

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

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In the Matter of :
 :
BAYER CROPSCIENCE, LP and :
NICHINO AMERICA, INC., : FIFRA-HQ-2016-0001
 :
 :
Petitioners. :
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1201 Constitution Avenue, NW
Washington, D.C.

Tuesday, May 10, 2016

The ARBITRATION in the above-entitled
matter was convened at 8:30 a.m., pursuant to
notice.

BEFORE:

SUSAN L. BIRO

Arbitrator

1 APPEARANCES:

2 On behalf of Respondent:

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1		C O N T E N T S			
2	WITNESS:	DIRECT	CROSS	REDIRECT	RE CROSS
3	Susan Lewis	19	23	76	
4	Charlotte Sanson	98	100	114	
5	Lee Hall	131	133		
6	Jeffrey Johnson	139	141	173	193
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1 P R O C E E D I N G S

2 ARBITRATOR BIRO: Good morning,
3 everyone. Please be seated. We're going on the
4 record in the matter of Bayer Crop LP and Nichino
5 America Inc., Petitioners, EPA Docket Number
6 FIFRA, F-I-F-R-A, -HQ-2016-0001. Good morning,
7 everyone. I'm Susan Biro. I'm the Chief
8 Administrative Law Judge of the Environmental
9 Protection Agency. With me here today is Michael
10 Wright, Senior Staff Attorney in the Office of
11 Administrative Law Judges, and two of our Junior
12 Staff Attorneys, Ryan Yaeger and Matt Barnwell.

13 Counsel, can you identify yourself for
14 the record? Petitioners first.

15 MS. SZMUSZKOVICZ: Good morning, Judge
16 Biro. My name is Kathy Szmuszkovicz and I
17 represent Bayer CropScience in this matter. With
18 me today are my colleagues, David Barker and
19 Daniel Eisenberg, and also a paralegal, Robert
20 Dewey, will be assisting with some of the
21 transactions with exhibits. We also have with us
22 from Bayer the Division Counsel for CropScience,

1 Kristine Kring, and the Vice President for
2 Regulatory Affairs from Bayer CropScience Dana
3 Sargent. We have our three witnesses, Charlotte
4 Sanson, Lee Hall, and Jeffrey Johnson from
5 Nichino, who is the CEO and also corporate
6 representative for the Nichino. And he is
7 accompanied by his counsel Ken Morris. Also with
8 us today are Nancy Delaney out of the Regulatory
9 Affairs Group at Bayer, and Dan Dyer who is out of
10 the Environmental Sciences Group. For two of the
11 Amici the American Soybean Association has Blair
12 Elias here representing the grower groups and also
13 the General Counsel of CropLife America, Rachel
14 Lattimore is here with us today.

15 ARBITRATOR BIRO: Okay, welcome
16 everyone. Could you pronounce your last name for
17 me one more time?

18 MS. SZMUSZKOVICZ: Sure. Szmuszkovicz.
19 It's easier to say than spell.

20 ARBITRATOR BIRO: Okay. I'm apologizing
21 in advance if I pronounce it incorrectly.

22 MS. SZMUSZKOVICZ: No apology necessary.

1 MS. GOERKE: Good morning, Your Honor.
2 My name is Ariadne Goerke and I represent EPA's
3 Office of Chemical Safety and Pollution
4 Prevention. And with me are my Co-Counsel Bob
5 Perlis and Scott Garrison. And we also have Susan
6 Lewis who is our witness testifying for the Office
7 of OPP, Office of Pesticide Programs.

8 ARBITRATOR BIRO: Great. We are here
9 today to hold a hearing on Petitioners' request
10 for a hearing in response to EPA's Notice of
11 Intent to Cancel four certain additional pesticide
12 registrations involving the ingredient
13 Flubendiamide under §6(b) of the Federal
14 Insecticide, Fungicide, and Rodenticide Act,
15 FIFRA.

16 Prior to this hearing we issued -- my
17 office issued, I issued, two Orders of Substance
18 and I received yesterday Petitioner's Objection to
19 our Ruling in that case. You have reserved all of
20 your rights to appeal those rulings and I will
21 have a standing, you know, Objections on behalf of
22 both parties to any ruling made in this case today

1 in which you take umbrage, you'd like to take up
2 on appeal so we don't have to concern yourself
3 with that.

