupported Assertions That Its Modeling Performs**
16 **Well.**

17 **Q: How does EFED characterize the performance of its model?**

18 A: EFED’s review documents consistently indicate EFED’s model performs well relative to
19 the observed data. For example, EFED’s February 20, 2015 review of the reports from Bayer’s
20 monitoring study includes several statements asserting that the model performs well:

- 21 • “Overall, the Agency believes the monitoring data tracks reasonably well with the
22 modeled data.”
- 23 • “The Agency believes the SWCC predictions fit the water column data quite well (Figure
24 6a and b).”

⁷ PBNX 30 at 4 (EPA Decision Memorandum (Jan. 29, 2016)).

1 • “The NC pond data provide a good match to the SWCC modeling (Figures 6a and b).”⁸

2 In addition, EFED’s July 15, 2015 response to Bayer’s June 30, 2015 white paper states:

3 • “The key findings from the pond monitoring study are that: 1) flubendiamide and des-
4 iodo accumulate in farm ponds similar to the accumulation predicted by EFED’s
5 exposure modeling; . . . Continued monitoring at these sites are unlikely to change this
6 understanding.”

7 • “In the North Carolina pond (which was the only pond without grassed waterways in the
8 watershed), the concentrations of des-iodo (and flubendiamide) observed closely
9 approximates the concentrations expected from exposure modeling.”⁹

10 Finally, EFED’s January 28, 2016 Ecological Risk Assessment Addendum indicates the
11 following regarding the Georgia monitoring data:

12 • “The accumulation measured in the first three years of the pond data least impacted by
13 the identified issues largely matched the initial 3 years of concentration predictions of
14 EFED’s aquatic exposure modeling.”¹⁰

15 **Q: What is your opinion on EFED’s characterization of its model?**

16 A: EFED concludes that its model “performs quite well,” despite conducting no statistical
17 analysis to identify how well the EFED model performed with respect to monitoring data. This
18 is contrary to the guidance in the EPA document on Guidance on the Development, Evaluation,
19 and Application of Environmental Models that suggests comparison of modeled results with
20 monitoring data when feasible and provides a number of quantitative methods for assessing such
21 comparisons.¹¹

22 Furthermore, EFED’s belief that its model performs well relative to observed field data is
23 incorrect, as demonstrated in the next section.

⁸ PBNX 35 at 12, 18.

⁹ PBNX 25 at 3-4.

¹⁰ PBNX 31 at 12.

¹¹ PBNX 51 (EPA, Guidance on the Development, Evaluation, and Application of Environmental Models (Mar. 2009) (excerpts).

1 2. **Statistical Analysis Shows That EFED’s Model Does Not Perform**
2 **Well.**

3 **Q: Did you perform any statistical analyses of the performance of EFED’s model?**

4 A: Yes.

5 **Q: Please describe the statistical measures you used in your analyses.**

6 A: Several statistical analyses are commonly used in assessment of hydrologic and water
7 quality models such as the model used by EFED. These commonly used statistical measures are
8 briefly introduced, followed by their computation for the North Carolina and Georgia monitoring
9 sites.

10 The Coefficient of Determination, or R^2 , describes how well observed outcomes are
11 replicated by the model, based on the proportion of total variation in observed data explained by
12 the model. An R^2 of 1 indicates that the regression line or model perfectly fits the data, while an
13 R^2 of 0 indicates that the line or model does not fit the data at all.

14 A common statistic used to understand the performance of hydrologic/water quality
15 models is the Nash-Sutcliffe Efficiency (NSE).¹² The NSE indicates how well the plot of
16 observed versus simulated data fits the 1:1 line (a line of perfect fit between a model and
17 observed data). This is the same as the Coefficient of Determination (R^2) when the intercept is
18 forced to be 0. NSE ranges from $-\infty$ to 1.0, with $NSE = 1$ being the optimal value. Values
19 between 0.0 and 1.0 suggest the model has some predictive ability, whereas values < 0.0 indicate
20 that the mean observed value is a better predictor than the modeled values. This would indicate
21 that simply taking the average of the observed data would be a better predictor than applying the
22 model, which indicates unacceptable performance of the model.

¹² D.N. Moriasi et al., *Model Evaluation Guidelines for Systematic Quantification of Accuracy in Watershed Simulations*, 50(3) Transactions ASABE 885-900 (2007).

1 Percent bias (PBIAS) is another measure used to assess model performance and measures
2 average tendency of the simulated data to be larger or smaller than their observed counterparts.¹³
3 PBIAS is the deviation of data being evaluated, expressed as a percentage. The optimal value of
4 PBIAS is 0.0, with small values indicating accurate model simulation. Positive values indicate
5 model underestimation bias, and negative values indicate model overestimation bias.

6 **Q: What ranges of statistical performance measures are considered acceptable for**
7 **hydrologic/water quality models?**

8 A: Ranges of statistics considered acceptable for hydrologic/water quality models are
9 highlighted in Engel et al. (2007)¹⁴ and Santhi et al. (2001).¹⁵ Engel et al. (2007) reviewed ranges
10 of statistical performances for hydrologic/water quality models. Santhi et al. (2001) suggested
11 the following NSE, R², and P_{BIAS} values as acceptable ranges for hydrologic/water quality model
12 performance:

- 13 NSE > 0.50
- 14 R² > 0.50
- 15 P_{BIAS} ±25%.

16 **Q: Please describe your statistical analysis of EFED’s modeling of flubendiamide and**
17 **des-iodo concentrations for the North Carolina site.**

18 A: The NSE, PBIAS, and R² were computed for EFED’s modeling of flubendiamide and
19 des-iodo concentrations in the water column and in sediment pore water at the North Carolina
20 site using the observed data from the site. EFED modeled two cases – their standard model and

¹³ *Id.*
¹⁴ B. Engel et al., *A Hydrologic/Water Quality Model Application Protocol*, 43(5) J. Am. Water Res. Ass’n 1223-36 (2007).
¹⁵ C. Santhi et al., *Validation of the SWAT Model on a Large River Basin With Point and Nonpoint Sources*, 37(5) J. Am. Water Res. Ass’n 1169-88 (2001).

1 an updated model considering flow through the pond. Statistics were computed for both. The
 2 results are summarized in the table below (Table 1). A copy of Table 1 is included at PBNX 83.

3 **Table 1.** NSE, PBIAS, and R² for North Carolina site EFED models and monitoring data.
 4

Model	North Carolina Site		
	NSE	PBIAS (%)	R ²
Flubendiamide in Water Column	-0.17	66	0.15
Flubendiamide in Water Column with Flow Through	-0.24	72	0.11
Des-iodo in Water Column	-0.22	-22	0.29
Des-iodo in Water Column with Flow Through	0.10	24	0.22
Flubendiamide in Pore Water	-0.41	-89	0.16
Flubendiamide in Pore Water with Flow Through	-0.14	-59	0.11
Des-iodo in Pore Water	-11.92	-227	0.42
Des-iodo in Pore Water with Flow Through	-3.37	-127	0.35

5
 6 **Q: Are the statistical performance measures for the North Carolina site within the**
 7 **acceptable range?**

8 A: No. All but one of the NSE values are negative, indicating the mean of the observed data
 9 is a better predictor than the EFED model. The only model with a positive NSE is for des-iodo
 10 in the water column with flow through. However, based on suggested NSE values for
 11 hydrologic/water quality models performance, this value is well below the level for acceptable
 12 model performance (NSE > .50). Further, the PBIAS values indicate that the model greatly over
 13 predicts des-iodo in pore water even when water flow through the pond is considered.

14 **Q: Based on your statistical analysis, what are your conclusions regarding EFED's**
 15 **model for the North Carolina site?**

16 A: In short, statistical analysis of the EFED model and monitoring data for the North
 17 Carolina site indicates that the model does not perform well. The mean of the monitoring data is
 18 a better estimate of the observed data than the model, indicating the model has no value as a
 19 predictive tool for future conditions. Given that the mean of observed data is a better predictor

1 of observed data than both EFED models, the mean of the observed data is the best predictor of
 2 future conditions. This supports continued collection of monitoring data to evaluate future trends
 3 and to address and clarify concerns of accumulation and the use of observed monitoring data
 4 rather than EPA’s modeling to guide regulatory determinations.

5 **Q: Please describe your statistical analysis of EFED’s modeling of flubendiamide and**
 6 **des-iodo concentrations for the Georgia site.**

7 A: A similar analysis was conducted for the Georgia monitoring site, which had two ponds
 8 at the site. The results are summarized in the table below (Table 2). A copy of Table 2 is
 9 included at PBNX 83.

10 **Table 2.** NSE, PBIAS, and R² for Georgia site EFED models and monitoring data.
 11

Model	Pond 1			Pond 2		
	NSE	PBIAS (%)	R ²	NSE	PBIAS (%)	R ²
Flubendiamide in Water Column	-4.52	-286	0.24	-2.81	-255	0.12
Flubendiamide in Water Column with Flow Through	-0.51	-121	0.28	-0.15	-103	0.10
Des-iodo in Water Column	-41.27	-661	0.50	-40.15	-748	0.32
Des-iodo in Water Column with Flow Through	0.64	-52	0.55	0.36	-70	0.30
Flubendiamide in Pore Water	-215.65	-2100	0.57	-494.69	-2888	0.34
Flubendiamide in Pore Water with Flow Through	-63.42	-1164	0.43	-149.67	-1616	0.29
Des-iodo in Pore Water	-428.14	-2310	0.59	-2478.93	-5694	0.29
Des-iodo in Pore Water with Flow Through	-21.78	-596	0.51	-152.07	-1574	0.24

12
 13 **Q: Are the statistical performance measures for the Georgia site within the acceptable**
 14 **range?**

15 A: No. Similar to the North Carolina site, all but one of the NSE values are negative for
 16 each pond, indicating the mean of the observed data is a better predictor than the model, and the
 17 only model with a positive NSE (des-iodo in the water column with flow through) is still well

1 below the level for acceptable performance. The very large, negative PBIAS values indicate that
2 the model vastly over predicts des-iodo in pore water, even when water flow through the pond is
3 considered.

4 **Q: How did the statistical measures for the Georgia site compare to those for the North**
5 **Carolina site?**

6 A: The NSE and PBIAS values for the Georgia site were much more negative generally than
7 those for the North Carolina site, suggesting the model deviates more from observed values in
8 Georgia than North Carolina. On the other hand, the R^2 values for the Georgia site were
9 comparable or larger than values for the North Carolina site. The lower NSE values and larger
10 negative PBIAS values at the Georgia site may be due to the grassed waterway at the site.
11 However, the data are insufficient to reach this conclusion.

12 **Q: What are your overall conclusions regarding your statistical analysis of EFED's**
13 **model for the North Carolina and Georgia sites?**

14 A: The statistical analysis of the EFED model performance at both the North Carolina and
15 the Georgia monitoring sites indicates the model performs very poorly. Based on statistical
16 values used by hydrologic/water quality modelers, there is no possibility of the model
17 performance being considered to perform "reasonably well" or "quite well" as the EFED
18 concludes. The only conclusion that should be reached for the EFED models is that they do not
19 perform well. It does not inform the exposure analysis better than the mean of the available field
20 data and should not be used to predict future trends.

1 **F. EFED’s Models Should Be Improved as a Long-Term Objective.**

2 **Q: Did EFED change its modeling approach in the modeling conducted and presented**
3 **in connection with EPA’s recent cancellation determination?**

4 A: Yes. Responding to longstanding criticism from the registrants, EFED updated its
5 modeling to consider variable volume and allow outflow from the modeled farm ponds.

6 **Q: What effect, if any, did this have on the performance of EFED’s modeling?**

7 A: EFED’s effort to improve the representation of pond conditions by considering variable
8 volume (flow through the pond) in the model is a step in the right direction. Model performance
9 was so poor, however, that the statistics do not indicate the model’s ability to simulate the
10 monitored data was improved as compared to the model that did not consider variable volume.

11 **Q: What does this mean for EFED’s modeling approach going forward?**

12 A: Further refinements are needed for representation of reality. Comparison of the modeled
13 concentrations with observed data indicate a significant over-prediction of observed data.
14 Continued refinement in representation of agricultural production and water systems within the
15 model is consistent with EFED’s tiered modeling approach.

16 **Q: Have you identified any other issues in EFED’s modeling approach?**

17 A: Yes. For some locations and situations, the current modeling approach does not represent
18 situations that are ecologically relevant. For example, modeling small ponds in arid regions such
19 as the Central Valley in California that dry up and using constituent concentrations at time steps
20 shortly before the ponds become dry do not represent situations that are of ecological relevance
21 given the severe stresses on the aquatic systems due to the ponds becoming dry. Such ponds are
22 unlikely to even exist given irrigation management practices.

1 **Q: Please describe what additional data and studies are needed in order to improve the**
2 **modeling for flubendiamide and des-iodo concentrations.**

3 A: Pore water data are critical to assessing the impacts of flubendiamide and des-iodo in the
4 environment. In general, pore water concentrations of constituents in the environment are not
5 widely studied, which is reflected in little scientific literature on this issue. Additional study of
6 pore water concentrations of constituents, including those of concern in this report, are needed.
7 Further, few models that predict pore water concentrations are available, and those that are
8 available have not been widely tested. Additional study of pore water and its constituents is
9 needed as is the further development and testing of models for predicting pore water
10 constituents.

11 **G. Monitoring Results Show That Flubendiamide and Des-Iodo Have Not**
12 **Accumulated to Levels of Concern.**

13 **Q: In your opinion, how useful is EFED’s model as a basis for risk assessments and**
14 **regulatory determinations?**

15 A: Because the EFED model does not accurately estimate flubendiamide and des-iodo
16 concentrations, it is not useful in assessing expected des-iodo concentrations to support a
17 science-based risk assessment. Thus, EFED should rely on the available monitoring data only in
18 reaching its regulatory determinations.

19 **Q: What do those data show?**

20 A: The best available monitoring data for exposure or risk evaluation come from the North
21 Carolina and Georgia pond studies, where both water column and pore water concentrations
22 were measured with product usage confirmed in the adjacent field. The following table (Table 3)
23 compares the toxicity endpoints identified by EFED and Bayer (as summarized in EPA’s risk
24 assessment documents) to the maximum values observed in each location for the Bayer

1 monitoring study. The USGS data are included in the summary table for comparative and
 2 confirmatory purposes. A copy of Table 3 is included at PBNX 84.

3 **Table 3.** Maximum observed flubendiamide and des-iodo concentrations compared to toxicity
 4 endpoints.
 5

Water Body	Sampling	Water Column <u>maximum</u> concentration, ppb		Pore Water <u>maximum</u> concentration, ppb	
		Flubendiamide	Des-iodo flubendiamide	Flubendiamide	Des-iodo flubendiamide
Toxicity Endpoints (NOEC / NOAEC)	EFED	15.5	1.9	1.5	0.28
	Bayer	33	4.0	2.6	19.5
Pond	Pond Studies	1.95	0.32	0.30	0.10
Intermittent Stream		0.62	0.05	0.19	0.17
Perennial Stream/River		0.09	0.01	0.19	0.05
Stream / River	USGS	0.93	0.07	not sampled	not sampled

6 Bayer NC and GA pond studies sampled monthly for 4.5 years; USGS – 5,004 samples from national
 7 monitoring network, over 3 years, approx. monthly (not all sites for full duration)
 8

9 As shown in Table 3, the maximum observed concentrations of flubendiamide and des-iodo in
 10 ponds, intermittent streams, and perennial streams in the water column and the pore water are all
 11 below the endpoints identified by EFED and Bayer. The real-world data, including more than
 12 1,000 overlying and pore water pond samples, do not show any concentrations indicating
 13 accumulation to or near identified toxicity endpoints.

14 **Q: What, if anything, do the data in Table 3 indicate with respect to the merits of**
 15 **EPA’s cancellation determination?**

16 A: As Dr. Moore explains in his testimony, the critical factor driving EPA’s cancellation
 17 decision is EPA’s determination that des-iodo levels in pore water will increase beyond the 0.28
 18 ppb endpoint that EPA has identified. As Dr. Moore further explains, EPA’s reliance on the 0.28
 19 ppb level of concern derived from the spiked water study is not scientifically sound, and the
 20 more relevant and scientifically sound endpoint is the 19.5 ppb level of concern from the spiked
 21 sediment study. As shown in the table above, after almost five years of product use in pond

1 settings similar to EFED's modeled pond scenario, not a single sample has exceeded even the
2 incorrect 0.28 ppb level of concern.

3 The maximum measured concentration of des-iodo in pore water was 0.17 ppb, which is
4 below EPA's incorrect 0.28 ppb level of concern, and 115 times lower than the proper 19.5 ppb
5 des-iodo pore water level of concern based on the spiked sediment study. The maximum 0.17
6 ppb pore water concentration was measured at a single site, with concentrations decreasing in
7 subsequent sampling taken at the same site. Moreover, out of 509 pore water samples from
8 Bayer's monitoring studies, only five samples were measured at or above 0.10 ppb.

9 **H. Monitoring of Flubendiamide and Des-Iodo Concentrations Should**
10 **Continue.**

11 **Q: What is your opinion on the continuation of Bayer's monitoring studies?**

12 A: Given the currently available data and the poor performance of the current models in
13 explaining monitored data, data collection efforts should continue. Currently, the mean of the
14 data is a better predictor than EFED's models of actual observations in the Bayer monitoring
15 sites. While the data do not suggest that flubendiamide or des-iodo is accumulating to levels of
16 concern, continuation and potential expansion of the monitoring studies would provide the most
17 reliable data on this question. It is my opinion, therefore, that the monitoring study should
18 continue for perhaps 2-4 additional years and expansion to additional sites should be considered.

19 If the monitoring is continued for a sufficiently long period, I would expect
20 concentrations in the pond sediment and pore water to eventually reach a plateau resulting from
21 the dynamic equilibrium of residues entering and leaving the watershed as described above and
22 confirmed by the monitoring data available to date.

1 **Q: Are there other data that should be considered on an ongoing basis?**

2 A: The USGS data set for flubendiamide and des-iodo in streams and rivers continues to
3 grow. This data set should continue to be explored to understand the concentrations of
4 flubendiamide and des-iodo under actual conditions as well as their spatial and temporal
5 distribution. Data from other sources may also be available that provide insight into the
6 concentrations and distributions of these constituents in the water environment.

7 **V. EXHIBITS**

8 **Q: Dr. Engel, in your testimony you referenced the following exhibits: PBNX 25, 30-31,**
9 **35-36, 50-51, and 80-84. PBNX 25, 30-31, 35-36, and 50-51 were previously produced as**
10 **attachments to Bayer and Nichino's Motion for Accelerated Decision. PBNX 80-84 are**
11 **copies of figures and tables introduced in your testimony and are being produced as part of**
12 **Bayer and Nichino's Prehearing Submission. Are these exhibits true and correct copies of**
13 **the documents you referenced?**

14 A: Yes.

15 **Q: Thank you, Dr. Engel.**

16 **Bayer and Nichino move to enter PBNX 25, 30-31, 35-36, 50-51, and 80-84 into**
17 **evidence.**

18

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

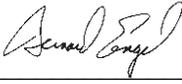
20 Executed on this 21st day of April, 2016.

21

22

23

24



Bernard Engel, Ph.D.

Verified Written Statement Of
Dwayne R. J. Moore, Ph.D.,
(Expert Witness)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of:

Bayer CropScience LP and
Nichino America, Inc.,

Petitioners.

)
)
)
)
)
)

FIFRA-HQ-2016-0001

**VERIFIED WRITTEN STATEMENT OF DWAYNE R. J. MOORE, PH.D.
ON BEHALF OF BAYER CROPSCIENCE LP AND NICHINO AMERICA, INC.**

TABLE OF CONTENTS

	<u>Page</u>
I. PROFESSIONAL EXPERIENCE.....	1
II. SCOPE OF TESTIMONY	4
III. SUMMARY OF CONCLUSIONS.....	5
IV. BACKGROUND	6
V. EPA’S AQUATIC INVERTEBRATE RISK ASSESSMENTS	8
A. EPA’s Ecological Risk Assessments Have Focused on Potential Risks to Benthic Aquatic Invertebrates.....	8
B. EPA Has Identified No Regulatory Risks of Concern for Aquatic Invertebrates Other Than Potential Chronic Risks to Benthic Invertebrates.....	11
VI. DERIVATION OF BENTHIC AQUATIC ENDPOINTS FROM THE SPIKED WATER AND SPIKED SEDIMENT STUDIES	14
A. Background.....	14
B. EPA’s Reliance on the Pore Water NOEC from the Spiked Water Study Is Not Scientifically Sound.....	18
1. The spiked water study is not the most relevant study to determine potential effects on benthic invertebrates for des-iodo.....	18
2. The des-iodo pore water endpoint derived from the spiked water study seriously overestimates potential effects on sediment dwelling invertebrates.....	20
3. The spiked water study has methodological flaws that further undermine its usefulness and reliability.....	22
C. The Spiked Sediment Study Is the Correct Study to Gauge Potential Toxic Effects to Benthic Aquatic Invertebrates.....	24
D. EPA’s Decision Documents Do Not Justify or Explain the Use of the Endpoint from the Spiked Water Study.....	27
E. EPA Did Not Follow Its Own Guidance in Extrapolating Risk Between Aquatic Compartments.....	28
F. Use of the Spiked Sediment Endpoint Results in No Risks of Concern to Benthic Aquatic Invertebrates.....	30
VII. CONCLUSION.....	31
VIII. EXHIBITS	31

1 **I. PROFESSIONAL EXPERIENCE**

2 **Q: Please state your name, and where you are employed.**

3 A: My name is Dr. Dwayne R. J. Moore. I am a Senior Vice President and Senior Scientist
4 at Intrinsik Environmental Sciences (US) Inc., located at 41 Campus Drive, Suite 202, New
5 Gloucester, Maine 04260.

6 **Q: Please describe your education background.**

7 A: I hold a Bachelor's of Science degree in Plant Sciences from the University of Western
8 Ontario, and Masters of Science and Doctor of Philosophy degrees in community ecology from
9 the University of Ottawa.

10 **Q: Please summarize your occupational history.**

11 A: I have served as an ecological risk assessor for the past 25 years, the first seven years
12 with Environment Canada (the Canadian analogue to the U.S. Environmental Protection Agency
13 (EPA)), the next seven years as a Senior Associate with The Cadmus Group, and the last 11
14 years as a Senior Vice President and Senior Scientist with Intrinsik Environmental Sciences.
15 During my career, I have led and conducted numerous refined risk assessments on the effects of
16 industrial chemicals and pesticides to aquatic life and wildlife.

17 While at Environment Canada, I developed guidance for conducting ecological risk
18 assessments of priority industrial substances, led and participated in priority substance
19 assessments, and developed water quality guidelines for toxic chemicals that ensure protection of
20 aquatic life. For the last 17 years, I have served as a consultant and ecological risk assessor to
21 private firms, non-government organizations, and various government agencies in Canada, the
22 United States, Europe and Australia. The agencies have included Environment Canada, Health
23 Canada, Canadian Nuclear Safety Commission, Canadian Department of Fisheries and Oceans,
24 Provinces of British Columbia and Ontario, Canadian Council of Ministers of the Environment,

1 U.S. Army Corps of Engineers, U.S. Department of Energy, U.S. Environmental Protection
2 Agency, Australian Pesticides and Veterinary Medicines Authority, and Department for
3 Environment in the United Kingdom.

4 PBNX 43 is a copy of my curriculum vitae further detailing my qualifications,
5 experience, publications and presentations.

6 **Q: Please describe your professional publications and your involvement in academic
7 and professional institutions.**

8 A: I have authored over 50 peer-reviewed publications and 11 book chapters, edited a book,
9 been a member of editorial boards for two major journals in the area of ecological risk
10 assessment and toxicology, and helped organize many Society of Environmental Toxicology and
11 Chemistry (SETAC) Pellston workshops on specialized topics in risk assessment.

12 **Q: Have you ever served on a FIFRA Scientific Advisory Panel (“SAP”)?**

13 A: Yes, I served on Scientific Advisory Panels convened under FIFRA in 1999, 2000, and
14 2004, addressing issues related to the ecological risks posed by chlorfenapyr, implementation of
15 probabilistic ecological assessments, and development of refined terrestrial and aquatic models
16 for assessments of pesticides. I have also served as a member of the US EPA Scientific
17 Advisory Board in 2006 and 2008, where I participated in a panel on the state of the practice for
18 ecological risk assessment, and provided advice on advancing the science and application of
19 ecological risk assessment in environmental decision making. In 1999, I served on the
20 Terrestrial Peer Input Panel that reviewed the refined terrestrial assessment methods report
21 developed by the Ecological Committee on FIFRA Risk Assessment Methods (ECOFRAM). In
22 2005, I reviewed the report prepared by the National Research Council of the National

1 Academies that convened to determine lessons learned from the Superfund Site Assessment for
2 the Coeur d'Alene River Basin in Idaho.

3 **Q: Please describe your areas of expertise.**

4 A: I am an expert in, among other areas, ecological risk assessments for pesticides and
5 industrial chemicals, wildlife exposure modeling, development of water quality guidelines and
6 criteria for protection of aquatic life, community ecology, statistics, uncertainty analysis, and
7 analysis of toxicity data. Since becoming a consultant in 1996, I have developed probabilistic
8 exposure and risk models for birds and mammals exposed to bait, granular, seed treatment and
9 flowable pesticides. I have also led and participated in many refined aquatic and wildlife
10 exposure and risk assessments for pesticides, including insecticides such as aldicarb, azinphos
11 methyl, bifenthrin, brodifacoum, carbofuran, carbosulfan, chlorpyrifos, clothianidin, dimethoate,
12 diphacinone, imidacloprid, malathion, and methyl parathion.

13 **Q: Please provide a sampling of the work you have performed on behalf of regulatory
14 agencies in Canada and the United States.**

15 A: For Environment Canada, I led a team that developed the guidance manual for deriving
16 Ideal Performance Standards (IPS, equivalent to environmental quality criteria) for pesticides in
17 Canada. Subsequent to preparation of the guidance manual, my team completed development of
18 IPS for protection of aquatic life for 8 priority pesticides in Canada. For the Pest Management
19 Regulatory Agency, I developed their first probabilistic ecological risk assessment for a
20 pesticide, chlorpyrifos. I have also taught several courses on statistics and probabilistic methods
21 to regulatory agencies including Canadian Council of Ministers of the Environment, Canadian
22 Pest Management Regulatory Agency, Ontario Ministry of the Environment, US EPA Office of
23 Pesticide Programs and others. For the Canadian Nuclear Safety Commission, I developed a

1 guidance manual for statistical analysis of monitoring data and for the Canadian Department of
2 Fisheries and Oceans, I reviewed available methods for conducting quantitative uncertainty
3 analyses. I led the ecological risk assessment for the polychlorinated biphenyl (PCBs)-
4 contaminated Housatonic River in Massachusetts on behalf of EPA, and the mercury-
5 contaminated East Fork Poplar Creek in Tennessee on behalf of the US Department of Energy. I
6 also co-led the ecological risk assessment of the Calcasieu Estuary in Louisiana, also on behalf
7 of EPA.

8 **II. SCOPE OF TESTIMONY**

9 **Q: Please describe the scope of testimony that you have been asked to provide.**

10 A: I was engaged by Bayer CropScience LP (Bayer) to review and evaluate the ecological
11 risk assessments conducted by EPA for benthic invertebrates potentially exposed to
12 flubendiamide. Specifically, I was asked: 1) to review the studies, data, guidelines, and risk
13 assessments for benthic invertebrates potentially exposed to flubendiamide and the degradation
14 metabolite, des-iodo flubendiamide (hereafter “des-iodo”), 2) to determine whether EPA had
15 properly evaluated the studies and data and had selected the correct toxicity study results
16 (endpoints) for its risk determination, and 3) to determine whether EPA’s proposed cancellation
17 of flubendiamide due to potential risks to benthic invertebrates was based on sound science.

18 In my analysis, I have considered the ecological risk assessments published by EPA,
19 including recent assessments issued in support of its January 29, 2016 Decision Memorandum,
20 the benthic invertebrates toxicity study reports for flubendiamide and des-iodo, and the
21 guidelines, publications, and other materials cited in this Written Statement.

22 **Q: Bayer and Nichino offer Dr. Moore as an expert in the areas of ecotoxicology;**
23 **ecological risk assessments for pesticides and industrial chemicals; and related areas**

1 **including development of water quality guidelines and criteria for protection of aquatic life**
2 **and analysis of toxicity data.**

3 **III. SUMMARY OF CONCLUSIONS**

4 **Q: Please provide a summary of the conclusions you reached in your analysis.**

5 A: My analysis focused on the issue of the potential chronic risk posed by flubendiamide
6 and des-iodo in sediment pore water to benthic invertebrates, which is the only significant risk
7 issue identified by EPA in its Notice of Intent to Cancel the flubendiamide registrations and the
8 Decision Memorandum explaining its cancellation determination. After review of the relevant
9 documents, studies, and data, and for the reasons described in this testimony, it is my opinion
10 that EPA's assessment of the risk posed to benthic aquatic invertebrates is fundamentally flawed.
11 Therefore, the Agency's decision to cancel on that basis is not supported by the science.

12 More specifically, based on my analysis I conclude that:

- 13 • The toxicity endpoint that EPA uses to justify cancellation of the flubendiamide
14 registrations is not appropriate. The toxicity endpoint for benthic invertebrates of 0.28
15 µg/L of des-iodo in sediment pore water (i.e., the water in the spaces between sediment
16 particles) was derived from a spiked water study that is not relevant for des-iodo and was
17 superseded by a subsequently conducted and more relevant spiked sediment study.
- 18 • The des-iodo spiked water study assesses the potential impacts of an exposure route,
19 spray drift, which is not a significant route of exposure for flubendiamide, and is
20 irrelevant for des-iodo.
- 21 • The spiked water study has other flaws, including a flawed statistical analysis that, if
22 corrected, would lead to a higher endpoint.
- 23 • Prior EPA statements, OECD guidance, and sound scientific considerations confirm that
24 the spiked sediment study is more relevant and the preferred approach to analyzing the
25 potential impacts of flubendiamide and des-iodo on benthic invertebrates.
- 26 • The spiked sediment study mimics the potential gradual buildup of des-iodo that could
27 occur over time in sediment and sediment pore water, as a result of flubendiamide
28 partitioning to sediment and degrading to des-iodo.

- 1 • EPA's decision documents provide no explanation or rationale for their decision to
2 regulate flubendiamide based on the des-iodo spiked water endpoint, rather than the more
3 relevant and scientifically sound des-iodo spiked sediment endpoint.
- 4 • The des-iodo pore water chronic toxicity endpoint based on the spiked sediment study
5 was calculated by EPA to be 19.5 µg/L, which is 70 times higher than the spiked water
6 endpoint EPA wrongly relies on.
- 7 • Observed des-iodo pore water concentrations in water bodies close to flubendiamide-
8 treated fields after five years of monitoring and seven years of product use are well below
9 the sediment pore water endpoint of 19.5 µg/L and thus, flubendiamide application poses
10 no risks of concern.
- 11 • EPA's risk assessments for flubendiamide and des-iodo provide no reliable scientific
12 basis to conclude that benthic invertebrates are at significant risk from the continued
13 registration and use of flubendiamide products.

14 **IV. BACKGROUND**

15 **Q: What is flubendiamide and how is it used?**

16 A: Flubendiamide is a selective, non-systemic insecticide that has been approved by EPA for
17 a variety of uses, including alfalfa, Brassica leafy vegetables, Christmas trees, corn, cotton,
18 cucurbit vegetables, fruiting vegetables, grapes, leafy vegetables, legume vegetables, low-
19 growing berries, peanuts, pistachio, pome fruit (e.g., apple, pear), sorghum, stone fruit (e.g.,
20 apricot, cherry, peach), sugarcane, sunflower, safflower, tobacco, tree nut crops (e.g., almond,
21 cashew, pecan, walnut), and others. Flubendiamide is used to control lepidopteran pests at the
22 larval and adult stages, including armyworms, bollworms, corn borers, cutworms, fruitworms,
23 hornworms, leaf rollers, loopers, moths, and many others. Flubendiamide may be applied by
24 ground spray, aerial spray and/or chemigation (i.e., application through an irrigation system)
25 depending on the formulation and use pattern.

26 **Q: How does flubendiamide work?**

27 A: Flubendiamide is a member of the diamide class of chemistry. Flubendiamide targets the
28 insect ryanodine receptor binding site, a site of little importance in mammals, and interferes with

1 the calcium release channel.¹ As a result, flubendiamide is selectively toxic to insect pests, but
2 has very low toxicity to humans and other mammals.

3 **Q: What is the focus of your analysis and testimony?**

4 A: On March 1, 2016, EPA announced its intent to cancel the registration of four pesticide
5 products containing the active ingredient flubendiamide.² In its Notice of Intent to Cancel
6 (NOIC), EPA explained that it was seeking cancellation based on a determination that continued
7 registration of flubendiamide products “will result in unreasonable adverse effects on the
8 environment.”³ The NOIC and the January 29, 2016 Decision Memorandum cite concerns about
9 flubendiamide’s mobility, persistence, and potential to accumulate, and “the extremely toxic
10 nature of the primary degradate NNI-001-des-iodo [des-iodo] to invertebrates of aquatic
11 systems.”⁴ My analysis is focused on the potential toxicity of flubendiamide and des-iodo to
12 aquatic invertebrates, particularly benthic invertebrates, and whether EPA’s assessment of
13 toxicity endpoints is consistent with sound science.

14 **Q: What topics will you cover in your testimony?**

15 A: In the text that follows, I begin with a general overview of how EPA conducted its
16 aquatic invertebrates assessment for flubendiamide and des-iodo. I then proceed with specific
17 comments on the available sediment toxicity studies for benthic invertebrates and EPA’s
18 rationale for selecting the effects metrics for their assessment from these studies.

¹ J.E. Casida, *Golden Age of RyR and GABA-R Diamide and Isoxazoline Insecticides: Common Genesis, Serendipity, Surprises, Selectivity, and Safety*, 28(4) Chem. Res. Toxicology 560-66 (2015).

² PBNX 19.

³ PBNX 20 at 11,559.

⁴ *Id.*; see also PBNX 30 at 1.

1 **V. EPA'S AQUATIC INVERTEBRATE RISK ASSESSMENTS**

2 **A. EPA's Ecological Risk Assessments Have Focused on Potential Risks to**
3 **Benthic Aquatic Invertebrates.**

4 **Q: Please describe the ecological risk assessments that EPA has conducted for**
5 **flubendiamide.**

6 A: EPA's Environmental Fate and Effects Division (EFED) assessed the ecological risks of
7 flubendiamide and des-iodo in three risk assessments conducted in support of the original
8 flubendiamide registrations in June 2008 and in support of the expansion of the registrations to
9 cover new crops and uses in May 2010 and December 2010.⁵ In connection with its January 29,
10 2016 cancellation determination, EPA issued an ecological risk assessment addendum to address
11 new studies and data that had been received and discussions and evaluations of flubendiamide
12 that had occurred since the December 2010 risk assessment.⁶

13 **Q: In its ecological risk assessments, has EPA identified areas where flubendiamide**
14 **does not pose any regulatory risks of concern?**

15 A: In its flubendiamide risk assessments, EPA has repeatedly confirmed that there are no
16 direct risks of regulatory concern with respect to mammals, birds, fish, crustaceans, estuarine and
17 marine mollusks, beneficial insects, bee pollinators, and plants.⁷

⁵ PBNX 27 (EFED Risk Assessment for the Section 3 New Chemical Registration of Flubendiamide (June 23, 2008)); PBNX 28 (EFED Risk Assessment for Legume Vegetable and Christmas Tree New Uses for the Insecticide Flubendiamide); PBNX 29 (EFED Ecological Risk Assessment for the New Use of Flubendiamide on Alfalfa and Certain Other Crops).

⁶ PBNX 31 (EFED Flubendiamide Ecological Risk Assessment Addendum (Jan. 28, 2016)).

⁷ PBNX 27 at PDF p. 2; PBNX 28 at 3-8 (PDF pp. 22-27); PBNX 29 at 38-41.

1 **Q: What risk of concern has EPA identified as the basis for the Agency’s**
2 **flubendiamide cancellation determination?**

3 A: The ecological concern behind EPA’s January 29, 2016 cancellation determination and
4 the March 4, 2016 NOIC is the potential for chronic risk to aquatic invertebrates.⁸ More
5 specifically, EPA’s concern is that flubendiamide and des-iodo would “accumulate in aquatic
6 systems” over time, “eventually exceeding Agency LOCs [levels of concern]” and creating “a
7 potential for risk to benthic invertebrates.”⁹

8 **Q: What are benthic aquatic invertebrates?**

9 A: Benthic aquatic invertebrates are a class of small organisms that includes insects,
10 crustaceans, mollusks, and worms that are aquatic (live in water), lack backbones (invertebrate),
11 and live in or on the sediment at the bottom of the water body (benthic), for part or all of their
12 life cycle.

13 **Q: Please describe the framework EPA used for assessing the ecological risks of**
14 **flubendiamide.**

15 A: In its original three ecological risk assessments, EPA assessed potential risk to aquatic
16 invertebrates with a screening-level (Level 1) risk assessment in which acute and chronic
17 estimated environmental concentrations (EECs) in overlying and benthic pore water and bulk
18 sediment were compared to corresponding effects endpoints (e.g., LC50 [concentration causing
19 50% mortality] for acute effects, NOEC¹⁰ [No observed effects concentration] for chronic

⁸ PBNX 30 at 10; PBNX 20 at 11,559.

⁹ PBNX 30 at 3.

¹⁰ In its assessments and data evaluation records, EPA uses the terms “No Observed Effect Concentration” (NOEC) and “No Observed Adverse Effect Concentration” (NOAEC) interchangeably. The two terms have slightly different meanings as a NOEC may also be derived for beneficial effects. To avoid confusion herein, I will use the NOEC nomenclature throughout.

1 effects) for aquatic invertebrates. This analysis results in a risk quotient (RQ, i.e., Acute RQ =
2 EEC/LC50 and chronic RQ = EEC/NOEC) to quantify the potential risk. EPA compares each
3 risk quotient to the corresponding Level of Concern (LOC, e.g., LOC for acute restricted use for
4 aquatic species = 0.05, LOC for chronic risk to all species = 1). Separate analyses were
5 conducted for flubendiamide and des-iodo.

6 EPA's January 28, 2016 ecological risk addendum provided in connection with its
7 cancellation determination (PBNX 31) was conducted after the generation of higher-tier, more
8 relevant data, including five years of real-world monitoring data and more environmentally
9 relevant toxicity data.

10 **Q: What is your understanding of EPA's approach to estimating environmental**
11 **exposures in its latest risk assessment and cancellation determination?**

12 A: As described in Dr. Engel's testimony, EPA's most recent risk assessment addendum
13 fails to properly reflect the higher-tier, real-world monitoring data, and its environmental
14 exposure estimates are based on overly conservative, theoretical modeling that does not
15 accurately reflect or predict real-world exposures.

16 **Q: What is your opinion on the toxicity endpoints EPA relies on to support its**
17 **cancellation determination?**

18 A: As discussed below, EPA's most recent risk assessment addendum (PBNX 31) and the
19 reasoning EPA provided in support of its cancellation determination (PBNX 30) ignore the
20 results of more relevant toxicity studies. EPA's ecological risk assessment relies on a toxicity
21 endpoint that is far lower than the science supports. For the reasons discussed below, EPA's
22 proposed cancellation of flubendiamide based on the spiked water toxicity endpoint for des-iodo
23 is not supported by the current science.