4 Based on those two prior Orders we
5 decided that there would be two issues to be
6 decided in this proceeding, whether Petitioners
7 complied with the condition of voluntary
8 withdrawal of their conditional registrations as
9 alleged by EPA, and whether the Administrator's
10 determination with respect to this condition of
11 the withdrawal is consistent with FIFRA.

12 We specifically ruled that the issue of
13 whether pesticide products have an unreasonable
14 adverse effect on the environment would not be
15 tried in these proceedings.

16 Prior to the hearing we also agreed that
17 the parties will have an opportunity to read over
18 these statements, but I want to assure you that I
19 have read everything, literally everything that
20 you have put into the record, which was no small
21 feat since some of the Petitioner's documents were
22 literally a ream of paper for one exhibit. So I

1 fully do know you through the background of this
2 matter.

3 Prior to the hearing we also agreed that
4 the Agency, EPA, would go first. So I think it's
5 appropriate to let the Agency begin by making an
6 opening statement, unless there are any
7 preliminary matters you want to discuss before we
8 begin.

9 MS. SZMUSZKOVICZ: We have no
10 preliminary matters at this time.

11 ARBITRATOR BIRO: Thank you. The EPA is
12 going first. Thank you.

13 MS. GOERKE: Thank you, Your Honor.
14 Your Honor, may it please the Court, my name is
15 Ariadne Goerke and I represent the Respondent,
16 EPA's Office of Chemical Safety and Pollution
17 Prevention. In 2006 Bayer CropScience and Nichino
18 submitted to EPA an application for registration
19 of pesticide products containing a new active
20 ingredient, Flubendiamide. After reviewing the
21 application and engaging in the typical back and
22 forth that occurs between EPA and applicants

1 before issuance of a registration, EPA determined
2 that Flubendiamide had risks of concerns.

3 In 2008 EPA approved and registrants
4 accepted the conditional registrations issued
5 under FIFRA §3(c)(7)(c). Because of certain risk
6 concerns with Flubendiamide, in approving the
7 registrations EPA required risk mitigation
8 measures on the label, data generation conditions,
9 and a cancellation condition. The cancellation
10 condition is the reason we are here today. That
11 condition required if at the end of the time
12 period established for the registration EPA
13 determined Flubendiamide causes unreasonable
14 adverse effects on the environment, within one
15 week of being notified of that finding the
16 registrants had to submit a request for voluntary
17 cancellation under FIFRA §6(f). EPA did make that
18 finding and informed the registrants.

19 A week later, instead of submitting the
20 required voluntarily cancellation request,
21 registrants informed EPA that they would not
22 comply. We sent registrants a Notice of Intent to

1 Cancel Flubendiamide products on February 29, 2016
2 under FIFRA °6(e). That Section provides for a
3 limited expedited hearing. The statutory
4 provision also states that the only matters for
5 resolution at hearing are whether the conditions
6 have been satisfied within the time provided and
7 that the Administrator's determination with
8 respect to the disposition of existing stocks is
9 consistent with FIFRA.

10 Your Honor has already ruled on motions
11 with have affirmed that the only matters for
12 resolution here are if the conditions have been
13 satisfied and whether the existing stocks
14 determination is consistent with FIFRA. It is
15 clear that registrants did not comply with the
16 voluntary cancellation condition. Susan Lewis,
17 Director of the Registration Division, has
18 submitted written testimony and will be cross-
19 examined by registrant's attorneys today regarding
20 the Agency's determination on existing stocks.
21 The Agency's determination, no sale or
22 distribution of Flubendiamide after issuance of

1 cancellation, was based on the registrant's
2 refusal to comply with an important condition in
3 their registration, to submit the voluntary
4 cancellation request if EPA made an unreasonable
5 risk determination. We submit that it is
6 consistent with FIFRA to protect and enhance the
7 integrity of the Pesticide Program by requiring
8 registrants to keep their promises to the Agency.
9 An effective program must be able to rely on
10 registrants who keep their commitments.