1 **B. EPA Has Identified No Regulatory Risks of Concern for Aquatic**
2 **Invertebrates Other Than Potential Chronic Risks to Benthic Invertebrates.**

3 **Q: What studies, if any, have been conducted to assess risks to aquatic invertebrates?**

4 A: Acute and chronic toxicity tests involving aquatic invertebrates have been conducted for
5 flubendiamide and des-iodo. Studies were conducted using water-only systems and on systems
6 containing water and sediment.

7 **Q: Please summarize the results of studies conducted using water-only study systems.**

8 A: Testing was conducted on *Daphnia magna*, a small crustacean also known as a water
9 flea, to evaluate the potential impacts on water column dwelling (i.e., non-sediment dwelling)
10 aquatic invertebrates to an acute exposure to flubendiamide and des-iodo and chronic exposure
11 to flubendiamide. These studies all showed no observed adverse effects at concentrations up to
12 their limits of solubility (29.9 µg/L for flubendiamide and 187 µg/L for des-iodo).¹¹ Similarly,
13 the following sediment dwelling species experienced no adverse effects to flubendiamide
14 exposure concentrations of 30 µg/L (the solubility limit for flubendiamide) or des-iodo
15 concentrations of 200 µg/L (slightly higher than the solubility limit for des-iodo) following acute
16 exposures in water only trials: *Lumbriculus variegatus*, *Hyaella azteca*, *Centroptilum*
17 *triangulifer*, *Chironomus tentans* and *Chironomus riparius*.¹² Because concentrations of
18 flubendiamide and des-iodo in water in the environment are limited by their solubility, these
19 studies indicate that the tested species could not be at acute risk in the environment as a result of
20 exposure to flubendiamide or des-iodo in the overlying water.

¹¹ PBNX 29 at 24.

¹² S. Thomas and H.O. Krueger, Wildlife International, Ltd., Benthic Organism Acute Toxicity Screens for Flubendiamide and NNI-0001 des-iodo, Bayer Study No. EBAMY010 (2010).

1 Acute and chronic toxicity testing of *D. magna* using formulated products showed risk
2 quotients that exceeded EPA's LOCs for some use patterns.¹³ However, as EPA has recognized,
3 chronic exposure is not a concern for the formulated products because the products do not persist
4 in their formulations in the aquatic environment. Acute exposure to formulated products is
5 likewise not a source of significant regulatory concern. As EPA confirmed in the January 29,
6 2016 Decision Memorandum, "[t]he acute risk issue is relatively minor and refers to enhanced
7 toxicity of the formulations" which is "applicable only to direct application to aquatic
8 environments through spray drift."¹⁴ However, spray drift exposure from flubendiamide is not a
9 significant concern, because "most of the contributions to aquatic environments are from means
10 other than spray drift (runoff and erosion)."¹⁵

11 **Q: What is the significance of these studies?**

12 A: As *D. magna* is the standard and well vetted surrogate for water column invertebrates in
13 ecotoxicity testing for pesticides, the above indicates that flubendiamide and des-iodo pose no
14 risks to water column dwelling (i.e., non-sediment dwelling) invertebrates. The lack of acute
15 effects on additional species at the solubility limits for flubendiamide and des-iodo further
16 supports the conclusion that these compounds pose no risk to water column invertebrates.

17 **Q: Please describe the studies conducted using water and sediment test systems.**

18 A: Studies of the potential chronic effects of flubendiamide and des-iodo on a benthic
19 aquatic invertebrate (*Chironomus riparius*, a type of midge also known as the harlequin fly) were
20 conducted using methods that included both water and sediment phases in one test system. The
21 first set of studies conducted and submitted to EPA were spiked water studies of flubendiamide

¹³ PBNX 27 at 53-54; PBNX 28 at 42-43; PBNX 29 at 29-30.

¹⁴ PBNX 30 at 3.

¹⁵ PBNX 27 at 68.

1 and des-iodo, in which the test material is introduced directly into the overlying water and
2 equilibrates between the overlying water, sediment, and sediment pore water during the test. The
3 second set of studies conducted and submitted to EPA were spiked sediment studies, in which
4 the test material is introduced into the sediment and the system is allowed to equilibrate before
5 the study begins.

6 **Q: Why are these studies significant?**

7 A: My analysis focuses on these studies because chronic risks to benthic aquatic
8 invertebrates have been identified by EPA as the only significant ecological risks of concern and
9 are the risks that EPA relies on to justify its cancellation determination.¹⁶ EPA's effects
10 endpoints for benthic aquatic invertebrates are lower for des-iodo than for flubendiamide, and
11 EPA's calculated RQs for des-iodo are higher.

12 **Q: How did EPA use these studies in its ecological risk assessment and cancellation
13 determination?**

14 A: In estimating chronic risk of flubendiamide and des-iodo to sediment dwelling aquatic
15 invertebrates, EPA relied on the results of spiked water studies for the midge, *Chironomus*
16 *riparius*. For the reasons I will discuss, it is my opinion that EPA's reliance on the results of the
17 spiked water studies to evaluate chronic risk to benthic aquatic invertebrates, rather than the
18 subsequent, more relevant spiked sediment studies, is not scientifically justified. As a result,
19 EPA's risk assessments for flubendiamide and des-iodo are flawed, and provide no reliable
20 scientific basis to conclude that benthic invertebrates are at significant risk from the continued
21 registration and use of flubendiamide products.

¹⁶ See, e.g., PBNX 30 at 10.

1 **VI. DERIVATION OF BENTHIC AQUATIC ENDPOINTS FROM THE SPIKED**
2 **WATER AND SPIKED SEDIMENT STUDIES**

3 **A. Background**

4 **Q: Let's discuss in more detail the chronic sediment studies conducted in support of**
5 **flubendiamide. Why were studies conducted with des-iodo as well as flubendiamide?**

6 A: Bayer CropScience conducted chronic toxicity testing on the degradation metabolite des-
7 iodo because initial toxicity studies suggested that des-iodo might be more toxic than the parent
8 compound flubendiamide for some receptor groups, e.g., sediment dwelling invertebrates.

9 **Q: What guidelines, if any, are there for conducting the chronic sediment tests?**

10 A: Following a standardized guideline for toxicity testing is important to ensure that the
11 results of the study are accurate and of the highest quality. To date, EPA has not published
12 guidelines for the conduct of chronic sediment testing.¹⁷ The Organisation for Economic Co-
13 operation and Development (OECD) has published guidelines for the conduct of standardized
14 toxicity studies, including chronic sediment studies.¹⁸

15 **Q: Please describe the chronic sediment tests conducted by Bayer in further detail.**

16 A: Bayer CropScience generated two chronic sediment toxicity studies involving exposure
17 of the midge, *C. riparius*, to des-iodo: one in which overlying water was spiked (hereafter
18 referred to as “the spiked water study”), which was submitted in support of the original
19 registrations,¹⁹ and one in which sediment was spiked (hereafter referred to as “the spiked

¹⁷ PBNX 44 at 11 (EFED Memorandum re Toxicity Testing and Ecological Risk Assessment Guidance for Benthic Invertebrates (Apr. 10, 2014)).

¹⁸ OECD Guidelines for the Testing of Chemicals, Section 2, available at http://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals_chem_guide_pkg-en (last visited Apr. 8, 2016).

¹⁹ Bayer CropScience AG, *Chironomus riparius* 28-Day Chronic Toxicity Test With NNI-001-des-iodo in a Water-Sediment System Using Spiked Water, Report No. DOM 23069 (2004) (“Spiked Water Study Report”).

1 sediment study”), which was conducted and submitted in 2010.²⁰ Similar studies were submitted
2 for flubendiamide.

3 The spiked water study followed the OECD guideline for sediment-water chironomid
4 toxicity tests using spiked water.²¹ OECD guidelines state that spiked water studies are
5 “intended to simulate a pesticide spray drift event.”²²

6 The spiked sediment study followed the OECD guideline for sediment-water chironomid
7 toxicity tests using spiked sediment.²³ The OECD guideline document for the spiked sediment
8 study states that such tests are “intended to simulate accumulated levels of chemicals persisting
9 in the sediment.”²⁴

10 The spiked water and spiked sediment studies both exposed *C. riparius* individuals from
11 their first instar through emergence and monitored time to emergence and survival of both males
12 and females. Because the chronic RQs are higher for des-iodo compared to the parent
13 compound, and because the des-iodo RQs are driving EPA’s cancellation decision, the remainder
14 of this section focuses on des-iodo. Many of the points, however, also apply to the
15 flubendiamide studies.

²⁰ S. Thomas et al., Wildlife International, Ltd., [14C]NNI-0001-desiodo: A Prolonged Sediment Toxicity Test With *Chironomus riparius* Using Spiked Sediment, Final Report, Bayer Study No. EBAMY006 (2010) (“Spiked Sediment Study Report”).

²¹ PBNX 45 (OECD Guidelines, Test No. 219: Sediment-Water Chironomid Toxicity Test Using Spiked Water (Apr. 13, 2004)).

²² *Id.* at 1.

²³ PBNX 46 (OECD Guidelines, Test No. 218: Sediment-Water Chironomid Toxicity Test Using Spiked Sediment (Apr. 13, 2004)).

²⁴ *Id.* at 1.

1 **Q: What were the reported results from the des-iodo spiked water study?**

2 A: In the spiked water study for des-iodo, the reported No Observed Effect Concentration
3 (NOEC) for the most sensitive endpoint (percent emergence) was 4 µg/L des-iodo in the
4 overlying water. This value is based on the nominal concentrations of des-iodo added to the
5 overlying water.

6 **Q: Did EPA adopt the 4 µg/L NOEC for des-iodo for the spiked water study?**

7 A: No. EPA chose to use the analytical data from the spiked water study to calculate a time-
8 weighted average (TWA) NOEC for des-iodo in sediment pore water of 0.28 µg/L.²⁵ The NOEC
9 of 0.28 µg/L for des-iodo in sediment pore water derived from the spiked water study is the most
10 sensitive endpoint for aquatic invertebrates, and EPA's cancellation determination is based on
11 predicted exceedances of this NOEC.

12 **Q: What is your opinion on EPA's calculation of the 0.28 µg/L des-iodo sediment pore
13 water NOEC?**

14 A: The calculation of a TWA NOEC for des-iodo in sediment pore water for a spiked water
15 study is not supported by sound science. As noted by the European Commission, spiked water
16 NOECs should be calculated for overlying water and then compared to estimated concentrations
17 in that compartment.²⁶ This is because at the outset of the test, concentrations in overlying water
18 vastly exceed the concentrations in pore water and thus any observed toxicity is likely the result
19 of exposure to overlying water. Including the largely irrelevant, very low initial concentrations
20 in sediment pore water in the TWA calculation skews the NOEC downward. Analytical data
21 from the spiked water study may be used to study partitioning behavior over time from overlying

²⁵ PBNX 33 at 15 (Des-iodo Spiked Water Study Data Evaluation Record (May 21, 2008)).

²⁶ PBNX 47 at 18 (European Commission, Working Document: Guidance Document on Aquatic Toxicology (Oct. 17, 2002)).

1 water to sediment and sediment pore water, but it was never intended to derive toxicity endpoints
2 for sediment and pore water.

3 **Q: What were the reported results of the des-iodo spiked sediment study?**

4 A: As noted above, the spiked sediment study was conducted specifically to assess potential
5 toxicity to sediment dwelling invertebrates in sediment pore water due to the potential
6 accumulation of des-iodo residues over time. The reported NOEC for des-iodo in the spiked
7 sediment study based on measured concentrations (consistent with OECD guidance and standard
8 practice) was 22 µg/L of des-iodo in sediment pore water, which was the highest level tested.
9 The actual level at which impacts on benthic invertebrates begin to occur was not determined in
10 the study and could be significantly higher.

11 **Q: Did EPA adopt the 22 µg/L NOEC for des-iodo for the spiked sediment study?**

12 A: No. In reviewing this study, EPA again chose to calculate a TWA endpoint, resulting in
13 a somewhat lower NOEC of 19.5 µg/L of des-iodo in sediment pore water.²⁷ The difference
14 from this value to the reported result is not as significant as for the spiked water study, because
15 for the spiked sediment study the system is allowed to equilibrate before the study begins.

16 Notably, the EPA-calculated NOEC of 19.5 µg/L is approximately 70 times higher than
17 the NOEC of 0.28 µg/L EPA derived from the less relevant spiked water study.

18 **Q: What is your opinion on EPA's reliance on the 0.28 µg/L des-iodo sediment pore
19 water endpoint in its risk assessment?**

20 A: The spiked water study has major flaws that should have precluded its use in the des-iodo
21 risk assessment for benthic invertebrates. As discussed in Section B below, the flaws include,
22 most significantly, the use of an exposure route quite different from what would occur in real-

²⁷ PBNX 34 at 14 (Des-iodo Spiked Sediment Study Data Evaluation Record (July 19, 2011)).

1 world conditions, resulting in significant overestimation of toxicity and risk. The spiked water
2 study also used inappropriate statistical analyses and laboratory conditions that differ from those
3 specified in OECD guidelines. As discussed below, a more appropriate and scientifically
4 relevant spiked sediment study is available and should have been used in the benthic
5 invertebrates risk assessment for des-iodo.

6 **B. EPA’s Reliance on the Pore Water NOEC from the Spiked Water Study Is**
7 **Not Scientifically Sound.**

8 **1. The spiked water study is not the most relevant study to determine**
9 **potential effects on benthic invertebrates for des-iodo.**

10 **Q: Which type of study is considered more relevant to the risk of concern identified by**
11 **EPA?**

12 A: As noted above, the OECD guideline document for spiked water studies states that such
13 tests are “intended to simulate a pesticide spray drift event,” whereas the OECD guideline for
14 spiked sediment studies states that those tests are “intended to simulate accumulated levels of
15 chemicals persisting in the sediment.”²⁸ Because the primary concern identified by EPA is the
16 potential accumulation of flubendiamide and its degradate des-iodo in sediment and sediment
17 pore water, the spiked sediment study is the more relevant and scientifically correct study to
18 measure potential effects to sediment dwelling invertebrates.

19 EPA previously agreed with this point. For example, in its May 2008 review of the
20 spiked water study, EPA identified as a “Major Guideline Deviation” the fact that “[o]verlying
21 water was spiked,” noting that EPA “prefer[s] that the sediment is spiked.”²⁹ As a result, Bayer
22 conducted a study using the preferred and more relevant spiked sediment approach, resulting in a
23 sediment pore water NOEC of 19.5 µg/L (EPA calculated) or 22 µg/L (derived in the study

²⁸ PBNX 45 at 1; PBNX 46 at 1.

²⁹ PBNX 33 at 2.

1 report). However, EPA decided in its final risk assessment addendum supporting the
2 cancellation decision to revert to the superseded and scientifically less sound NOEC of 0.28 µg/L
3 from the spiked water study.

4 **Q: Why is the spiked sediment study more relevant?**

5 A: The greater relevance and reliability of the spiked sediment study is confirmed when one
6 considers the characteristics of flubendiamide and des-iodo and their behavior in the
7 environment. Flubendiamide degrades slowly under laboratory and field conditions.³⁰ The two
8 major degradation routes, aquatic and soil photolysis and anaerobic aquatic metabolism, could
9 not occur during spray drift. Using the pesticide spray drift route of exposure for des-iodo is
10 inappropriate because flubendiamide cannot degrade to des-iodo during spray drift prior to
11 entering the aquatic environment.

12 Further, runoff of des-iodo to aquatic systems in large spikes is highly unlikely given the
13 very slow degradation rate from the flubendiamide parent compound to des-iodo in soil. Des-
14 iodo has, in fact, only been detected in minor amounts in the top soil layers in three field
15 dissipation studies.³¹ Thus, runoff is likely to contribute small pulses of des-iodo to water
16 bodies over extended periods of time rather than large, short-term spikes. As described in Dr.
17 Engel's testimony, monitoring studies conducted by Bayer CropScience in a Georgia pond
18 demonstrated that des-iodo concentration maxima occurred several months after flubendiamide
19 concentrations peaked. Such a result is a strong indication that des-iodo in the sediment was the

³⁰ PBNX 27 at 12 (PDF p. 17); PBNX 28 at 10 (PDF p. 29).

³¹ P. Babczinski, Bayer CropScience AG, Outdoor Soil Degradation of 14C-NNI-0001, Study No. M1251280-9 (2004); H. Reiner, Bayer CropScience AG, Metabolism of [phthalic acid ring-UL-14C]NNI-0001 in Confined Rotational Crops, Report MEF-008/03, DOMA Edition No. MO-04-009109 (2004); H. Reiner, Bayer CropScience AG, Metabolism of [aniline ring-UL-14C]NNI-0001 in Confined Rotational Crops, Study No. M 1301192-7 (2004).

1 result of slow degradation of the parent compound in sediment rather than transport to aquatic
2 systems by spray drift or runoff events shortly after application.

3 **Q: Please summarize your opinions on EPA's use of the spiked water study endpoint**
4 **instead of the spiked sediment study endpoint.**

5 A: OECD guidance, EPA's own assessments, and sound science dictate that the spiked
6 sediment study is the most relevant and scientifically sound study for measuring potential toxic
7 effects of des-iodo through agricultural runoff and degradation. EPA's reliance on the NOEC of
8 0.28 µg/L from the spiked water study to justify its cancellation determination is not
9 scientifically sound.

10 **2. The des-iodo pore water endpoint derived from the spiked water**
11 **study seriously overestimates potential effects on sediment dwelling**
12 **invertebrates.**

13 **Q: What is the practical effect of EPA's use of the spiked water study endpoint?**

14 A: The use of a simulated spray drift event to derive a sediment pore water NOEC for *C.*
15 *riparius* larvae exposed to des-iodo in pore water seriously overestimates potential toxicity.

16 Spiking water with a pesticide results in high concentrations in the overlying water
17 immediately following test initiation. The concentrations in overlying water then decline as the
18 compound moves into the sediment compartment. Indeed, measured concentrations in the spiked
19 water study demonstrated highest concentrations of des-iodo in overlying water on Day 0 of the
20 spiked water study followed by a steady decline to roughly one third of initial concentrations by
21 Day 28.³² Conversely, concentrations in sediment pore water were low initially, followed by a
22 peak on Day 7 and slow decline to Day 28.³³

³² Spiked Water Study Report at 19-20.

³³ *Id.*

1 This is significant because sediment-water studies evaluate overall toxicity of the system
2 and are not designed to provide toxicity endpoints for each of the overlying water, pore water,
3 and bulk sediment media. The exposure route in sediment-water studies dictates which toxicity
4 endpoint is the most meaningful. In the case of spiked water studies, the exposure route being
5 evaluated is spray drift added to the overlying water. Thus, for this type of study and according
6 to the OECD guidelines, it is the overlying water NOEC that is the most meaningful endpoint.
7 Analytical pore water measurements are useful to help understand the partitioning behavior of
8 pesticides over time from the overlying water to sediment and sediment pore water. However,
9 pore water NOECs in spiked water studies are of little relevance and not based on sound science.
10 Not surprisingly, when overlying water is a much less important route of exposure, as in the
11 spiked sediment study, the sediment pore water NOEC increased at least 70-fold to $\geq 19.5 \mu\text{g/L}$.³⁴
12 Previous studies, e.g., Lydy et al. (1990) with carbaryl, parathion and aldicarb,³⁵ have similarly
13 found much increased toxicity for pesticides introduced via spiked water rather than spiked
14 sediment in sediment bioassays with *C. riparius*.

15 **Q: How does EPA's use of the spiked water study endpoint affect its risk assessment?**

16 A: EPA's reliance on the pore water NOEC derived from the spiked water study
17 significantly overestimates the toxicity of des-iodo by measuring the wrong route of exposure,
18 and results in an endpoint that is not relevant to the exposure that would occur in the real world.