11 The Pesticide Regulatory Program
12 strongly believes that this corporate behavior
13 should neither be encouraged nor rewarded. This
14 type of behavior threatens the integrity of the
15 regulatory process and has the potential to affect
16 other applicants who come before the Agency.

17 Thank you.

18 MS. SZMUSZKOVICZ: Good morning, Your
19 Honor. Thank you for the opportunity to make a
20 brief opening statement. We are here before you
21 today on a very unusual situation, to our
22 knowledge a unique situation. It's unique in at

1 least three ways.

2 First, the terms of EPA's 2008
3 Preliminary Acceptance Letter are unique to our
4 knowledge. The Letter included a one of a kind
5 multi-step condition that in the first instance
6 imposed specific obligations on EPA to engage in
7 scientific dialogue about the relevant
8 Flubendiamide data and to engage in scientific
9 dialogue about the Agency's conclusions. It also
10 put the burden on EPA to make a finding on
11 unreasonable adverse effects if it concluded that
12 Flubendiamide no longer met the FIFRA registration
13 standards. These steps were necessary predicates
14 to the provision which has been referred to in the
15 parties' papers as a voluntary cancellation
16 provision. It is therefore incorrect to say that
17 voluntary cancellation standing alone was a
18 condition of registration. Voluntarily
19 cancellation was one component of a multi-part
20 condition that first required EPA to review the
21 data and engage in a good faith scientific
22 dialogue with the registrants on both the data and

1 its conclusions, culminating in a valid scientific
2 determination by EPA on whether Flubendiamide
3 poses an unreasonable risk of adverse effects.

4 Second, in addition to the unique 2008
5 Letter, this situation is unique in the way EPA
6 implemented the terms of the 2008 Letter. Up
7 until the fall of 2015 EPA acted consistently with
8 the Letter and the underlying science. However,
9 EPA's actions taken in December and January were
10 not consistent with the Letter. This is why the
11 registrants continue to assert that whether the
12 conditions of registration have been satisfied is
13 an issue in this proceeding.

14 Third, in addition to the unique Letter
15 and the unique EPA implementation, to our
16 knowledge this is the first time that FIFRA §6(b)
17 hearing has been convened under FIFRA. The
18 registrants wish to emphasize up front that
19 regardless of their disagreements and concerns
20 over the process that EPA followed here, had the
21 science shown that Flubendiamide does not meet the
22 FIFRA registration standard the registrants would

1 have withdrawn the products from the marketplace.
2 The fact and expert testimony and documentary
3 evidence submitted by the registrants in their
4 prehearing exchange established first that EPA did
5 not undertake the multi-step process required
6 under FIFRA to make a determination that a
7 registration no longer meets the FIFRA
8 registration standard, and second, that EPA's
9 assessment of Flubendiamide's environmental risks
10 was scientifically unsound; third, that EPA
11 improperly discounted or outright ignored
12 Flubendiamide's benefits to growers, agriculture,
13 and the environment, and, fourth, that as a result
14 the voluntary cancellation condition was never
15 properly triggered.

16 The Tribunal did not agree to allow the
17 registrants to make all these arguments here and
18 we will not do so. We appreciate the right to
19 appeal the preliminary rulings in the Tribunal's
20 recognition of the opportunity to make offers of
21 proof to help ensure that to the degree possible
22 the record for review by the Environmental Appeals

1 Board is as complete as it can be.

2 Turning now to the two issues on which
3 the Tribunal will accept evidence. First, for the
4 conditions of registration we will focus on the
5 procedural aspects of what has taken place as
6 opposed to the substance. Still at issue is
7 whether the so called voluntary cancellation
8 condition, if lawful, was properly triggered and
9 invoked by EPA. The documentary and testimonial
10 evidence shows that EPA was required to review the
11 Flubendiamide data to engage in a measured
12 scientific dialogue with Bayer and Nichino on both
13 the data and the EPA's conclusions before making
14 the cancellation demand. The facts show that EPA
15 did not do so. Among other things, EPA presented
16 its conclusions, including a single revised
17 toxicological endpoint and its unreasonable
18 adverse effects determination in its decision
19 memorandum and supporting documents all on the
20 same day that it made its cancellation demand.
21 Thus the required dialogue on EPA's conclusions
22 did not occur and could not have occurred.

1 On the second issue, existing stocks,
2 Congress established §6(b) hearings for the
3 express purpose of reviewing EPA's existing stocks
4 determination, including an exploration of how and
5 why the proposal was made and whether it was
6 consistent with FIFRA. Here EPA has departed from
7 its own policy with the stated intent of punishing
8 the registrants for exercising rights guaranteed
9 to them under FIFRA, including the right to
10 request this hearing. EPA argues that its
11 existing stocks provision is unreviewable because
12 EPA can prohibit any sale or use of existing
13 stocks if it so wishes. EPA further argues that
14 it need not take into account the benefits of the
15 product or potential disruption to growers in
16 doing so.

17 That position, taken to its logical
18 conclusion would mean that growers, the IR-4, the
19 general public, and registrants, all of whom have
20 already been shut out of EPA's cancellation
21 decision, would now also be shut out of its
22 existing stocks determination. Under no

1 circumstances could an EPA existing stocks
2 proposal be challenged for being too onerous.
3 Registrants respectfully submit that this is not
4 consistent with FIFRA, which is of itself a
5 risk-benefit law.

6 We understand that the Tribunal has
7 ruled that EPA has discretion to act on existing
8 stocks and to punish registrants if it so chooses
9 regardless of risk-benefit considerations.
10 Respectfully, there must be limits at EPA's
11 discretion to avoid the procedural protections
12 Congress provided by statute to such stakeholders
13 and limits on its ability to shield its science
14 and risk-benefit balance from legitimate peer
15 review discussion and debate. We hope that
16 ultimately those limits will be upheld.

17 As you know, the parties view this case
18 very differently. For the registrants this is an
19 extreme example of EPA elevating a political
20 objective over science. The circumstances are so
21 stark that the registrants found it necessary to
22 take the unusual step of requesting review.

1 Neither registrant has ever undertaken anything
2 like this before. It is extraordinary, especially
3 considering that it involves challenging the very
4 Agency that holds so much power of the
5 registrants' livelihood.

6 In terms of the order of the hearing,
7 Your Honor explained this morning that EPA will go
8 first and will present its sole witness, Miss
9 Susan Lewis, and the registrants will then present
10 three fact witnesses, Miss Charlotte Sanson, Mr.
11 Lee Hall, and Mr. Jeffrey Johnson. We will make
12 an offer of proof to the EAB on the portion of
13 these three witnesses' testimony that were
14 included under the May 3 order and also on the
15 full testimony and exhibits of the four experts
16 whose testimony and exhibits were excluded under
17 the same order.

18 Thank you for your attention and
19 consideration of the registrants' evidence.

20 ARBITRATOR BIRO: Thank you. Okay, Miss
21 Goerke, do you want to call your first witness.

22 MS. GOERKE: Yes, thank you. I'd like

1 to call Susan Lewis. Do you prefer if I stand
2 here or do you have a preference?

3 ARBITRATOR BIRO: Yes. If you could
4 stand to the right.

5 MS. GOERKE: Okay.

6 Whereupon,

7 SUSAN LEWIS

8 was called as a witness and, having been first
9 duly sworn, was examined and testified as follows:

10 DIRECT EXAMINATION

11 BY MS. GOERKE:

12 Q Good morning.

13 A Good morning.

14 Q Would you please state your name and
15 current title for the record?

16 A Susan Torgus Lewis, and I'm Director of
17 Registration Division in the Office of Pesticide
18 Programs.

19 Q I would like to draw your attention to
20 your written testimony. I don't know if it's
21 helpful to have it on the screen or I can just
22 pull it up from a Respondent Exhibit list. It is

1 Item Number 10. If you want I can pull that up.

2 If you can. Do you have your --

3 SPEAKER: Yes.

4 MS. GOERKE: Yes. Exhibit 10.

5 Respondent Exhibit 10.

6 BY MS. GOERKE:

7 Q Do you see that?

8 A I do.

9 Q Is that the -- is this testimony that
10 you have prepared for this hearing?

11 A It is.

12 Q Are there any changes that you would
13 like to make to this testimony?

14 A Yes. There is one minor typographical
15 error on page 13. First full paragraph, it starts
16 with "I made the determination".