³⁴ PBNX 34 at 2.

³⁵ M.J. Lydy et al., *Effects of Sediment and Route of Exposure on the Toxicity and Accumulation of Neutral Lipophilic and Moderately Water Soluble Metabolizable Compounds in the Midge, Chironomus riparius*, in 13 *Aquatic Toxicology and Risk Assessment* 140-64 (W.G. Landis and W.H. van der Schalie eds., 1990).

1 **3. The spiked water study has methodological flaws that further**
2 **undermine its usefulness and reliability.**

3 **Q: Did you reach any other opinions based on your analysis of the spiked water study?**

4 A: Yes. In addition to an inappropriate route of exposure and EPA's use of the wrong
5 medium (i.e., sediment pore water) to calculate the NOEC, the spiked water study contains
6 methodological errors that further undermine the reported toxicity endpoints.

7 **Q: Please describe the methodological errors you noted.**

8 A: First, the statistical analysis reported in the study incorrectly combined data from two sets
9 of controls to increase the statistical power of the study. Two control treatments are necessary
10 when a chemical is poorly soluble in water and must be dissolved in a solvent to reach
11 experimental concentrations. The purpose of the solvent control is to verify that the solvent did
12 not have an additional effect on exposed organisms.³⁶

13 OECD guidelines do not allow combining of data from no-solvent and solvent-control
14 treatments. This type of post hoc data manipulation is unacceptable in statistics, wherein
15 hypotheses must be stated before data are collected.³⁷ Statistical modifications must be made to
16 the level at which significance is determined when post hoc comparisons are made, due to the
17 increased likelihood of falsely rejecting the null hypothesis. In this case, a Holm-Bonferroni
18 correction should have been applied to the p-value.³⁸ This correction using the William's
19 multiple sequential t-test (i.e., the test used by the study authors) would have doubled the NOEC
20 for des-iodo in overlying water in the spiked water study to be 8 µg/L, rather than the 4 µg/L
21 NOEC reported in the study.

³⁶ PBNX 45 at 4-6.

³⁷ J.H. Zar, *Biostatistical Analysis* (5th ed. 2010).

³⁸ H. Abdi, *Holm's Sequential Bonferroni Procedure*, in 2 *Encyclopedia of Research Design* 573-77 (N. Salkind ed., 2010).

1 Second, the control treatments, which each had 4 replicates, were combined after
2 statistical comparison with the Student's t-test. OECD guidelines state that a Student's t-test
3 must include at least 6 replicates for each treatment for the test to be valid. With fewer than the
4 recommended number of replicates, statistical power is reduced, thus reducing the likelihood of
5 finding a significant difference between no-solvent and solvent-control treatments.

6 Third, in the original analyses, the no-solvent and solvent-control results were
7 inappropriately statistically compared to exposure treatment results using William's multiple
8 sequential t-test. This test allows multiple means to be compared to a single value (i.e., the
9 control), but requires that all results trend in a monotonic manner (i.e., magnitude of effect
10 increases as treatment concentration increases).³⁹ However, the spiked water study with des-iodo
11 did not have a monotonic concentration-response relationship for the most sensitive endpoint
12 (i.e., percent emergence), and therefore using William's test to analyze the data was
13 inappropriate.⁴⁰ A more appropriate statistical test for this scenario is Dunnett's test.⁴¹ When the
14 data are analyzed using Dunnett's test, with the control treatments separated, the NOEC for des-
15 iodo in overlying water is 8 µg/L, twice the NOEC in the original analyses.

16 Fourth, the OECD guidelines provide specific instructions regarding study conditions in
17 sediment toxicity studies, e.g., sediment composition and provision of food to test organisms.
18 The spiked water study had several issues in this regard. For example, the OECD guidelines

³⁹ F. Bretz and L.A. Hothorn, *A Powerful Alternative to William's Test With Application to Toxicological Dose-Response Relationships of Normally Distributed Data*, 7(2) *Envtl. & Ecological Stat.* 135-54 (2000).

⁴⁰ *Id.*

⁴¹ PBNX 48 at 37, 42, 58 (OECD, *Current Approaches in the Statistical Analysis of Ecotoxicity Data: A Guidance to Application* (May 9, 2006)).

1 specify that the peat in the sediment must have a pH of 5.5-6.0 and be air dried.⁴² The spiked
2 water study used peat that had a pH of 2-4, and no mention was made of how the peat was dried.
3 In addition, the OECD guidelines specify provision of 0.25-0.5 mg of fish food/day/chironomid
4 larvae for the first 10 days of the test and 0.5-1 mg of fish food/day/chironomid larvae for days
5 11 to 28.⁴³ In the spiked water study, feeding rates were 1 mg of fish food/day/chironomid
6 larvae each day of the study. The impact of the departures from OECD guidelines with regard to
7 sediment pH and feeding rate are unknown, but it is possible that the behavior, bioavailability
8 and toxicity of des-iodo to chironomids may have been affected.

9 **C. The Spiked Sediment Study Is the Correct Study to Gauge Potential Toxic**
10 **Effects to Benthic Aquatic Invertebrates.**

11 **Q: What study should have been used to assess the potential impact of des-iodo on**
12 **benthic aquatic invertebrates?**

13 A: As discussed above, the OECD guideline for sediment-water chironomid toxicity tests
14 using spiked sediment states that these tests are “intended to simulate accumulated levels of
15 chemicals persisting in the sediment,” and EPA previously identified the spiked sediment study
16 as its preferred approach for these purposes as well.⁴⁴ The spiked sediment study for des-iodo
17 followed the appropriate exposure regime for des-iodo because the degradate would potentially
18 accumulate slowly over time in the sediment rather than arriving as a pulse in the overlying
19 water from spray drift or runoff events shortly after application. Sediment pore water exposure
20 would cease following adult emergence to the terrestrial environment.

⁴² PBNX 45 at 3.

⁴³ *Id.* at 7.

⁴⁴ PBNX 46 at 1; PBNX 33 at 2.

1 **Q: What are the relevant toxicological endpoints from the spiked sediment study?**

2 A: According to EPA, the TWA NOECs for the des-iodo spiked sediment study were 7.18
3 µg/L in overlying water, and 19.5 µg/L in sediment pore water.⁴⁵ The study report, consistent
4 with the OECD reporting guidelines, reports a slightly higher NOEC of 22 µg/L in sediment pore
5 water based on mean, measured concentrations. However, the actual NOECs in the spiked
6 sediment study are likely higher than all of these values because no effects were observed at *any*
7 test concentration for any endpoint including mortality, mean development time, mean
8 emergence ratio or development rate.⁴⁶

9 **Q: Did you note any methodological flaws with respect to the spiked sediment study?**

10 A: The spiked sediment study for des-iodo, like the spiked water study, also pooled the data
11 from blank and solvent controls for the statistical analyses.⁴⁷ However, when the proper
12 statistical tests – either a Holm-Bonferroni p-value correction or a Dunnett’s test with separate
13 control groups – are used, the results are unchanged, i.e., no statistically significant effects occur
14 with any endpoint for any test concentration. Thus, the time-weighted average NOEC of 19.5
15 µg/L calculated by EPA for des-iodo in sediment pore water⁴⁸ is unaffected.

16 The spiked sediment study for des-iodo had several minor deviations from the OECD
17 guideline⁴⁹: 1) ground rabbit food was used instead of flaked fish food, 2) the light intensity was
18 446 lux, which is below the 500 – 1000 lux range specified in the guideline, and 3) the pH of the

⁴⁵ PBNX 34 at 2.

⁴⁶ Spiked Sediment Study Report at 21.

⁴⁷ *Id.* at 16.

⁴⁸ PBNX 34 at 2.

⁴⁹ PBNX 46 at 6, 9.

1 peat component was not reported and the moisture content of the sediment was below
2 recommended levels.

3 Control mortality in the spiked sediment study for des-iodo was less than 30%, and thus
4 acceptable. In addition, the authors observed that unusual chironomid behaviors “were few in
5 number and occurred in the controls as well as the treatment groups . . . [any unusual behaviors
6 observed] were not considered to be treatment-related.”⁵⁰

7 **Q: How do these flaws impact the spiked sediment study results?**

8 A: Although the spiked sediment study has minor flaws, the flaws do not detract from the
9 results of the study. This sentiment was echoed in the EPA’s reviewer comments, i.e., “there
10 were no significant deviations from OECD Guideline 218 that would affect the scientific
11 soundness of this study.”⁵¹ Furthermore, the exposure route in the spiked sediment study, i.e.,
12 potential accumulation in sediment pore water as a result of degradation of the parent compound,
13 mirrors the exposure route for benthic invertebrates in aquatic systems near treated areas.

14 **Q: What is the toxicity endpoint EPA calculated based on the spiked sediment study?**

15 A: The time-weighted average NOEC in sediment pore water for *C. riparius* exposed to des-
16 iodo in the spiked sediment study is 19.5 µg/L,⁵² which is 70-fold higher than the corresponding
17 NOEC of 0.28 µg/L⁵³ in the spiked water study. The difference may in fact be greater because
18 no effects were observed in the spiked sediment study and thus the Lowest Observed Effect
19 Concentration (LOEC) is unknown and the NOEC is a lower bound.

⁵⁰ Spiked Sediment Study Report at 20.

⁵¹ PBNX 34 at 19.

⁵² *Id.* at 2.

⁵³ PBNX 33 at 15.

1 **D. EPA’s Decision Documents Do Not Justify or Explain the Use of the**
2 **Endpoint from the Spiked Water Study.**

3 **Q: Did EPA provide an explanation for its decision to base its cancellation decision on**
4 **the spiked water study endpoint?**

5 A: The documents EPA has produced in support of its cancellation decision do not justify or
6 explain in any transparent fashion the Agency’s decision to rely on the scientifically incorrect
7 pore water NOEC of 0.28 µg/L for des-iodo to support its cancellation determination.

8 EFED’s January 28, 2016 Ecological Risk Assessment Addendum suggests that the
9 NOEC of 0.28 µg/L was EPA’s consistent position, by comparing EPA’s current use of that
10 endpoint to the June 2008, May 2010, and December 2010 risk assessments.⁵⁴ Yet those
11 assessments were all conducted before EPA completed and released its July 2011 review of the
12 spiked sediment study, which EPA “prefer[s]” and which results in a more scientifically relevant
13 and much higher 19.5 µg/L endpoint.⁵⁵

14 Although EPA’s reversion to the NOEC of 0.28 µg/L in December 2015 was the subject
15 of significant discussion between the registrants and EPA leading up to the January 29, 2016
16 cancellation determination, the January 28, 2016 EFED Addendum and the January 29, 2016
17 Decision Memorandum do not mention, let alone provide an explanation for, EPA’s decision to
18 regulate flubendiamide based on the superseded spiked water study. Instead, both documents
19 simply present the 19.5 µg/L endpoint from the spiked sediment study as among the “final suite”
20 of available effects toxicity endpoints.⁵⁶

⁵⁴ PBNX 31 at 8.

⁵⁵ PBNX 33 at 2; PBNX 34 at 2.

⁵⁶ PBNX 30 at 5; PBNX 31 at 9.

1 Only by examining the underlying data and modeling and comparing them to EPA’s
2 statements regarding the exceedances is it clear that EPA selected the 0.28 µg/L endpoint as an
3 “Agency LOC” [level of concern] and the basis for its cancellation determination, while rejecting
4 and incorrectly characterizing the 19.5 µg/L endpoint as a “[Bayer/Nichino]-suggested” endpoint
5 with which EPA did not agree.⁵⁷ As a former regulator, and as a scientist who has spent years
6 conducting and assessing ecotoxicological risk assessments, I found EPA’s lack of discussion of
7 this point striking. Given how critical EPA’s choice of endpoint was to its cancellation
8 determination, the Agency’s lack of transparency about how and why that endpoint was selected
9 is troubling.

10 **E. EPA Did Not Follow Its Own Guidance in Extrapolating Risk Between**
11 **Aquatic Compartments.**

12 **Q: Have you reviewed the January 29, 2016 Addendum to Clarify Invertebrate**
13 **Terminology that EPA provided in connection with its cancellation determination?**

14 A: Yes.

15 **Q: Was there a part of that Addendum that struck you as relevant to EPA’s selection**
16 **and use of aquatic invertebrate toxicity endpoints?**

17 A: Yes. In the “Invertebrate Terminology” Addendum, EPA makes the following statement:
18 “As a second policy check, EFED consulted guidance entitled ‘Toxicity Testing and Ecological
19 Risk Assessment Guidance for Benthic Invertebrates’ (USEPA 2014), which suggests that
20 endpoints from water-only toxicity tests with invertebrates are important risk evaluation tools to
21 ascertain potential risk to sediment organisms because bioavailability into benthic organisms is
22 largely mediated by dissolved concentrations of the toxicant in sediment pore waters or

⁵⁷ PBNX 30 at 7.

1 overlying water.”⁵⁸ The Addendum then goes on to state, “It then follows that risk estimates
2 based on water column environmental exposures compared with overlying water expressed
3 endpoints from sediment toxicity tests with invertebrates would have reasonable applicability as
4 a surrogate for risks to aquatic invertebrates existing in the water column because the dissolved
5 water concentration of the toxicant remains the important source of exposure.”⁵⁹

6 **Q: What do you understand this to mean?**

7 A: What EPA is stating in a convoluted way is that dissolved pesticide concentrations
8 control toxicity to both sediment dwelling and water column dwelling invertebrates and thus risk
9 can be extrapolated between the two receptor groups.

10 **Q: Does this type of extrapolation make sense for flubendiamide and des-iodo?**

11 A: No, it does not. What the Invertebrate Terminology Addendum fails to note is that
12 EPA’s 2014 guidance document states that “pesticides with higher sorption [to sediment]
13 (partitioning) values are expected to result in greater exposure of benthic-dwelling invertebrates
14 compared to pesticides with lower sorption values.”⁶⁰ Because invertebrates that only occur in
15 the water column (i.e., pelagic invertebrates) are not exposed to sediment, they would have lower
16 exposures than benthic invertebrates for pesticides that readily sorb to sediment particles.
17 Flubendiamide and des-iodo readily bind to sediment.⁶¹ Thus, risks cannot be extrapolated
18 between water column dwelling and sediment dwelling invertebrates because the former have
19 lower exposures than do the latter for pesticides that readily bind to sediment such as
20 flubendiamide and des-iodo.

⁵⁸ PBNX 32 at 2-3.

⁵⁹ *Id.* at 3.

⁶⁰ PBNX 44 at 4-5.

⁶¹ *See, e.g.*, PBNX 27 at 28.

1 **F. Use of the Spiked Sediment Endpoint Results in No Risks of Concern to**
2 **Benthic Aquatic Invertebrates.**

3 **Q: Do the exposure data indicate any risks of concern based on the 19.5 µg/L sediment**
4 **pore water endpoint from the spiked sediment study?**

5 A: As described in Dr. Engel’s testimony, environmental exposures to des-iodo are properly
6 evaluated using the higher-tier, real-world monitoring data generated by the registrants at EPA’s
7 direction. The results after almost five years of monitoring in water bodies near areas with seven
8 years of product use and the analysis of more than 1,000 overlying and pore water samples, all
9 measured concentrations are well below even the NOEC of 0.28 µg/L for des-iodo that EPA
10 wrongly relies on. The highest measured concentration was 0.17 µg/L, measured at a single site,
11 which subsequently declined in later sampling at the same site. Only five pore water samples
12 had concentrations of des-iodo at or above 0.10 µg/L. The 0.17 µg/L maximum concentration is
13 115 times lower than the scientifically justified NOEC of 19.5 µg/L for des-iodo in pore water
14 from the spiked sediment study.

15 In short, when the correct NOEC from the spiked sediment study is used, chronic risk to
16 benthic invertebrates from exposure to des-iodo in sediment pore water is far less of a concern
17 than portrayed by EPA in recent documents. Observed concentrations in water bodies close to
18 treated fields after five years of monitoring and seven years of product use do not come close to
19 approaching a properly determined sediment pore water NOEC of 19.5 µg/L.

20 **Q: Do the exposure data show any exceedances of any of the toxicological endpoints**
21 **identified by EPA or Bayer?**

22 A: No. As shown in Table 3 to Dr. Engel’s written testimony, the maximum observed
23 concentrations of flubendiamide and des-iodo in overlying water and sediment pore water are
24 below all of the toxicity endpoints identified by EPA or Bayer.

1 In light of these results, it is questionable whether further monitoring is even necessary.
2 The observed levels of flubendiamide and des-iodo do not suggest any risks of concern that
3 could provide a scientific basis to justify a cancellation determination.

4 **VII. CONCLUSION**

5 **Q: Please summarize your opinions with respect to EPA's use of the 0.28 µg/L des-iodo**
6 **sediment pore water toxicity endpoint to justify its determination that flubendiamide**
7 **products pose unreasonable adverse effects and should be cancelled.**

8 A: Based on the above, I conclude that EPA has no scientific basis for using the chronic pore
9 water NOEC of 0.28 µg/L that was derived for des-iodo from the spiked water study. Instead,
10 the chronic NOEC of 19.5 µg/L derived from the spiked sediment study should have been used.
11 When the correct NOEC is used along with the results from the multi-year monitoring studies,
12 chronic risk to benthic invertebrates is not a concern. Thus, EPA has no scientific basis for
13 canceling the flubendiamide registrations.

14 **VIII. EXHIBITS**

15 **Q: Dr. Moore, in your testimony you referenced the following exhibits: PBNX 19-20,**
16 **27-34, and 43-48. PBNX 19-20, 27-34, and 43-48 were previously produced as attachments**
17 **to Bayer and Nichino's Motion for Accelerated Decision. Are these exhibits true and**
18 **correct copies of the documents you referenced?**

19 A: Yes.

20 **Q: Thank you, Dr. Moore.**

21 **Bayer and Nichino move to enter PBNX 19-20, 27-34, and 43-48 into evidence.**

22

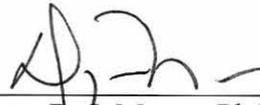
1 I declare under penalty of perjury that the foregoing is true and correct.

2 Executed on this 22nd day of April, 2016.

3

4

5



Dwayne R. J. Moore, Ph.D.

Verified Written Statement Of
David Ames Herbert Jr., Ph.D.
(Expert Witness)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of:

Bayer CropScience LP and
Nichino America, Inc.,

Petitioners.

)
)
)
)
)
)

FIFRA-HQ-2016-0001

**VERIFIED WRITTEN STATEMENT OF AMES HERBERT JR., PH.D.
ON BEHALF OF BAYER CROPSCIENCE LP AND NICHINO AMERICA, INC.**

TABLE OF CONTENTS

	<u>Page</u>
I. BACKGROUND AND EXPERIENCE	1
II. INTRODUCTION TO IPM AND IRM.....	3
III. OPINIONS REGARDING FLUBENDIAMIDE AND ITS BENEFITS	7
IV. OPINIONS REGARDING FLUBENDIAMIDE’S ROLE IN IPM AND IRM.....	14
V. OPINIONS REGARDING EPA’S ASSESSMENT OF FLUBENDIAMIDE’S BENEFITS	15
VI. OPINIONS REGARDING THE IMPACT OF FLUBENDIAMIDE’S CANCELLATION AND EPA’S PROPOSED EXISTING STOCKS PROVISION	17
VII. EXHIBITS	22

1 **I. BACKGROUND AND EXPERIENCE**

2 **Q: Please state your name, and where you are employed.**

3 A: My name is Dr. Ames Herbert, Jr. I am a professor of entomology in the Virginia Tech
4 Department of Entomology, which is located at the Tidewater Agricultural Research and
5 Extension Center, commonly abbreviated as TAREC.

6 **Q: Please describe your educational background.**

7 A: I hold a Bachelor's of Science degree in Biology from Johnson State College, and
8 Masters of Science and Doctor of Philosophy degrees in entomology from Auburn University.

9 **Q: Please describe your occupational history in general terms.**

10 A: I came to TAREC in 1988 as an Assistant Professor of Entomology in 1988. I was
11 promoted to Associate Professor in 1994 and to Full Professor in 2002. A copy of my curriculum
12 vitae further detailing my qualifications, experience, publications and presentations is provided
13 as PBNX 37.

14 **Q: Please describe the focus of your current employment.**

15 A: The focus of my work at TAREC is to develop (25 percent Research appointment) and
16 implement (75 percent Extension appointment) programs to improve management of insect pests
17 of soybean, peanut, cotton and small grains that reduce reliance on pesticides while maintaining
18 crop quality and profitability. I have state-wide responsibility for the insect pests of these crops,
19 including 600,000 acres of soybean, 18,000 acres of peanut, 90,000 acres of cotton, and 350,000
20 acres of small grains grown by Virginia farmers annually.

21 My research focuses on the development of better pest control practices (Integrated Pest
22 Management, abbreviated as "IPM") to improve productivity while protecting the environment,
23 and includes the conduct of field studies comparing the efficacy of different insecticides in
24 controlling various insect pests on the aforementioned crops. My Extension work includes

1 meeting and engaging directly with growers across the state to learn about the problems growers
2 are facing in the field and to promote improved grower practices based upon our research
3 findings.

4 **Q: Have you held any other positions pertinent to your qualifications to testify at this**
5 **hearing?**

6 A: Yes, I have served as the Commonwealth of Virginia's Integrated Pest Management
7 Coordinator since 1997. My responsibilities in this position include: (1) to lead the development
8 of the USDA-NIFA grant that funds the IPM program in the Virginia Tech College of
9 Agriculture and Life Sciences, and (2) to coordinate the activities of participating weed
10 scientists, plant pathologists, and entomologists in their efforts to reduce pesticide use while
11 fostering improved conditions in schools and public housing, agricultural crops, recreational
12 lands, plant nurseries, and homegrounds.

13 **Q: Have you published any studies or articles pertinent to your qualifications to testify**
14 **at this hearing?**

15 A: I have conducted over 100 pesticide field studies and authored over 65 papers in
16 scientific journals and over 130 Extension publications. I provide insect pest and insecticide
17 control recommendations to growers in several annually updated crop production guides,
18 including the Virginia Cooperative Extension's annual Pest Management Guide for Field Crops
19 (PBNX 42), the Virginia Cotton Production Guide and Virginia Peanut Production Guide.

20 **Q: Please identify any professional recognitions you have received.**

21 A: I have received recognition for my work in furtherance of IPM practices, including the
22 Insects Research and Control Conference Recognition Award for Excellence in Cotton

1 Integrated Pest Management, which I received this year, and a Lifetime Achievement Award,
2 which I received from the Friends of Southern IPM in 2012.

3 **Q: Please describe the scope of the testimony that you have been asked to provide?**

4 A: I was asked to testify in my position as an entomologist and IPM specialist and opine on
5 the following topics: (1) IPM and Insect Resistance Management (abbreviated as “IRM”)
6 generally, (2) flubendiamide’s attributes and the benefits that they provide soybean, cotton and
7 peanut growers in Virginia and the surrounding region; (3) flubendiamide’s role as an IPM and
8 IRM tool, (4) EPA’s assessment of flubendiamide’s benefits; and (5) the consequences to
9 Virginia’s growers of flubendiamide’s cancellation and EPA’s existing stocks provision.

10 **Q: Bayer and Nichino offer Dr. Herbert as an expert in the areas of entomology; pest**
11 **control management; insecticide efficacy and best practices, with a focus on soybeans,**
12 **peanuts, cotton, and small grain crops; and IPM and IRM.**

13 **II. INTRODUCTION TO IPM AND IRM**

14 **Q: You mentioned that you are the IPM Coordinator for the Commonwealth of**
15 **Virginia. What is IPM?**

16 A: IPM is the implementation of diverse methods of control (e.g., using pest resistant
17 varieties, altering planting times to escape periods of greatest pest pressure, conserving beneficial
18 species, and using insecticides only when pest populations overwhelm these other management
19 efforts), paired with scheduled pest monitoring to efficiently manage pests while reducing
20 unnecessary pesticide applications. The IPM paradigm has been promoted and practiced in U.S.
21 agriculture since the mid-1970s.

22 **Q: How are IPM-recommended practices communicated to growers?**

23 A: Each year entomologists at universities across the U.S publish IPM recommendations that
24 address the crops and insect pests local to their state. These publications identify and recommend

1 particular insecticides for use to control identified crop pests for each crop. I help coordinate the
2 content for these publications for Virginia. One such publication is PBNX 42, which is the 2016
3 version of the Pest Management Guide for Field Crops published by the Virginia Extension
4 Cooperative. I am also familiar with the IPM publications of other universities.

5 **Q: What are the key goals of Integrated Pest Management?**

6 Conserving beneficial species, also termed ‘natural enemies’, is a cornerstone of IPM
7 programs. Crop fields are the equivalent of small, temporary agroecosystems that, when left
8 alone, generate thousands of natural enemies—predators, spiders, parasites—that can feed on
9 pest species and in many cases prevent them from ever reaching levels that require insecticide
10 application. Previous research studies have shown that a rich and diverse natural enemy
11 community can be critical for suppressing pest populations and reducing the number of
12 insecticide applications that growers have to use.

13 **Q: You mentioned the importance to IPM of protecting natural enemies. How can a
14 grower protect natural enemies of pests using IPM?**

15 A: Growers can do so by avoiding the use of pesticides unless necessary, applying pesticides
16 when least likely to impact beneficial insects, and by choosing pesticides that narrowly target
17 pests and not beneficial insects. The use of broad-spectrum insecticides can destroy natural
18 enemies resulting in reduced pest control, and flaring of secondary pests that may require
19 additional insecticide sprays. This is why the use of broad-spectrum insecticides is generally
20 discouraged when a narrow spectrum or more specific insecticide will control the target pest. As
21 USDA has noted in PBNX 41, an important component of IPM is to use “the most specific pest
22 control option,” available for that pest. For the reasons above, I encourage growers to use
23 insecticides that are consistent with IPM whenever feasible to do so.

1 **Q: What is Insect Resistance Management?**

2 A: Insect Resistance Management, abbreviated as IRM, refers to practices to prevent the
3 development of pest resistance to insecticides. Over time, insect pests are known to develop
4 resistance to insecticides, especially if there is an over reliance and over use of insecticides with
5 the same mode of action (abbreviated as “MOA”).

6 **Q: What IRM practices can prevent the development of resistance?**

7 A: A standard recommended practice for preventing or slowing resistance development is to
8 rotate insecticides with different modes of action, especially if multiple applications are used
9 during the growing season. This practice is described well in PBNX 39, which is the 2016 Insect
10 Control Guide for Agronomic Crops published by the Mississippi State University Extension
11 Publication. As stated in that publication: “With foliar insecticides, you can delay resistance by
12 not exposing successive generations of pests to insecticides from the same class. Rotating
13 different classes of insecticides against different generations of pests is an effective resistance
14 management tool because insects resistant to one class of chemistry are often susceptible to
15 insecticides from a different class.”

16 **Q: What is meant by the term “Mode of Action” when used with respect to**
17 **insecticides?**

18 A: An insecticide’s MOA is the mechanism by which it kills the species it is intended to
19 target. Insecticides are divided into different classes, each with a different MOA.

20 **Q: What will happen if growers do not practice IRM by rotating MOAs?**

21 A: When IRM is not practiced, resistance may develop. For example, until relatively
22 recently, growers across the U.S. have relied heavily on insecticides in the pyrethroid class to
23 control *Helicoverpa zea*, a caterpillar pest that attacks a wide variety of agricultural crops. The

1 accepted common name of this pest is Corn earworm (so named because the worm is found in
2 the tips of sweet corn ears), but it is also known by other names depending on the crop that it is
3 attacking (e.g., Cotton bollworm for its destruction of cotton bolls, Tomato fruitworm for boring
4 into tomatoes and peppers, and Soybean podworm for its destruction of soybean pods and seed).
5 This repeated use of pyrethroids over many years has resulted in Corn earworm populations
6 developing resistance to those products

7 **Q: What pest resistance, if any, have you observed in Virginia fields during your**
8 **studies?**

9 A: My laboratory at the TAREC has been monitoring the susceptibility of Corn earworm to
10 pyrethroid insecticides since 2003. We have seen a gradual increase in resistance so that in the
11 last few years, more than 30% of individual insects tested are now surviving exposure. As a
12 result, Virginia growers are experiencing control failures and in some cases, requiring
13 retreatment of problem fields. I have encountered and written about the development of Corn
14 earworm resistance to pyrethroids in the past, including in PBNX 40, which is an article I
15 cowrote regarding pyrethroid resistance in soybean crops in Virginia. In that article, I described
16 high corn earworm resistance levels that were being encountered by growers that year.
17 Resistance levels and occurrences can vary year to year, and as you can see in the tables at the
18 end of the article, the large majority of the insecticides and mixes registered for use in soybeans
19 contain pyrethroids or organophosphates. The article notes that new diamides would be coming
20 on the market in 2013 and that this would better enable growers to manage pyrethroid resistance;
21 yet now EPA is proposing to cancel flubendiamide, which would undo some of that important
22 progress and reduce grower IRM options considerably.

23 **Q: What is the significance of a grower needing to re-treat problem fields?**

1 A: Retreatment is problematic for a number of reasons. First, it means that the grower must
2 spend more on pest control than anticipated, cutting into the profitability of the grower's crop.
3 Second, it means that the grower is applying more pesticide and that, as a result, more pesticide
4 is being released into the environment. Finally, if the original pesticide application does not
5 control the insect pest, making retreatment necessary, a grower may lose a substantial portion of
6 his harvest before retreatment can get the insect pest back under control. For these reasons, it is
7 critically important that growers have access to compounds with different MOAs, so that these
8 compounds can be rotated in a manner that avoids resistance development.

9 **Q: What experience, if any, do you have studying flubendiamide and its use to control**
10 **insect pests?**

11 A: In my research role at TAPEC, I have studied flubendiamide's performance in the field in
12 controlling pests on a variety of crops grown in Virginia. A number of these same field research
13 trials, including 10 that I conducted, were included in PBNX 22, Bayer's benefits submissions to
14 EPA. In my extension role, I have had the benefit of close to thirty years of experience speaking
15 with and learning from growers about the crops they grow, the pests that attack those crops, the
16 role of IPM and IRM in managing pest problems, and the consequences of grower failure to
17 adopt IPM and IRM. Because flubendiamide has been on the market for approximately 8 years,
18 I have had considerable opportunity to discuss its use in Virginia with growers, and observe the
19 real-world impacts it has had on the ability of growers to control caterpillar pests.

20 **III. OPINIONS REGARDING FLUBENDIAMIDE AND ITS BENEFITS**

21 **Q: What is flubendiamide?**

22 A: Flubendiamide, under the trade name of Belt[®], is an insecticide designed to target
23 lepidopteran larval, or caterpillar, pests of agricultural crops. The specificity of its mode-of-
24 action—that it kills only caterpillars—makes Belt[®] unique among insecticides. This attribute is a

1 fundamental difference from all other agricultural insecticides. Many of the insecticides used to
2 control caterpillars also kill other non-caterpillar insects.

3 **Q: What is Belt[®]'s Mode of Action?**

4 A: Belt[®] is in a relatively new and unique class of insecticides—the diamides—that was
5 designed to target caterpillar pests. There are only two other insecticides in this class,
6 chlorantraniliprole and cyantraniliprole, and those products target a broader list of species than
7 flubendiamide.

8 **Q: Please describe Belt[®]'s efficacy.**

9 A: Belt[®]'s efficacy in controlling pests on a wide variety of pests is comprehensively
10 detailed in the Benefits Analysis that Bayer submitted to EPA, and which I have reviewed in
11 preparation for my testimony. Belt[®]'s efficacy is further detailed in the legal brief submitted by
12 Grower groups opposing flubendiamide's cancellation and its accompanying grower declarations
13 and other exhibits, which I also reviewed in preparation for my testimony. As detailed in PBNX
14 22 and the Growers' Brief, numerous field research trials over recent years by entomologists at
15 major universities across the U.S. have consistently shown that timely foliar applications of
16 Belt[®] provide excellent levels of control that usually exceed the results of predecessor
17 compounds (pyrethroids, organophosphates) for a great variety of caterpillar pests, and across
18 many crops.

19 **Q: You have testified that Belt[®] is targeted at caterpillar pests. What type of caterpillar**
20 **pests do growers encounter in Virginia and surrounding fields?**

21 A: One example of a pest that Belt[®] controls is the Corn earworm, which is one of the most
22 destructive caterpillar pests in the southeast and mid-southeastern U.S. This pest requires
23 constant surveillance by growers, and in many cases necessitates the use of insecticides when

1 populations exceed the economic threshold. When I refer to the “economic threshold” I mean
2 when the value of the potential crop loss exceeds the cost of control and it therefore becomes
3 economically advisable to apply pest control.

4 In field trials that I conducted in Virginia as well as in the fields of local growers with
5 which I am familiar, Belt[®] consistently controls Corn earworm infestations in cotton, peanuts,
6 and soybeans (i.e., it eliminates the large majority of the caterpillar pests in a crop after
7 application and continues to protect the crop through its residual activity). This is reflected in
8 field studies that I conducted, which are included in the appendix to Bayer’s benefits submission
9 to EPA, PBNX 22. Belt[®]’s efficacy in controlling Corn earworm and Soybean looper is also
10 reflected in the data submitted to EPA by Angus Catchot, an Extension Entomologist at
11 Mississippi State University, which is also included in the appendix to PBNX 22. Note that EPA
12 does not dispute that Belt[®] is efficacious in controlling these pests.

13 **Q: What is the difference between a systemic and a non-systemic insecticide?**

14 A: A systemic insecticide is taken up by the plant via the plant’s foliage or its root to be
15 incorporated into the above ground plant parts. In practice this means that when a systemic
16 insecticide is applied to the soil around a crop’s roots, the insecticide is taken up into the above
17 ground parts of the crop through the roots, such that an insect feeding on the crop will be
18 exposed to the insecticide. A non-systemic insecticide is not taken up by the plant via the foliage
19 or its roots. Non-systemic insecticides are typically sprayed on the exterior of the crop such that
20 insects feeding on the crop will then be exposed to the insecticide.

21 **Q: Is Belt[®] systemic or non-systemic?**

22 A: Belt[®] is not a systemic insecticide. That is, it is not taken up by the plant via the foliage
23 and / or roots and is not incorporated into the above-ground plant parts.

1 **Q: What is the significance of this for IPM?**

2 A: Systemic insecticides, once taken up by the plant, can expose pests to the active
3 ingredient of the product for much longer period of time compared to non-systemic foliar-
4 applied insecticides. Prolonged pest exposure to systemic insecticides, particularly at sub-lethal
5 dosages, which can expose multiple generations of the pests, has resulted in the development of
6 resistance by some insects to certain products. Because Belt[®] is non-systemic, target pests are
7 only exposed during specific windows of time (up to three weeks), greatly reducing the
8 possibility of resistance development. Having a shorter window of activity also allows growers
9 to rotate products with different MOAs, which is a recommended practice for preventing
10 resistance development. When Belt[®] became available, we started recommending it to our
11 growers as a non-pyrethroid option. Chlorantraniliprole, one of the only IPM alternatives
12 identified in the EPA BEAD Review of Bayer CropScience LP Flubendiamide Benefits
13 Document, PBNX 23, is a systemic insecticide, and its use could therefore have greater potential
14 to result in the development of pest resistance.

15 **Q: What does it mean for an insecticide to have residual activity?**

16 A: Residual activity refers to an insecticide's continued effectiveness in the days, weeks and
17 months after it is applied on a crop. Systemic compounds tend to have very long residual
18 activity, whereas non-systemic compounds tend to have comparatively shorter residual activity.

19 **Q: From an IPM perspective, what is the significance of Belt[®]'s residual activity?**

20 A: Although it lacks the season-long residual activity of systemic compounds, Belt[®] does
21 have longer residual activity than pyrethroids if applied correctly and in the absence of excessive
22 rainfall. Belt[®] is applied as a foliar spray and once dried on the leaf surface, field trials have
23 shown that caterpillars feeding on treated leaf surfaces are killed for up to three weeks after

1 application. This is not the case with most other non-systemic insecticides, which only remain
2 active for hours or days. Belt[®]'s longer residual activity offers a huge advantage to growers
3 because it requires fewer applications. The fewer the applications of a pesticide that are
4 required, the less active ingredient that is released into the environment.

5 If applied at the right time in the pest cycle, e.g., when pests are first encountered, a
6 single application of Belt[®] can provide season-long control. This is in contrast to short-lived
7 products (pyrethroids) that may require one or more re-treatments to achieve equal levels of
8 control. For example, there have been seasons in Virginia, when the Corn earworm infestations
9 in soybean crops were so severe that they have required repeated applications of pyrethroids,
10 because of their short residual activity.

11 Yet while it has longer residual activity than pyrethroids, Belt[®]'s residual activity
12 remains modest enough that it will not generally be exposed to more than one generation of pest.
13 This attribute makes Belt[®] a better IRM fit than systemic compounds with season-long residual
14 activity.

15 **Q: Is Belt[®] toxic to other insects besides the caterpillars that it was designed to target?**

16 A: Belt[®] was designed to provide specific activity against caterpillar pests. Research
17 (including an ongoing Ph.D. student project under my supervision) has found that Belt[®] has
18 virtually no negative impact on natural enemy populations. In a 2-year study in southeast
19 Virginia soybean fields, the student found an astounding number of natural enemy species—111
20 different species—including many spider species never previously reported. Applications of
21 Belt[®] had no negative impact on these populations, compared with a pyrethroid insecticide that
22 severely reduced natural populations during the time when they would be present to feed on pest
23 species. These findings are important because when natural enemy species are conserved, they

1 can help control crop pest populations. These findings are also consistent with those of
2 numerous other entomologists, including Eric Natwick at the University of California Desert
3 Research and Extension Center, who wrote to EPA that “the narrow spectrum of flubendiamide
4 gives this diamide compound an advantage over broader spectrum diamides for inclusion into
5 IPM schemes because flubendiamide is less likely to impact beneficial insect/arthropod
6 populations including pollinators.” That letter is reproduced in the appendix to Bayer’s benefits
7 submission, beginning on page 253 of PBNX 22. Belt[®]’s comparatively low toxicity to
8 beneficials is also illustrated in Table 9 of PBNX 100, which is the 2016 Spray Bulletin for
9 Commercial Tree Fruit Growers published by the Virginia, West Virginia, and University of
10 Maryland Extension, which reflects the views of surveyed entomologists in this growing region.
11 Unlike Altacor[®] (chlorantraniliprole), Avant[®] (indoxacarb) and Entrust[®]/Delegate[®] (spinosin),
12 which are products EPA has suggested as alternatives, Belt[®] has low toxicity to all of the listed
13 beneficial insects. I also note that the IR-4 Project in its letter to EPA, PBNX 26, and EPA in its
14 BEAD analysis, PBNX 23, each recognize the importance of Belt[®]’s low toxicity to beneficial
15 insects.

16 **Q: What impact if any does Belt[®] have on pollinator species?**

17 A: As EPA has acknowledged, Belt[®] is non-toxic to honey bees and other pollinators. This
18 is an increasingly important attribute for an insecticide to have, given growing concerns about
19 the health of honey bee populations in the U.S. EPA has increasingly been scrutinizing pesticide
20 impacts on pollinators, placing increasing restrictions on the use of compounds that it believes to
21 be toxic to pollinators, and cancelling others that it believes present to great a risk. The USDA,
22 which I understand was not consulted as part of EPA’s cancellation decision, has also raised
23 concerns regarding the impacts of insecticides on pollinator species, and published an Agronomy

1 Technical Note on “Preventing or Mitigating Potential Negative Impacts of Pesticides on
2 Pollinators Using Integrated Pest Management and Other Conservation Practices,” which is
3 PBNX 41.