17 Q And for the court reporter's benefit --
18 excuse me -- that is Bates stamp page 20106.

19 A That first full paragraph, second line,
20 the typo says OCSSP and which should end with
21 CSPD.

22 Q Thank you. Is this a true and correct

1 copy to the best of your knowledge and belief of
2 your testimony?

3 A Yes.

4 MS. GOERKE: Your Honor, Respondent
5 would like to move to have Exhibit 10, Susan
6 Lewis' written testimony admitted into the record
7 as it read.

8 MS. SZMUSZKOVICZ: No objection, Your
9 Honor.

10 MS. GOERKE: Additionally I have a --

11 ARBITRATOR BIRO: Exhibit 10 is admitted
12 into the record.

13 BY MS. GOERKE:

14 Q Additionally I have a list of Exhibits
15 that accompanied your written testimony that are
16 incorporated into your written testimony. That is
17 in the front of your binder. It does not have an
18 exhibit number on it. Could you please take a
19 moment to review that list, marked Respondent
20 Index of Exhibits.

21 A Yes.

22 Q Are you familiar with the items that are

1 marked RE1 through 9?

2 A I am.

3 MS. GOERKE: Your Honor, I would like --
4 Respondent would like to move to have the Index of
5 Exhibits and the Exhibits -- well, just the
6 Exhibits, not the Index, entered into the record.

7 ARBITRATOR BIRO: Is there any
8 objection?

9 MS. SZMUSZKOVICZ: Thank you, Your
10 Honor. We have no objections at this time, but
11 subject to the scope of the admissibility of the
12 exhibits we just want to ensure consistency.

13 ARBITRATOR BIRO: So you don't object or
14 you do?

15 MS. SZMUSZKOVICZ: We do not object, but
16 we ask for rulings on the scope of all the
17 Exhibits that would be entered, and so if there
18 are objections that we have not heard from EPA,
19 which of course if given to us we reserve the
20 right to do, we wanted to be able to just ensure
21 that there is a consistency on the type of
22 Exhibits that are admitted into evidence. If you

1 indicate -- can represent now it has no further
2 objections to our Exhibits then we would have no
3 further objections.

4 ARBITRATOR BIRO: Do you need time to
5 talk about that now?

6 MS. SZMUSZKOVICZ: It would -- if we
7 could take a minute to do that, Your Honor, that
8 would be -- that would be --

9 MS. GOERKE: EPA does not have any
10 objections to the Exhibits that were planned to be
11 entered that we were aware of last week that was
12 sent to Michael Wright that indicated Exhibits
13 that accompanied their witnesses. We do not have
14 any objections since we --

15 ARBITRATOR BIRO: Okay. So without
16 objection, then Respondent's Exhibits 1-9 are
17 admitted into the record.

18 MS. GOERKE: Thank you, your Honor. I
19 don't have any further introductory remarks for
20 Ms. Lewis.

21 CROSS-EXAMINATION

22 BY MS. SZMUSZKOVICZ:

1 Q Good morning.

2 A Good morning.

3 Q We've met, but for the record I wanted
4 to introduce myself. My name is Kathy
5 Szmuszkovicz and in this matter I'm representing
6 Bayer CropScience, one of the registrants. Thank
7 you for being here.

8 I plan to just ask a few questions that
9 are introductory and foundational in nature. You
10 understand that EPA has offered you both as a fact
11 witness and as an expert witness in this matter,
12 do you not?

13 A Correct.

14 Q And as an expert witness you've been
15 offered as an expert in two areas, the pesticide
16 registration process and EPA decision making
17 related to that process. Is that your
18 understanding?

19 A Yes.

20 Q So some of my questions will be about
21 the facts and some will be about the opinions you
22 offer and the basis of the opinions that you

1 offered. Many of my questions will call for a yes
2 or no answer. And I would ask that you answer
3 either yes or no. If the EPA legal team believes
4 that further explanation is necessary they will be
5 able to follow up with additional questions once
6 we are done with our conversation.

7 I'd like to start with your background
8 and qualifications. And I'm going to be handing
9 you what's been marked as PBNX 123, which is a
10 copy of your curriculum vitae that EPA provided to
11 us in the prehearing exchange. So we'll follow
12 the protocol of showing it to your counsel first
13 and then give it back to you.

14 A Okay.

15 Q Have you had an opportunity to look at
16 this and confirm whether it is your curriculum
17 vitae?

18 A It is.

19 Q Thank you. And based on the information
20 in your vitae you've been in management roles at
21 EPA since 1989, is that correct?

22 A Correct.

1 Q And before that for two years, between
2 1987 and '89 you coordinated scientific and
3 regulatory assessment for fungicides, correct?

4 A Correct.

5 Q And am I understanding correctly that by
6 stating that you coordinated those assessments you
7 were not the person responsible for preparing the
8 scientific and regulatory assessments in the first
9 instance?

10 A Correct.

11 Q Thank you. And then to round out your
12 experience at EPA, for seven years, from 1980 to
13 1987 you were a staff member on the data pollen
14 team, which identified human health data
15 requirements for older pesticides and determined
16 how EPA would process registrants responses, such
17 as commitments to generate data, requests for low
18 volume and minor use waivers, amendments to label
19 uses, time extensions, and cancellations. Is that
20 accurate?

21 A Yes.

22 Q In terms of your education would you

1 please tell the Tribunal what university you
2 attended and what degree you obtained?

3 A Sure. Virginia Tech and I have a degree
4 in business administration.

5 Q Do you have any degrees in science?

6 A No.

7 Q And you have been in no scientific role
8 within EPA?

9 A Correct.

10 Q Did you -- were you in any scientific
11 positions -- did you act as a scientist in any of
12 your positions at EPA?

13 A No.

14 Q Also, just from a foundational
15 standpoint I'd love to ask you a few questions
16 about the documents that you reviewed. And so
17 first of all there were the 9 Exhibits that you
18 sponsored. And did you review each of those
19 Exhibits?

20 A Yes.

21 Q I'd like to ask you to turn to
22 Respondent's Exhibit which contains several 2008

1 emails between EPA and Bayer.

2 And there should be a notebook on -- you
3 have the notebook. Did you review any other EPA
4 emails or emails between EPA and the registrants,
5 or the applicants at that time, from that time
6 period?

7 A From 2008 I --

8 Q For --

9 A -- prior to the decision, not that I'm
10 aware of, but it's possible.

11 Q Well, do you remember asking to look at
12 any other emails from that time period?

13 A We asked to try to get the emails that
14 were relevant around the time of the decision.

15 Q And so --

16 A I believe I was given all of the emails.

17 Q Thank you. And then these -- I take it
18 these were selected from amongst those? Did you
19 do the selection?

20 A No.

21 Q Now I'd like to ask you to turn to the
22 registrant's Exhibits. And there is a list at the

1 front of Volume I of those Exhibits.

2 A Okay.

3 Q Thank you.

4 A All right.

5 Q Volume I. Do you see that there's a
6 hearing Exhibit Index at the front of that?

7 A Mm-hmm.

8 Q And there is some overlap and I've made
9 some notes on some of the Exhibits that are both
10 the EPA's and the registrants'. But I'd like to
11 go through this list with you and have you
12 identify the Exhibits that you reviewed. So PBNX
13 7 and 8 are the equivalent of the EPA's Exhibits
14 RE 3 and RE 2. So we know that you reviewed
15 those. Did you review the Flubendiamide pesticide
16 fact sheet from 2008?

17 A I have seen that, yes.

18 Q And PBNX 10. If you could just start
19 there and say through 16, which are the next
20 unique Exhibits, whether you reviewed any of these
21 documents.

22 A The extension request I have seen.

1 Q Okay. The extension request? Which
2 numbers would those be?

3 A The letters granting. I -- I don't
4 recall specific, but I am aware that every time
5 that we granted an extension there was an initial
6 record of that.

7 Q Thank you.

8 A So the ones that happened while I was
9 there were definitely ones I had seen.

10 Q Okay. So that would include the number
11 -- PBNX Number 11 in August 2015, which is an
12 email from Carmen Rodia regarding the draft list
13 of required additional studies?