4 **Q: Why would Belt[®]'s lack of toxicity to pollinators be important to Growers?**

5 A: Growers have a great incentive to use practices and pesticides that protect their crop from
6 pests, while protecting pollinators. Indeed, many growers rely on honey bees to pollinate their
7 crops¹ and pay honey bee producers to place hives near their fields during critical pollination
8 periods. As noted by USDA in PBNX 41 at PDF p. 6, “35 percent of global agricultural
9 production, including more than 100 crop species, is either somewhat or completely dependent
10 upon pollinators,” and “[t]he value of insect pollinated crops in the United States alone ranges
11 between \$18 and \$27 billion each year.” USDA identifies flubendiamide as a compound with
12 “little to no effects on bees” in PBNX 21 at 5. Based on my experience collaborating with
13 growers in Virginia, the last thing a grower wants is to the kill honey bees that were introduced
14 in order to enhance crop yields. Belt[®] is that rare bee-safe product with no restrictions on the
15 label pertaining to pollinators. Many of the alternatives to Belt[®] identified by EPA in the BEAD
16 Analysis, including pyrethroids, are toxic to pollinators and have restrictions on their use as a
17 result.

18 **Q: What is Belt[®]'s efficacy in controlling pests on peanuts?**

19 A: In 2010, I conducted a Heliothine (caterpillar) complex study, which showed Belt[®] to be
20 the most efficacious insecticide for protecting peanuts, which are an important crop for the
21 Virginia agricultural economy. In that study, Belt[®] was found to have nearly 90 percent efficacy,
22 out-performing similar compounds and products from other classes of peanut insecticides. In an

¹ D. Ames Herbert, Jr., and Michael Flessner, Pest Management Guide Field Crops 2016 (Virginia Coop. Extension Publ'n 456-016, 2016) (Exhibit 42) at 1-45.

1 earlier study evaluating selected foliar treatments for control of the beet armyworm pest on
2 peanuts, which appears on page 152 of PBNX 22, Belt[®] was also found to be among the most
3 efficacious treatments. In my experience, Belt[®] is also considered a favorable IPM-friendly
4 insecticide among peanut growers because it is non-toxic to the insects that pollinate flowering
5 peanut plants.

6 **IV. OPINIONS REGARDING FLUBENDIAMIDE’S ROLE IN IPM AND IRM**

7 **Q: How would you characterize Belt[®]’s overall profile as an IPM option for growers?**

8 A: Belt[®] is a product that fits perfectly with IPM programs, provides excellent control of
9 lepidopteran pests while conserving natural enemies, and is non-toxic to pollinators—a ‘smart
10 bomb’ that targets caterpillar pests with no collateral damage to important natural enemies or
11 pollinators. For these reasons, I recommend use of Belt[®] for the control of a variety of caterpillar
12 pests in my annual pest and insecticide control recommendations.² I would note as well that the
13 letters from growers, food processors and entomologists appended to PBNX 22 speak to this, as
14 does the Growers’ Brief and the grower declarations in support of that Brief.

15 **Q: How would you characterize Belt[®]’s overall profile as a tool for growers practicing**
16 **IRM?**

17 A: Belt[®] has a number of characteristics that make it an important tool in resistance
18 management. Because of Belt[®]’s very narrow spectrum of activity, it is only applied when
19 needed to combat lepidopteran pests minimizing unnecessary exposure and resistance
20 development. From an IRM perspective, Belt[®] also has optimal residual activity. As Eric
21 Natwick noted in his letter to EPA (which can be found on pages 254-255 of PBNX 22),
22 flubendiamide has “has good residual activity” but that activity “is short enough to not span the

² See D. Ames Herbert, Jr., and Michael Flessner, Pest Management Guide Field Crops 2016 (Virginia Coop. Extension Publ’n 456-016, 2016) (Exhibit 42).

1 lifecycle of most, if not all lepidopteran pests.” With Belt, unlike systemic insecticides, multiple
2 generations of an insect pest are much likely to be exposed, with a resulting reduction in the risk
3 of resistance development.

4 **V. OPINIONS REGARDING EPA’S ASSESSMENT OF FLUBENDIAMIDE’S**
5 **BENEFITS**

6 **Q: Dr. Herbert, are you familiar with EPA BEAD’s analysis of Bayer’s benefits**
7 **submission?**

8 A: Yes, in preparation for my testimony, I reviewed PBNX 23, which is EPA BEAD’s July
9 24, 2015 memorandum reviewing Bayer’s benefits submission.

10 **Q: What is your assessment of BEAD’s analysis?**

11 A: BEAD largely acknowledged the benefits of flubendiamide but underestimated the
12 overall value of growers having access to the product. For example, BEAD agreed that
13 pyrethroids “are the likely alternatives to flubendiamide in alfalfa, peanuts, and soybeans” but
14 contended that because flubendiamide is used on “very few acres” on these crops, there is
15 “consequently little benefit to those growers.” The benefits of a product like flubendiamide are
16 better measured not by the total number of acres treated, but by the particular attributes the
17 product provides for growers (e.g. its highly-specific efficacy against caterpillar pests and lack of
18 toxicity to bees and natural enemies of pests.) Flubendiamide provides an important tool for
19 growers to use if and when specific caterpillar pest pressures arise, consistent with IPM.
20 Flubendiamide is likely to play a larger role as IPM practices are adopted more widely, as the
21 importance of pollinator protection increases, and as resistance issues grow. It would therefore
22 be a mistake to deny growers the use of this important pest control tool.

23 **Q: Dr. Herbert, are you familiar with PBNX 30?**

1 A: Yes, I am. PBNX 30 is EPA's Decision Memorandum in support of its Notice of Intent
2 to Cancel Flubendiamide. I reviewed this document in preparation for my testimony.

3 **Q: What was the purpose of your review of this document?**

4 A: I reviewed EPA's Decision Memorandum to understand the role that flubendiamide's
5 benefits played in the Agency's decision to cancel flubendiamide.

6 **Q: What is your assessment of the role that flubendiamide's benefits played in EPA's**
7 **cancellation decision?**

8 A: In the Decision Memorandum, the Agency asserts that although flubendiamide presents a
9 variety of benefits to growers and the environment, there will still be "alternatives" if EPA
10 cancels all flubendiamide registrations. EPA's cursory benefits summary discounts the
11 significance of many of flubendiamide's benefits while ignoring others entirely. For example,
12 the Decision Memorandum nowhere mentions flubendiamide's lack of toxicity to pollinators, a
13 critical benefit for growers and the environment. Nor does EPA explain whether or to what
14 extent the flubendiamide alternatives that it identifies can replicate flubendiamide's benefits.
15 This is a critical omission considering that the evidence suggests that there is no compound that
16 can entirely replicate flubendiamide's benefits. EPA identifies pyrethroids as the most likely
17 replacement to flubendiamide, but fails to note that unlike flubendiamide, pyrethroids are toxic
18 to pollinators if not applied properly, as are spinetoram and the spinosyns. EPA identifies insect
19 growth regulators such as diflubenzuron and methoxyfenozide (which is also toxic to pollinators)
20 as flubendiamide alternatives, but these compounds do not provide the same type or level of
21 lepidopteran pest control as flubendiamide. EPA identifies cyantraniliprole as an alternative,
22 even though that compound is not generally used to control lepidopteran pests. EPA also
23 identifies chlorantraniliprole as a flubendiamide replacement, but as discussed above, that

1 compound is systemic, broader-acting, and therefore more likely to prompt development of
2 insect resistance.

3 **VI. OPINIONS REGARDING THE IMPACT OF FLUBENDIAMIDE'S**
4 **CANCELLATION AND EPA'S PROPOSED EXISTING STOCKS PROVISION**

5 **Q: In your expert opinion, how would flubendiamide's cancellation impact agriculture**
6 **in the region that you study?**

7 A: Based on my direct knowledge of soybean, peanut, and cotton crops in Virginia, the most
8 common and destructive pest threats to those crops, and historic grower practices, in my opinion
9 the lack of access to Belt[®] could result in movement of growers back to more broad-spectrum
10 insecticides, reversing important progress made toward grower adoption of IPM management
11 practices. Prior to the advent of Belt[®], many growers relied on the use of insecticides in the
12 pyrethroid class for controlling caterpillar pests and would likely resort to those if Belt[®] was no
13 longer available. EPA acknowledges in the BEAD analysis that many growers are likely to
14 substitute use of pyrethroids for Belt[®] if it is no longer available. This substitution of pyrethroids
15 presents three problems: one, that resistance to pyrethroids has been confirmed for Corn
16 earworm, Soybean looper, and other caterpillar pests; two, it has been proven that pyrethroids
17 destroy non-target beneficial natural enemy species; and three, pyrethroids are toxic to
18 pollinators and cannot be applied if crops are flowering and bees are actively foraging. Those
19 growers seeking to continue to practice IPM will have very limited remaining options for control
20 of caterpillar pests and will be less equipped to combat pest resistance if and when it develops.

21 **Q: What is your understanding of EPA's proposed existing stocks provision for**
22 **flubendiamide?**

23 A: My understanding of EPA's proposal is based on my review of PBNX 20, which is
24 EPA's Notice of Intent to Cancel. According to that Notice, beginning on the date of

1 cancellation, flubendiamide in the hands of end users (i.e. the growers or applicators themselves)
2 could continue to be used. Beginning on that same date, the Registrants could no longer
3 manufacture flubendiamide nor could flubendiamide products continue to be distributed or sold.
4 Only flubendiamide already in the hands of growers or applicators could continue to be applied
5 in the field.

6 **Q: What is your opinion regarding how the existing stocks provision would impact**
7 **growers in your region?**

8 A: My opinion is that this provision, if enacted, would be very disruptive to growers in
9 Virginia. There are a number of reasons for this. First, the timing of cancellation—which is
10 anticipated for early July—coincides almost exactly with the height of caterpillar pest season for
11 area soybean, peanut and cotton growers. Second, because Belt[®] is a product that growers tend
12 to wait and see if they need, growers are much less likely to secure a supply in advance to have
13 on-hand. As a result, if EPA’s existing stocks provision is adopted as is, EPA would cut off the
14 supply of Belt[®] to growers in the weeks right before they are most likely to need and therefore
15 purchase Belt[®] to manage lepidopteran pests plaguing their crops. If, for example, there is an
16 outbreak of Corn earworm in soybean crops in August, growers who have previously relied upon
17 Belt[®] to control these pests will not be able to obtain a supply of Belt[®] to manage that outbreak.
18 Instead, growers will likely have to secure and substitute much broader acting, and IPM-
19 disruptive pyrethroids.

20 **Q: What is the basis for your understanding that Belt[®] is a product that growers tend**
21 **to wait and see if they need?**

22 A: These comments are based on my conversations with and observations of growers in
23 Virginia over my 27+ years—talking with them at winter meetings, summer field days, and one-

1 on-one at their farm shops. There is wide range in attitudes about what pest products are used
2 and when they are purchased. And, there is a general difference in the purchasing approaches
3 between products growers know they are going to use on every field (e.g., a pre-emergence
4 herbicide) versus a product that would be used only if and when a specific problem arises. In
5 Virginia, my experience has been that growers take a wait-and-see approach to purchasing a
6 product like Belt. They stay informed via farm press publications and my Extension's blog
7 'Virginia Ag Pest and Crop Advisory' (<http://blogs.ext.vt.edu/ag-pest-advisory/>) that is delivered
8 by email weekly during the growing season to more than 500 growers, crop advisors, extension
9 agents and industry personnel. If a bad caterpillar problem appears to be imminent, only then
10 would growers contact their distributor to secure the product they need. This is in contrast to
11 grower purchasing approaches with respect to, for example, a pre-emergence herbicide that is
12 part of the grower's annual crop management plan. The grower would be likely to purchase the
13 herbicide in the winter or early spring because the grower knows the herbicide will be applied
14 each growing season.

15 **Q: You mentioned that early July is close to the height of lepidopteran pest season.**
16 **Please elaborate on that point.**

17 A: Belt[®] is used exclusively for caterpillar control. In Virginia as in much of the mid-
18 Atlantic, Corn earworm is the predominant caterpillar pest, as it attacks such a wide variety of
19 crops including cotton, soybean, peanut, tomatoes and other vegetables. Because of how
20 damaging a pest the Corn earworm is, entomologists and IPM specialists have devoted a lot of
21 effort to understanding how this pest develops in our agricultural fields. We have learned that
22 Corn earworm undergoes three generations (from egg-to larva-to pupa-to adult moth) in a
23 summer season. In Virginia, first-generation moths lay their eggs on seedling corn and a few

1 weed hosts. Second-generation moths lay eggs on corn ear silks, and caterpillars feed on the
2 developing ears. The third generation is the one that actually attacks the host crops (cotton,
3 soybeans, peanuts, tomatoes and other vegetables), usually beginning in late July through early
4 to mid-August. With the exception of sweet corn, most insecticide spray programs target this
5 third generation.

6 **Q: For the crops and crop pests that you study, how if at all, does the timing of**
7 **lepidopteran outbreaks vary?**

8 A: There is some variation, depending on the crop. We can begin with cotton. Virginia is
9 the northernmost location in the U.S. where cotton is grown, which means that we have a shorter
10 growing season than states further to the south. It is only warm enough to grow cotton in our
11 southeastern counties (totaling about 86,000 acres). To ‘beat the frost,’ Virginia growers must
12 therefore plant fast-growing, early-maturing cotton varieties, and plant them as soon as soil and
13 air temperatures are warm enough. Most of the crop is planted in the first two weeks of May.
14 This means that the cotton crop is fairly uniform across our region in terms of crop maturity.
15 Corn earworm, which when it feeds on cotton is called Cotton bollworm, feeds on cotton bolls
16 when they are developing. I wrote the section on cotton in this year’s Pest Management Guide
17 for Field Crops, published by the Virginia Cooperative Extension, which is PBNX 42. In that
18 publication, which is used by Virginia growers, I provide guidance on the major cotton pests, the
19 damage they can do to cotton, and recommendations for sampling for these pests and
20 determining if the threshold has been reached where it becomes necessary to apply insecticides.
21 In the Virginia cotton crop, bolls start developing in late July and early August. If cotton fields
22 are going to be treated for Corn earworm, it will be in August when bolls are tender and
23 attractive to Corn earworm caterpillars. If flubendiamide is cancelled in early July, and no more

1 sales to growers are permitted from then on, growers will lose an important tool for controlling
2 Corn earworm only weeks before treatment is needed.

3 **Q: How, if at all do growing practices differ for soybeans?**

4 A: Soybean is a more complicated crop than cotton with respect to both its geographic
5 distribution across the state and the cultural practices used by the grower. Virginia growers plant
6 about 600,000 acres of soybean each year, and in about two thirds of the Commonwealth's
7 counties—from the Eastern Shore to the Shenandoah Valley. Two basic soybean cropping
8 systems are used: full season and double crop. Full season fields are planted from April through
9 late May. Double crop fields are planted in late June to late July into small grain fields (wheat or
10 barley) after the grain has been harvested. Unlike with cotton, soybean growers spread their
11 harvest schedule by planting varieties in several maturity ranges (early, mid and full). This wide
12 range of planting dates and maturity groups results in a lot of farmscape diversity—where a field
13 with seedling soybeans can be only a field path away from a field that has plants that are tall and
14 flowering. Corn earworm moths are mainly attracted to fields that are flowering and setting
15 young, tender pods. Caterpillars feed on the pods and developing seed—so they generally
16 bypass fields that are not in that stage of development. That means that in comparison to cotton,
17 because of the wide diversity and large geographic area of soybean fields, this crop can be
18 infested by Corn earworm over a much longer window of time. Double crop fields, for example,
19 may continue to require use of Belt[®] into the late summer and early fall.

20 **Q: How does peanut growing compare to cotton and soybean?**

21 A: The Virginia peanut crop is very similar to the cotton crop, in that Virginia is also the
22 northernmost production region for peanuts in the U.S. Virginia peanut growers are therefore
23 faced with the same short growing season constraints as cotton growers. Peanuts are planted on

1 about 18,000 acres annually in Virginia and in the same counties as cotton is grown. Corn
2 earworm is not quite as damaging a pest in peanut compared to soybean and cotton because
3 caterpillars feed only on the leaves (indirect damage) instead of on bolls or soybean pods (direct
4 damage). However, extensive leaf feeding can still result in yield losses, so growers must be
5 vigilant and protect fields if large caterpillar populations develop. Corn earworm moths move
6 into peanut fields at about the same time as they do cotton fields, generally in late July to mid-
7 August. As a result, if flubendiamide can no longer be distributed after the first week of July,
8 peanut growers will be denied access to Belt[®] just as it is likely to be needed the most.

9 **Q: What, in your opinion, would be a less-disruptive approach to existing stocks?**

10 A: In my opinion, if flubendiamide is cancelled, it would be far less disruptive to permit
11 growers to continue to acquire and use whatever supplies of Belt[®] remain available once
12 production ceases in the beginning of July. This would avoid forcing growers in Virginia and
13 nearby states to find a substitute for Belt[®] in the height of the caterpillar pest season, and instead
14 allow them to use remaining stocks of Belt[®] to control lepidopteran pests through the crop
15 harvest. Growers would then have time during the winter to develop plans regarding the control
16 of lepidopteran pests in the following growing season.

17 **VII. EXHIBITS**

18 **Q: Dr. Herbert, in your testimony you referenced the following exhibits: PBNX 20-23,**
19 **26, 30, 37, 39-42; and 100. PBNX 20-23, 26, 30, 37 and 39-42 previously were produced as**
20 **attachments to Bayer and Nichino's Motion for Accelerated Decision and Exhibit PBNX**
21 **100 is being produced as part of Bayer and Nichino's Prehearing Submission. Are these**
22 **exhibits true and correct copies of the documents you referenced?**

23 A: Yes.

24 **Q: Thank you, Dr. Herbert.**

1 **Bayer and Nichino move to enter PBNX 20-23, 26, 30, 37, 39-42; and 100 into**
2 **evidence.**

3

4

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

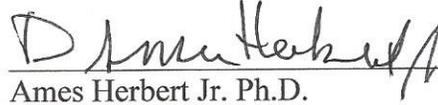
2 Executed on this 21st day of April, 2016.

3

4

5

6


Ames Herbert Jr. Ph.D.

Verified Written Statement Of
John Palumbo, Ph.D.
(Expert Witness)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of:

Bayer CropScience LP and
Nichino America, Inc.,

Petitioners.

)
)
)
)
)
)

FIFRA-HQ-2016-0001

**VERIFIED WRITTEN STATEMENT OF JOHN PALUMBO, PH.D.
ON BEHALF OF BAYER CROPSCIENCE LP AND NICHINO AMERICA, INC.**

TABLE OF CONTENTS

	<u>Page</u>
I. BACKGROUND AND EXPERIENCE	1
II. IPM AND IRM	4
III. OPINIONS REGARDING FLUBENDIAMIDE’S ATTRIBUTES	5
IV. FLUBENDIAMIDE’S USE ON LEAFY VEGETABLE AND BRASSICA (COLE) LEAFY VEGETABLE CROPS	11
V. FLUBENDIAMIDE’S USE ON MELONS	15
VI. OPINIONS REGARDING EPA’S ANALYSIS OF FLUBENDIAMIDE’S BENEFITS	15
VII. OPINION REGARDING CANCELLATION AND EPA’S PROPOSED EXISTING STOCKS POLICY	18
VIII. EXHIBITS	23

1 **I. BACKGROUND AND EXPERIENCE**

2 **Q: Please state your name and address.**

3 A: My name is John Palumbo. My business address is 6425 West 8th Street, Yuma, Arizona.

4 **Q: What is your occupation?**

5 A: I am a Professor of Entomology in the University of Arizona Department of Entomology,
6 which is located at the Yuma Agricultural Center.