14 A Yes.

15 Q You would have reviewed that and also
16 12, 13, 14, 15, and 16, all of which are current?

17 A Yes.

18 Q Okay. 17 is also Respondent's Exhibit,
19 so we know that you reviewed that. And PBNX 18 is
20 Respondent's Exhibit 7 so we know you've reviewed
21 that. PBNX 19, that was EPA's press release about
22 the cancellation. Are you familiar with that?

1 A I've seen that.

2 Q PBNX 20 is the same as RE 8, so we know
3 you've reviewed that. PBNX 21, the 2008 B Public
4 Interest Finding. Did you review that?

5 A I read that, yes.

6 Q Thank you. And then we move back into
7 2015 and 2016 documents, from 22 to 26. Those are
8 all current.

9 A Yes.

10 Q Would you take a look and see if you
11 read those.

12 A I believe that your number 23 was one of
13 our Exhibits.

14 Q Okay.

15 A I have read probably portions of some of
16 the others.

17 Q Okay. Thank you. And then moving to
18 Number 27, that was the 2008 EFED risk assessment.
19 Did you review that?

20 A Yes.

21 Q And there are several other 2010
22 documents here, risk assessments, ecological risk

1 assessments, 28 and 29. Do you remember reading
2 those?

3 A I am familiar but I did not read those
4 at that time.

5 Q Okay. And PBNX 30, EPA's decision
6 memorandum for Flubendiamide cancellation?

7 A Yes.

8 Q Okay. And 31, 32 are both EPA documents
9 from 2016.

10 A Yes.

11 Q PBNX 33, the des-iodo Spiked Water data
12 evaluation record from 2008?

13 A That DER, no.

14 Q Okay. Okay. And the next document is
15 also a DER from 2011.

16 A No.

17 Q 35, the EFED review of water monitoring.

18 A I'm familiar with it, yes.

19 Q And EPA's EFED review in 2015, that PBNX
20 36.

21 A That I'm uncertain.

22 Q Okay. And then the next group, 37-51,

1 have been excluded from this proceeding by Judge
2 Biro's Order. So we will skip over those. 52 is
3 the same as RE 9, so we know you reviewed that.
4 And then the PBNX 80 through 115 have been
5 excluded under Judge Biro's order. Did you review
6 PBNX 116, the verified written statement of
7 Charlotte Sanson?

8 A Yes.

9 Q And PBNX 117, the verified statement of
10 Lee Hall?

11 A Yes.

12 Q And PBNX 118, the verified statement of
13 Jeffrey Johnson?

14 A Nichino?

15 Q Yes.

16 A Yes.

17 Q Okay. And then 119 through 122 have
18 been excluded by Judge Biro. Thank you. Now are
19 you aware that Judge Biro has issued two
20 preliminary orders in this matter, one on April 25
21 and one on May 3?

22 A Yes.

1 Q And did you review either or both of
2 those?

3 A The first one I reviewed. The second
4 one which just happened I have not reviewed.

5 Q Did you review the Amicus brief that was
6 filed by the Center For Biological Diversity?

7 A Briefly, yes.

8 Q In terms of EPA's submissions, did you
9 review the brief that EPA submitted opposing the
10 registrants' request for an accelerated decision
11 on whether they were entitled to a 6(b) hearing?

12 A Yes.

13 Q In terms of other sources that you
14 relied on for your testimony, on page 200095 of
15 your testimony, that's Exhibit 10 -- the small
16 number is on the right.

17 A Yeah.

18 Q It's page 2 and the large numbers are
19 200095.

20 A On -- which -- which page are you on?

21 Q It ends in 95 in the smaller numbers.

22 A Okay.

1 Q And right before the background section
2 you mention that you're relying in part on
3 discussions with your staff in the Registration
4 Division. Correct?

5 A Correct.

6 Q And you're relying in part on
7 discussions with staff in the Environmental
8 Impacts Division. Correct?

9 A Yes.

10 Q And you're relying in part on
11 discussions with staff in the Biological and
12 Economic Analysis Division.

13 A Yes.

14 Q And this list does not include
15 discussions with staff in the Health Effects
16 Division?

17 A That's correct.

18 Q And that's the division that looks at
19 human health impacts?

20 A Yes.

21 Q Okay. And you were present, were you
22 not, at the internal EPA meeting that took place

1 on December 16, the day after EPA met with the
2 CEOs of the two registrants?