7 **Q: Please describe your education background.**

8 A: I earned my Bachelor's of Science and Masters degrees in entomology in 1982 and 1985,
9 respectively. My Masters thesis title was "Influence of *Sphaeralcea* spp. on Survival and
10 Reproductive Behavior of Boll Weevil, *Anthonomous grandis* Boheman, in Arizona." I earned
11 my Ph.D. in entomology in 1989 from Oklahoma State University, and my dissertation was the
12 "Development of Management Strategies for Squash Bug, *Anasa tristis* (De Geer) Populations in
13 Cucurbits."

14 **Q: Please describe your occupational history in general terms.**

15 A: My C.V. is provided as PBNX 110. Before becoming a full Professor of Entomology in
16 2002, I held other positions at the University of Arizona, including as an Associate Professor and
17 Research Scientist of Entomology from 1996 to 2002, and before that as an Assistant Professor
18 and Research Scientist of Entomology from 1990 to 1996. Throughout that entire time period, I
19 have also held the role of Extension Specialist.

20 **Q: Please describe your current work in further detail.**

21 A: My primary role at the University of Arizona has been to develop and direct an applied
22 research and extension program to investigate the management of the key pests associated with
23 Arizona vegetable production. Thus, my work is focused on the study of insect biology and
24 ecology and the application of that knowledge to develop innovative IPM strategies in vegetable

1 cropping systems. This includes the study of insect feeding, reproduction, and crop-pest
2 interactions, in the field and the laboratory, and work to quantify and statistically describe
3 distribution patterns of insect populations.

4 **Q: Please describe your responsibilities as an Extension Specialist.**

5 A: My goals are to provide empirically-based information on the management of insect
6 populations in vegetable crops that can be directly applied by growers throughout the
7 southwestern United States. I evaluate pesticide chemistries with new modes of action and
8 investigate alternative uses for existing insecticides and biological control tactics. Based on our
9 laboratory and field evaluations of chemical pesticides, biological control tactics, and pest-
10 prevention practices, the extension program provides empirical information on the management
11 of insect populations that can be directly applied by vegetable growers throughout the
12 southwestern United States. A fundamental goal of our work is to reduce overall pesticide usage
13 in the production of vegetables, and the associated environmental and occupational risks. In
14 particular, the Extension seeks to develop, validate, and deliver to growers information and
15 economically viable methods for managing pests that reduce grower reliance on higher risk,
16 "broadly-toxic" pesticides, such as organophosphates, carbamates, and pyrethroids, while
17 maintaining crop yield and quality.

18 **Q: What kind of crops do you work with?**

19 A: My work primarily involves Leafy vegetables (lettuce, spinach, celery), Brassica (Cole)
20 Leafy vegetable crops (broccoli, cauliflower, cabbage, Brussels sprouts, kale, collards, and
21 kohlrabi), and melons (a subset of crops within the Cucurbit vegetable group).

22 **Q: You indicated that part of your responsibility is to deliver to growers information
23 and economically viable methods for managing pests. How do you do this?**

1 A: As an Extension Specialist, I am viewed by vegetable growers and pest control advisors
2 (“PCAs”) as an unbiased, objective source of information and assist them in making informed
3 pest management decisions. In my experience, when a new IPM technology or strategy is
4 developed it has a much greater chance of being adopted by growers when it can be
5 demonstrated to growers and PCAs first-hand. By working with growers and PCAs
6 cooperatively through their participation in the experimental process, they witness the results of
7 IPM within their own farming operations. Likewise, I learn about their practices and the pest
8 problems that they face from their participation in this process. Many of my applied research
9 projects are conducted in local vegetable fields in collaboration with local growers and PCAs.
10 This allows me to interact directly with the growers and PCAs who actually face pest
11 management issues and gain valuable insights into vegetable production and practical insect
12 management.

13 **Q: Dr. Palumbo, have you published in any areas pertinent to your qualifications to**
14 **testify in this case?**

15 A: Yes, I have published extensively in peer-reviewed journals on topics including insect
16 management in vegetable and melon crops, insecticidal control and resistance management, and
17 comparative insecticide efficacy. A representative sample of my publications is included in my
18 C.V.

19 **Q: Please describe the scope of the testimony that you have been asked to provide?**

20 A: I was asked to testify in my position as an entomologist and IPM specialist and opine on
21 the following topics: (1) Integrated Pest Management and Insect Resistance Management
22 generally; (2) flubendiamide’s attributes; (3) an overview of Leafy vegetable crops and the
23 benefits that flubendiamide provides for growers; (4) an overview of the benefits that

1 flubendiamide provides for melon growers; (5) EPA's assessment of flubendiamide's benefits;
2 and (6) the consequences to southwestern growers of flubendiamide's cancellation and EPA's
3 existing stocks provision.

4 **Q: Bayer and Nichino offer Dr. Palumbo as an expert in the areas of entomology; insect**
5 **pest management; and insecticide efficacy and best practices, with a focus on Leafy**
6 **vegetables, Brassica (Cole) Leafy vegetable crops, and melons.**

7 **II. IPM AND IRM**

8 **Q: You mentioned that your work involved developing innovative IPM strategies in**
9 **vegetable cropping systems. Please elaborate on what you mean by IPM and what role it**
10 **plays in your work?**

11 A: IPM stands for Integrated Pest Management. IPM is a scientifically-based, worldwide
12 standard for managing pests. It encourages the use of multiple and flexible strategies for the
13 control of insects, weeds, rodents and other vertebrates and plant, animal and human diseases.
14 An IPM approach favors the use of biological pest control methods and management practices
15 aimed at avoiding or preventing pest outbreaks where these methods can be feasible and
16 effective. With respect to IPM for insect pests, the use of chemical insecticides remains
17 necessary to allow the production of vegetables at the level of quality and affordability expected
18 and demanded by consumers in the United States. A key goal of my IPM work is to reduce and
19 optimize the use of chemical insecticides, through development and implementation of practices
20 such as insect pest sampling, "action thresholds," selection of appropriate products, resistance
21 management, and other methods derived from an understanding of the biological, ecological, and
22 environmental interactions occurring within cropping systems. Because of my expertise in IPM,
23 I am frequently called upon by local growers and PCAs to discuss their pest problems and offer
24 potential solutions. Overall, these experiences have provided me with a unique and in-depth

1 knowledge of the management practices used by the vegetable industry to control insect pests in
2 Arizona and southern California.

3 **Q: You referred to resistance management as a means of optimizing the use of chemical**
4 **insecticides. What is resistance management?**

5 A: Resistance management is a means of combatting the development of pest resistance to
6 insecticides. Resistance management includes avoiding misuse or over-use of a product. A
7 resistance management program is an important component of an IPM program. Insecticide
8 resistance is a constant threat to local IPM programs that the leafy vegetable industry takes
9 seriously. A good example of a crop and pest specific IRM strategy is the IRM Guidelines for
10 Beet Armyworm in Lettuce that we published on August 20, 2014 (PBNX 111). The guidelines
11 include: (1) applying insecticides only when needed; (2) avoiding consecutive applications of
12 the same insecticide on the same field, and instead rotating Mode of Actions (“MOAs”); (3)
13 where a product/MOA is required more than once, limiting the total usage of that product to 2
14 applications per field per crop season; (4) using only recommended products and rates necessary
15 to accomplish desired control; and (5) applying insecticides by ground sprays to optimize spray
16 deposition and coverage.

17 **III. OPINIONS REGARDING FLUBENDIAMIDE’S ATTRIBUTES**

18 **Q: What experience, if any, do you have studying flubendiamide and its use to control**
19 **insect pests?**

20 A: Since its introduction into the market, I have studied and evaluated flubendiamide’s
21 efficacy in controlling Lepidopteran pests that feed on leafy vegetable crops and melons, and its
22 role in IPM and IRM programs. I have, for example, conducted numerous field studies
23 comparing the efficacy of various insecticides, including flubendiamide, in controlling specific
24 pests on specific crops, a number of which are appended to PBNX 22, Bayer’s benefits

1 submission to EPA. I have communicated my findings and my recommendations regarding
2 flubendiamide to growers in Arizona. Critically, because of the frequency with which I meet and
3 engage with growers and PCAs regarding the pest management issues they face, I have also
4 gained valuable insight into the real-world benefits that flubendiamide provides in growers'
5 fields. This work has also provided me a detailed understanding of the key role that pesticide
6 costs play in driving grower decision-making regarding which compounds to use.

7 **Q: What is flubendiamide?**

8 A: Flubendiamide is the active ingredient for the product Belt[®]. It is an insecticide designed
9 to target Lepidopteran larval complex (commonly referred to as caterpillar) pests of agricultural
10 crops.

11 **Q: Which of the crops that you study are treated with Belt[®]?**

12 A: I study Leafy vegetables, Brassica (Cole) Leafy vegetable crops, and melons, and
13 growers in Arizona and southern California use Belt[®] on all of these crops.

14 **Q: Please describe Belt[®]'s efficacy in controlling pests on the crops that you study?**

15 A: Based on over 10 years of experience documenting flubendiamide's activity (including
16 during pre-registration field trials), and my understanding of its toxicological profile, I have
17 found that flubendiamide is one of the more efficacious and therefore valuable insecticide
18 alternatives presently available for managing Lepidopteran pests in Leafy vegetables, Brassica
19 (Cole) Leafy vegetable crops and melons.

20 **Q: Is use of Belt[®] consistent with IPM?**

21 A: Belt[®] has a number of attributes that make it suitable for IPM, including: selective
22 efficacy, non-systemic activity, rainfastness, good residual activity, a good human health and
23 safety profile, low toxicity to beneficial insects, and cost effectiveness.

1 **Q: What do you mean when you describe Belt[®] as having selectivity?**

2 A: Belt[®] is a very narrow spectrum compound selective for control of Lepidopteran species
3 only. Other types of insects, including beneficials, are not harmed by exposure to Belt[®]. In
4 contrast, broad spectrum compounds such as pyrethroids tend to kill more insects, including
5 those that are not being targeted for control.

6 **Q: Why is Belt[®]'s selectivity an attribute for IPM?**

7 A: Selectivity is an IPM attribute because it means that growers are narrowly treating the
8 problem pest, rather than also eliminating other non-target insects, including beneficials. A core
9 principle of IPM is to manage each pest problem as narrowly as possible, reducing unnecessary
10 pesticide exposure.

11 **Q: What do you mean by non-systemic activity?**

12 A: Systemic insecticides are those that are taken up into the plant through the root or plant
13 foliage. Non-systemic insecticides, such as flubendiamide, are not taken up into the plant
14 through the root or plant foliage. Note that while Belt[®] is non-systemic, it does have
15 translaminar properties. This means that when applied to the leaf surface of lettuce leaves,
16 flubendiamide penetrates the leaf surface and moves into the cuticle, epidermis and mesophyll of
17 the leaf, providing a reservoir of the insecticide within the effected leaf.

18 **Q: Why is Belt[®]'s non-systemic, translaminar activity an attribute for IPM?**

19 A: Because Belt[®] is non-systemic it can be applied by growers on an as needed basis and
20 easily rotated with other MOAs. Systemic compounds, because of their often season-long
21 residual activity, cannot be applied in this “treatment window” approach. Once growers apply
22 chlorantraniliprole, for example, the compound is taken up into the crop and pests will continue
23 to be exposed to it throughout the growing season. For this reason, as reflected in PBNX 112 at

1 PDF p. 3, I recommend that growers “[d]o not apply a foliar [d]iamide spray prior to or
2 following the use of a soil application of chlorantraniliprole.” Otherwise, growers would risk
3 exposing multiple generations of Lepidopteran pests to diamides, which could result in the
4 development of Lepidopteran resistance.

5 Belt[®]'s translaminar movement is advantageous because it means that the spray coverage
6 of flubendiamide on crops is less critical than it would be for other non-systemic insecticides
7 such as pyrethroids. Lepidopteran insects feeding on the lower (abaxial) leaf surface will
8 become intoxicated with flubendiamide that has been applied only to the upper (adaxial) leaf
9 surface. In contrast, if pyrethroids are spray applied, and the bottom surface of the leaf is
10 missed, a caterpillar feeding on the bottom surface of the leaf will not be exposed and may
11 therefore survive treatment.

12 **Q: You indicated that Belt[®] is rainfast. What does that mean?**

13 A: It means that once applied to a crop and given a chance to dry, Belt[®] will remain
14 efficacious even after a rainstorm.

15 **Q: What is the significance to growers of Belt[®] being rainfast?**

16 A: It is significant because it means that growers need not reapply Belt[®] after a rainstorm.
17 Rainfastness is a particularly important attribute in Arizona because of the potentially disruptive
18 role seasonal monsoons play in Arizona agriculture. Alfalfa or melon growers who have applied
19 a pesticide that is not rainfast may be forced to harvest the crop early if they learn that a
20 monsoon thunderstorm is likely. If they have applied a rainfast product like Belt[®], they can wait
21 out the monsoon to harvest the crop, knowing that it will continue to control Lepidopteran pests
22 after the storm has passed. This attribute is described by Ken Narramore, an independent PCA in
23 Arizona, on page 38 of Bayer's benefits submission, PBNX 22. Belt's short pre-harvest interval

1 (abbreviated PHI) also means that it can be applied on short notice, which is another important
2 attribute for growers facing frequent but uncertain storms during Arizona's monsoon season. It
3 enables a grower to harvest a crop early to avoid damage from a strong storm.

4 **Q: What do you mean by residual activity?**

5 A: By residual activity, I refer to the period of time after application of the insecticide that
6 the insecticide remains efficacious in controlling the targeted pest. If an insecticide is described
7 as having little residual activity, this means that it is only effective for a period of hours after it is
8 applied. An insecticide with long residual activity may remain efficacious for many weeks, and
9 possibly for the entire growing season of the crop.

10 **Q: What is the basis for your opinion that Belt[®] has good residual activity?**

11 A: Based on field studies, flubendiamide provides a consistent 14 day residual control in
12 lettuce. This is a good, modest amount of residual activity for a non-systemic compound.
13 Compounds such as pyrethroids that are only active for hours up to a few days, often must be
14 repeatedly reapplied throughout the growing season to adequately control crop pests.

15 **Q: Why is Belt[®]'s residual activity an attribute for IRM?**

16 A: Belt[®]'s modest residual activity is an important attribute for IRM because it only remains
17 efficacious long enough to expose a single generations of a Lepidopteran population to the active
18 ingredient and control that pest, reducing selection pressure on flubendiamide to the population.
19 Insecticides with longer residual activity expose multiple generations of crop pests, increasing
20 selection pressure on those populations with the potential for resistance to develop.

21 **Q: What do you mean when you say that Belt[®] has a good human health and safety**
22 **profile?**

1 A: Flubendiamide has essentially no human health concerns, and its use on Leafy vegetables
2 therefore significantly reduces health risks to growers, applicators, PCAs, field workers and
3 consumers. This is extremely important for the production of Leafy vegetables and Brassica
4 (Cole) Leafy vegetable crops destined for the fresh market. The production of lettuce and other
5 Leafy vegetables is very labor intensive and requires significant use of field workers, leading to
6 significant worker exposure to applied insecticides. It is common to find workers in fields any
7 given day of the week, performing irrigation, thinning, cultivation, weeding, and harvest. PCAs
8 also scout fields intensively (on average 4 times per week) to make insect management
9 decisions. Thus the probability of exposure to insecticides on lettuce is very high.

10 **Q: What do you mean by Belt[®] having low toxicity to beneficial insects and pollinators?**

11 A: I mean that flubendiamide is a very narrow spectrum compound selective for control of
12 Lepidopteran species only, and has been found to be safer for natural insect enemies of those
13 pests and for pollinators compared with many of the alternatives. This is in part due to its
14 selectivity and also to the fact that it has minimal contact activity. Flubendiamide's low toxicity
15 to beneficials is demonstrated in a series of figures in Bayer's benefits submission, on pages 33-
16 37 of PBNX 22.

17 **Q: Why is low toxicity to beneficial insects and pollinators an attribute for IPM?**

18 A: The selective activity of flubendiamide's mode of action (MOA) allows growers to apply
19 the compound at any time during the crop season without fear of disrupting natural enemy
20 populations important for keeping secondary pests (i.e., *Liriomyza* leafminers) suppressed. In
21 addition, flubendiamide's safety to pollinators has made it an important alternative in all desert
22 crops. Melon crops, for example, require pollination services for fruit production, so it is critical
23 that applied insecticides do not harm pollinators.

1 **Q: What do you mean by Belt[®] being cost effective?**

2 A: Flubendiamide (Belt[®] and Vetica[®]) is the least expensive alternative that provides
3 excellent control of Beet Armyworm, Cabbage looper and Diamondback moth in a single
4 application. Flubendiamide provides Lepidopteran efficacy as good as or better than the other
5 alternatives, but at a lower cost to the grower. This is important in the production of Leafy
6 vegetables, where growers may spend 20-30% of their growing costs on insect management.
7 Thus, growers and PCAs prefer to use a product that is a) effective, b) inexpensive, c) easy to
8 apply (translaminar), and d) safe to use. In my opinion, flubendiamide's cost effectiveness is a
9 major reason why flubendiamide use has grown in Arizona lettuce.

10 **Q: What is the basis for your opinion that Belt[®] is a competitively priced IPM option?**

11 A: My opinion is based on years of observation and conversations with local PCAs and
12 insecticide distributors. Based on grower and PCA surveys (as described in PBNX 113) that I
13 have reviewed, while spinetoram has been and remains the most commonly used insecticide, it is
14 now followed by flubendiamide, chlorantraniliprole, methomyl and acephate.

15 **IV. FLUBENDIAMIDE'S USE ON LEAFY VEGETABLE AND BRASSICA (COLE)**
16 **LEAFY VEGETABLE CROPS**

17 **Q: Please provide an overview of the major pests targeting leafy vegetable crops in**
18 **Arizona and its surroundings.**

19 A: This varies somewhat by crop, but lettuce is a good representative crop to discuss for the
20 Leafy vegetable crop group. There are four major pests of lettuce in the American Southwest:
21 Lepidopteran pests, sweet potato whitefly, western flower thrips, and aphids. The four pests
22 dominate in different growing seasons. Lepidopteran pests (which include beet army worm,
23 cabbage looper, and corn earworm, among others) are present in the highest numbers in the fall.
24 Of the four major pests, the Lepidopteran pests are consistently the most damaging to crops and

1 therefore require the most control. When plants are small, feeding damage from worms can
2 cause severe reduction to stand establishment, dramatically diminishing the number of plants in
3 the field. As harvest nears, the risk of loss increases as worms feed on or contaminate the
4 marketable product.

5 **Q: Describe, based on your experience and observation, how growers control**
6 **Lepidopteran pests on lettuce?**

7 A: Lepidopteran larvae require multiple pesticide applications to prevent losses in yield and
8 quality. Growers treat lettuce 5 to 6 times (sometimes more under heavy pressure) for
9 Lepidopteran control on fall lettuce and 4 to 5 times on spring lettuce. The average number of
10 applications is down considerably from 25 years ago when growers predominately relied on
11 pyrethroids, organophosphates and carbamates for Lepidopteran control, and therefore were
12 making 12 to 14 applications per season. This change shows the importance of the development
13 of new and effective insecticide alternatives to protect Leafy vegetables and produce high-quality
14 lettuce destined for the fresh market.

15 Control of the Lepidopteran larvae complex is critical at two key times during the
16 production of lettuce and Brassica (Cole) Leafy vegetable crops. First, emerging seedlings
17 during stand establishment through thinning are very susceptible to larval feeding that can
18 severely stunt or kill seedlings by extreme defoliation. This can also slow growth enough to
19 affect crop uniformity. Absent effective economical control of these Lepidopteran larvae,
20 significant plant losses can occur during stand establishment (the time from crop germination to
21 emergence of young seedling plants). I have personally observed stand reductions as high as
22 50% in fields where Lepidopteran control was not achieved. Damage is less serious from
23 thinning to heading stages, but under heavy pressure can result in reduced head size. Feeding

1 damage is economically important once cupping (when the lettuce plant initiates head formation)
2 begins as larvae may feed on the head or heart, rendering it unmarketable. Contamination of
3 lettuce heads, celery hearts, and Brassica (Cole) Leafy vegetable crops with either live larvae or
4 frass (which is caterpillar excrement) will render it unmarketable. If Lepidopteran control is not
5 achieved prior to harvest, shippers and buyers will reject an entire field. Without effective
6 Lepidopteran control, a significant acreage of the Arizona lettuce crop would be lost to larvae
7 contamination and could not be harvested.

8 **Q: How does Belt[®]'s efficacy in controlling Lepidopteran pests compare to other**
9 **commonly used compounds?**

10 A: When Belt[®] is used on lettuce infested by multiple Lepidopteran species, no additional
11 insecticides are required to achieve complete control. Many of the other alternatives used for
12 Lepidopteran control in Leafy vegetables require the addition of a pyrethroid or organophosphate
13 in the spray tank to achieve comparable control to flubendiamide. For example, growers using
14 alternatives such as methoxyfenozide, emamectin benzoate, indoxacarb, methomyl, chlorpyrifos,
15 or acephate would instead need to combine them with a pyrethroid to provide comparable control
16 to flubendiamide.

17 Growers also use less active ingredient when they apply flubendiamide. On a per spray
18 basis, growers apply lower application rates of flubendiamide than most of the competing
19 alternatives, and in many cases, dramatically lower. For instance, at the highest labeled rate,
20 flubendiamide (Belt[®]) in lettuce is applied at 0.047 lbs of active ingredient per acre (abbreviated
21 "LAA") compared to the "broad spectrum" compounds (i.e., acephate, chlorpyrifos, methomyl)
22 that are applied at rates at or over 1.0 lb of active ingredient per acre (LAA). The most
23 commonly used pyrethroid (bifenthrin at 0.10 LAA) is also used at higher rates than

1 flubendiamide. Similarly, many of the other selective, low-risk products used for Lepidopteran
2 control are applied at higher rates than flubendiamide (i.e., methoxyfenozide at 0.19 LAA,
3 inidoxacarb at 0.11 LAA, and spinetoram, 0.05 LAA).

4 **Q: How do the other diamide compounds compare to Belt[®]?**

5 A: Chlorantraniliprole, like flubendiamide, is also a diamide and therefore provides a
6 number of similar attributes in managing Lepidopteran pests. However, chlorantraniliprole has
7 broader activity than flubendiamide and it is a systemic compound, as demonstrated in a field
8 trial that I conducted in 2007 (PBNX 114). When it is applied to soil, chlorantraniliprole is
9 highly xylem mobile via root uptake. In practice this means that when applied to the soil,
10 chlorantraniliprole will exhibit much longer residual activity than products applied as foliar
11 sprays. As I have explained above, this extended residual can expose multiple generations of
12 Lepidopteran populations to lethal and sub-lethal doses of the toxicant, increasing the risk of
13 resistance in local populations. Because flubendiamide has more limited residual activity and is
14 not systemic, it is a better fit for Leafy Vegetable IPM programs than is a systemic compound
15 such as chlorantraniliprole. Growers using chlorantraniliprole also have to apply more active
16 ingredient (0.065 LAA) than when using flubendiamide (0.046 LAA).

17 **Q: On what do you base your opinion regarding Belt[®]'s role in controlling lettuce crop**
18 **pests?**

19 A: I base my opinion on field trials that I conducted, on the field trials conducted by other
20 entomologists that I have reviewed, and on my direct observations of Belt[®]'s effectiveness in
21 managing caterpillar pests in Arizona fields. I have also reviewed Bayer's benefits submission,
22 which provides a comprehensive overview of field data and grower and entomologist
23 testimonials regarding Belt[®]'s efficacy. Bayer's benefits submission includes field studies that I

1 conducted in 2006 and 2012 evaluating the comparative efficacy of compounds including
2 flubendiamide in controlling insect pests. Those studies can be found on pages 148-151 of
3 PBNX 22. In the first study, which assessed flubendiamide’s control of lepidopterous larvae on
4 fall lettuce, I found that “flubendiamide treatments provided significant reductions of large
5 larvae comparable to the other materials evaluated,” and “also provided good residual control as
6 indicated by significant reductions in small larvae late in the trial.” PBNX 22 at 148. The
7 second study assessed cross-spectrum control and therefore assessed the efficacy of Belt[®] as a
8 mixture with another compound called Movento[®]. The Belt[®] mixture was one of three
9 treatments found to have “provided the most consistent activity against [Cabbage looper]
10 larvae.” *Id.* at 150.

11 **V. FLUBENDIAMIDE’S USE ON MELONS**

12 **Q: Please describe flubendiamide’s use to control pests on melon crops.**

13 A: Flubendiamide is also used in melon production in Arizona and California, which are the
14 primary states responsible for production of cantaloupes and honeydews. Flubendiamide is an
15 ideal compound control of Lepidopteran pests (particularly cabbage looper and beet armyworms)
16 on melons because of its bee safety and lack of toxicity to natural enemies important in the
17 natural suppression of *Bemisia* whiteflies and *Liriomyza* leafminers. Furthermore, flubendiamide
18 formulated as Vetica[®] (an in-can mixture of flubendiamide and buprofezin) is commonly used
19 during flowering and pollination periods because it can provide control of both Lepidopteran
20 pests and sweetpotato whitefly, while not harming honey bees or natural enemies of those pests.

21 **VI. OPINIONS REGARDING EPA’S ANALYSIS OF FLUBENDIAMIDE’S**
22 **BENEFITS**

23 **Q: Dr. Palumbo, are you familiar with EPA BEAD’s analysis of Bayer’s benefits**
24 **submission?**

1 A: Yes, in preparation for my testimony, I reviewed PBNX 23, which is EPA BEAD's July
2 24, 2015 memorandum reviewing Bayer's benefits submission and PBNX 30, which is EPA's
3 Decision Memorandum.

4 **Q: What is your assessment of BEAD's analysis?**

5 A: In the BEAD analysis of Bayer's benefits submission, EPA largely agrees with Bayer's
6 claims regarding flubendiamide's benefits. I note that for some high value crops such as
7 almonds, peppers and tobacco, EPA claims that growers would transition to IPM-friendly
8 alternatives (methoxyfenozide, other diamides and spinosyns), based on an assumption that these
9 growers will choose to incur the higher costs of using these alternatives. While I do not study or
10 work with these particular crops, EPA's assumption would not be valid for Leafy Vegetable
11 growers.

12 With respect to alfalfa, EPA correctly acknowledges that alfalfa growers are likely to rely
13 on pyrethroids if flubendiamide is no longer available. EPA claims, however, that since the
14 treated acreage for flubendiamide is low, the impact of increased pyrethroid usage would be
15 insignificant. For the alfalfa produced in the desert valleys of Arizona and California, I disagree
16 with EPA's conclusion that the shift to pyrethroids would be insignificant. First, the aim should
17 be to promote greater use of IPM by growers, rather than forcing growers back to IPM-disruptive
18 compounds. Second, the "very small percent of alfalfa acres" that EPA describes may not be
19 large from a national perspective, but from the standpoint of growers in the American Southwest,
20 this crop is economically important and growers certainly do not consider the amount of acreage
21 to be minor. Depriving Arizona and southern California growers of the use of flubendiamide
22 would force many to use pyrethroids, jeopardizing important gains made in the practice of IPM

1 in this region, which has increasingly adopted the use of selective insecticides in conjunction
2 with natural enemy conservation to keep Lepidopteran pests under economic injury levels.

3 Growers who switch to pyrethroids will have to make more frequent applications to
4 control Lepidopteran pests such as cutworm and alfalfa caterpillar. Furthermore, because honey
5 bees and other native bees often forage un-invited in blooming alfalfa fields, risk to these
6 pollinators will increase significantly when pyrethroids are used. BEAD appears to recognize
7 this, but discounts its significance because of its claim that a “very small percent of alfalfa acres”
8 will be affected. In doing so, EPA ignores important regional distinctions. Alfalfa is a major
9 crop in Arizona and southern California, and the loss of Belt[®] will have significant
10 repercussions. Alfalfa is a low-value crop relative to almonds or peppers, with slim profit
11 margins. If growers lose access to the competitively priced flubendiamide, growers will opt
12 instead for the less expensive broad spectrum materials available (pyrethroids, methomyl and
13 chlorpyrifos). At the same time, the longer-term impacts of disrupting IPM programs for
14 Lepidopteran pests in this region could prove extremely costly to agriculture and the
15 environment.

16 With respect to lettuce, other than acknowledging on page 4 of PBNX 23 that
17 flubendiamide was used on 13% of lettuce crops nationally between 2011 and 2013, BEAD did
18 not substantively respond to benefits information submitted by Bayer, growers, entomologists
19 and IPM specialists. Based on my personal experience and my review of relevant data, Belt[®]
20 has become a critical tool for lettuce growers in the American southwest. This is supported by
21 recent survey data from the University of Arizona, PBNX 113, indicating that flubendiamide
22 (Belt[®] and Vetica[®]) is one of the most commonly used products for Lepidopteran control in
23 lettuce. That survey found that “[f]oliar uses of Diamides (Coragen[®], Voliam Xpress[®], Vetica[®],

1 Belt[®]) were the fourth most commonly chemistry used in lettuce in 2014-2015,” that “[s]ince
2 they were first registered in 2008, PCAs have steadily incorporated this new chemical class into
3 their management programs,” and that “[t]he use of Belt increased significantly this season,
4 whereas soil uses of Coragen continue to decline.”

5 I note that while Bayer also submitted data and information regarding the benefits
6 flubendiamide provides for watermelon growers (as a representative crop), BEAD does not
7 appear to have considered or responded to that section of Bayer’s submission, beyond
8 acknowledging, on page 4 of PBNX 23, that 14% of watermelon crops in the United States are
9 treated with flubendiamide.

10 **VII. OPINION REGARDING CANCELLATION AND EPA’S PROPOSED EXISTING**
11 **STOCKS POLICY**

12 **Q: In your opinion, if EPA cancels flubendiamide’s registrations, what compounds are**
13 **growers most likely to replace it with?**

14 A: If flubendiamide is removed from the market, I would anticipate an increase in pyrethroid
15 usage, primarily used in combination as tank-mixtures with other selective products
16 (methoxyfenozide, emamectin benzoate and indoxacarb). EPA’s Decision Memorandum
17 acknowledges that many growers will shift to pyrethroids, but also includes a vague and
18 generalized claim “that there are efficacious alternatives for flubendiamide.” In my opinion, the
19 consequences of flubendiamide’s cancellation will be much more complicated, particularly when
20 focusing on particular crops and particular regions of the country.

21 The cancellation of flubendiamide would likely lead to increased usage of
22 organophosphates (acephate, chlorpyrifos) and carbamates (methomyl and acephate) because of
23 their lower costs. As noted in PBNX 115, growers applying organophosphates or carbamates all

1 may require a pyrethroid to provide control of Lepidopteran insects comparable to
2 flubendiamide.

3 I would also expect to see more use of Voliam Xpress[®], which is an in-can mixture of
4 chlorantraniliprole and lambda-cyhalothrin. It is less expensive and equally effective as
5 Coragen[®], but it would also increase pyrethroid exposure in the cropping system. Also,
6 approximately 10% of the lettuce grown in Arizona is destined for export markets (including
7 Japan, Canada and the European Union). These global markets provide desert lettuce growers
8 with niche opportunities to sell fresh-market and value-added produce, but not without trade
9 regulations that can influence pest management decisions made by the grower. Many of the
10 buyers in these countries are prohibiting the local shippers from using certain pyrethroids
11 (bifenthrin, lambda-cyhalothrin, zeta-cypermethrin) on crops destined for foreign markets.
12 Because growers cannot always predict which fields will be harvested for the export market,
13 some shippers prohibit the use of certain pyrethroids from their entire growing operation. This
14 has eliminated the use of certain products such as Voliam Xpress[®], methoxyfenozide,
15 indoxacarb, emamectin benzoate and methomyl for Lepidopteran control. Belt[®], in contrast, can
16 be applied without resulting in any complications for export to foreign markets.

17 **Q: What is the basis for your opinion that growers are most likely to replace Belt[®] with**
18 **organophosphates and pyrethroids?**

19 A: The number one driver of the shift back to organophosphates and pyrethroids is likely to
20 be cost. Flubendiamide is a very competitively-priced IPM-friendly compound. Based upon my
21 experience and knowledge of grower practices, many growers will not be willing to spend more
22 on insecticides, particularly for low-margin crops like lettuce, which means that growers will

1 likely look to less expensive alternatives (e.g. pyrethroids) rather than more expensive IPM-
2 friendly alternatives.

3 **Q: What impact would a shift back to pyrethroids, organophosphates and carbamates**
4 **have on agriculture and the environment?**

5 A: These compounds are generally IPM-disruptive. They are more likely to result in pest
6 resistance and they are more likely to kill beneficial insects because of their broad spectrum of
7 activity. These compounds lack residual activity, which means that they often have to be
8 reapplied, resulting in more pesticides ending up in the natural environment. These compounds
9 also generally present comparatively heightened health risks to farm workers.

10 **Q: What impact, if any, would the cancellation of flubendiamide registrations have on**
11 **IPM and IRM in Arizona?**

12 A: Flubendiamide plays an important role in the region's IRM. Because of its unique MOA,
13 flubendiamide provides growers with an additional MOA with which to rotate throughout the
14 crop season. Flubendiamide is not cross resistant with any of the other classes of chemistry
15 being used to control Lepidopteran insects in leafy vegetables, so there is no threat of hidden
16 selection pressure. Our current University of Arizona IRM program for the Lepidopteran
17 complex therefore recommends rotations of flubendiamide, spinetoram, emamectin benzoate, or
18 chlorantraniliprole throughout the crop season. Flubendiamide's cancellation would make it
19 more difficult for growers to adequately rotate through MOAs to avoid the development of pest
20 resistance.

21 The goals of our IPM programs for Leafy vegetables, Brassica (Cole) Leafy vegetable
22 crops and melons in Arizona are to implement innovative pest management strategies that reduce
23 the industry's reliance on broadly-toxic pesticides without sacrificing yield, quality and

1 profitability, and while minimizing dietary and environmental risks. As described in PBNX 113,
2 our IPM programs appear to be achieving our goal, with insecticide use data indicating that the
3 usage of compounds such as flubendiamide has significantly reduced the vegetables industry's
4 reliance on organophosphates and carbamates. EPA's decision to cancel flubendiamide risks
5 undoing those important gains.

6 An active ingredient such as flubendiamide provides an ideal alternative for growers due
7 to its selective activity against all of their major Lepidopteran pests, and it fits in existing IPM
8 and IRM programs for leafy vegetable, Cole crops and melons. It is my opinion that without the
9 availability of insecticides like flubendiamide, economic production of Leafy vegetables in
10 Arizona and California may not be sustainable.

11 **Q: What is your understanding of EPA's proposed existing stocks provision for**
12 **flubendiamide?**

13 A: My understanding of EPA's proposal is based on my review of PBNX 20, which is
14 EPA's Notice of Intent to Cancel. According to that Notice, beginning on the date of
15 cancellation, flubendiamide in the hands of the growers or applicators (the "end users") could
16 continue to be used. However, beginning on that same date, the Registrants could no longer
17 manufacture flubendiamide, nor could flubendiamide products continue to be sold or distributed
18 by dealers or distributors. Only flubendiamide already in the hands of growers or applicators
19 could continue to be applied in the field.

20 **Q: What is your opinion regarding how the existing stocks provision would impact**
21 **growers in your region?**

22 A: My opinion is that this provision would be disruptive to growers in Arizona and southern
23 California. To explain why, it is first necessary to provide some background on pest control

1 purchasing and management in this region. The PCAs have a more active role in pesticide
2 purchasing in this region than they may have in other parts of the country. The growers either
3 employ the PCAs directly or hire the PCAs on a contract basis to consult. The PCAs typically
4 scout the growers' fields and determines when insect management is needed and what insecticide
5 should be used. Depending on the state, the PCAs submit a recommendation to either the
6 Arizona Department of Agriculture or the California Department of Pesticide Regulation prior to
7 applying the insecticide, and the recommendation, once approved, is then sent to a distributor or
8 dealer who maintains the insecticide inventory. The dealer or distributor then sells the product to
9 the growers, delivering the product to certified applicators who actually apply the product to the
10 growers' fields.

11 Because, under this system, neither the grower nor the pesticide applicator generally
12 stores substantial quantities of insecticides, permitting them to exhaust their existing stocks
13 would be a largely meaningless gesture. EPA's proposed existing stocks policy would
14 effectively prevent growers from applying flubendiamide from the date of cancellation
15 forward. This is because the pesticide dealers and distributors that actually possess significant
16 supplies of flubendiamide would be prohibited from selling or distributing those remaining
17 supplies for use by the pesticide applicators hired by the growers. As a result, when lepidopteran
18 pest numbers hit their peak this fall (as described above), the PCAs who would normally
19 recommend treatment of fall lettuce with flubendiamide will suddenly no longer be able to obtain
20 the product for their growers. This policy would also deprive growers of the use of
21 flubendiamide right in the middle of the monsoon season (which runs from mid-June through the
22 end of September) when its rainfastness and short PHI are most needed.

1 **Q: What, in your opinion, would be a less disruptive approach to existing stocks for**
2 **growers in Arizona and southern California?**

3 A: If the flubendiamide registrations are to be cancelled, a far less disruptive approach to
4 existing stocks would be to permit distributors and dealers to sell their existing inventories, such
5 that growers will have the benefit of flubendiamide's lepidopteran control through the monsoon
6 season and the end of the fall growing season. In addition, allowing Registrants to sell the
7 limited existing stocks they may have on hand at the time of cancellation will allow for a more
8 gradual and less disruptive phase-out of the product, and provide growers and PCAs with time to
9 adopt new strategies and find alternative sources of products after flubendiamide is cancelled. If
10 EPA's existing stocks policy is instead adopted as proposed, growers will lose access to
11 flubendiamide just as they are likely to need it the most.

12 **VIII. EXHIBITS**

13 **Q: Dr. Palumbo, in your testimony you referenced the following exhibits: PBNX 20,**
14 **22-23, 30, and 110-115. PBNX 20, 22-23, and 30 previously were produced as attachments**
15 **to Bayer and Nichino's Motion for Accelerated Decision and Exhibits 110-115 are being**
16 **produced as part of Bayer and Nichino's Prehearing Submission. Are these exhibits true**
17 **and correct copies of the documents you referenced?**

18 A: Yes.

19 **Q: Thank you, Dr. Palumbo. Bayer and Nichino move to enter PBNX 110-115 into**
20 **evidence.**

21

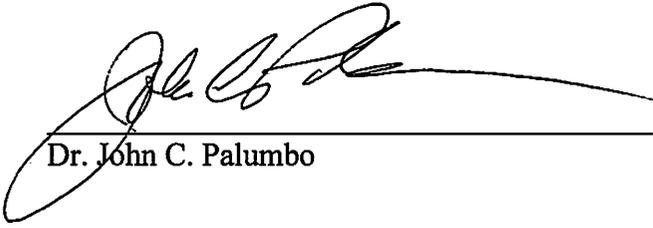
1 I declare under penalty of perjury that the foregoing is true and correct.

2 Executed on this 21st day of April, 2016.

3

4

5



Dr. John C. Palumbo