3 A Is this with Jim Jones?

4 Q Yes.

5 A I was there.

6 Q Thank you. And do you -- naturally took
7 those discussions into account also?

8 A Yes.

9 Q Is there anything else that you relied
10 on to prepare your testimony?

11 A Recently I re-read portions of the law
12 just to refresh my knowledge.

13 Q Thank you. I'd like to ask you to turn
14 back to Respondent's Exhibit 4, the 2008 emails.
15 And you mentioned a moment ago that you had
16 reviewed all the emails in this Exhibit.

17 A Yes.

18 Q I'd like to ask you to start on page --
19 the very first page. It's -- for the record it's
20 200020. And this is an email from EPA to Bayer,
21 is it not?

22 A It is.

1 Q And could you state for the record what
2 the date of the email is?

3 A July 17, 2008.

4 Q Thank you. And asking you now to turn
5 your attention to the following pages that run
6 from 20021 to 200025. They -- these pages include
7 EPA's July 17, 2008 draft of a Preliminary
8 Acceptance Letter for Flubendiamide, do they not?

9 A Correct.

10 Q Okay. And turn your attention to page
11 200024, paragraph 6. In this paragraph EPA
12 suggested that the registrar, at this point it
13 appears that it's just referring to Bayer, submit
14 an irrevocable request for voluntary cancellation
15 within 60 days of the date EPA granted the
16 registration. Is that -- is that correct?

17 A Yes.

18 Q And the EPA proposed that it would
19 decide at a future date whether to accept that
20 request. Is that correct?

21 A Can you repeat that again?

22 Q Sure. EPA -- in paragraph 6 EPA was not

1 suggesting that the voluntary cancellation request
2 would become immediately effective in 60 days?

3 A That's correct.

4 Q At some point in the future, at least
5 not until sometime in July 2013, EPA would decide
6 whether to accept the cancellation request?

7 A Correct.

8 Q But they'd asked for it up front?

9 A Yes.

10 Q Okay. And it's a little bit -- a little
11 bit hard to follow, but in the same draft EPA says
12 that it would only accept the voluntary
13 cancellation if after review of the data EPA could
14 not make a determination that condition --
15 continued registration of Flubendiamide will not
16 result in unreasonable adverse effects on the
17 environment. And I'm quoting from the letter.
18 Those are not my words. I know it's a little
19 confusing.

20 A Could you give the number please?

21 Q Sure. It's in 6(b). So just at the
22 bottom of the page 200024.

1 A I see, yes.

2 Q Do you need a minute to read it?

3 A Yes.

4 Q Okay. So what I read into the record
5 was exactly what it said here, it was not an
6 interpretation.

7 A Mm-hmm.

8 Q And you're familiar with that paragraph?

9 A Yes.

10 Q Thank you. Okay. Turning to the next
11 page, 200025, and now looking at paragraph 7, this
12 EPA draft paragraph indicates that the
13 registrations will expire on a date certain,
14 "unless EPA determines at its sole discretion to
15 extend the registration". Is that correct?

16 A Yes.

17 Q Okay. Okay. Turning now to the next
18 page, 200026, could you identify for the record
19 what this document is?

20 A Yes. This appears to be -- it's dated
21 July 23, 2008 and it's an email from their --
22 their response back to their -- our initial

1 proposal of the preliminary acceptance letter.

2 Q Thank you. And turn your attention to
3 page 200028. This is part of Bayer's July 23,
4 2008 response. And three paragraphs from the
5 bottom you see that Bayer suggested to deleting
6 all of paragraph 6, which we discussed a moment
7 ago.

8 A Yes.

9 Q And then reading -- continuing on to
10 200028 to 200029, Bayer suggested that if after
11 you viewed the data and scientific discussion
12 between EPA and Bayer, EPA would have several
13 options, one of which would have been for EPA to
14 cancel the registrations. Would you take a moment
15 to look at that --

16 A Sure.

17 Q -- and see if you can confirm that?

18 A This is on the top of 29?

19 Q Yes. Starting -- starting on 28 right
20 underneath where it says "Bayer CropScience
21 understands and agrees".

22 A Yes.

1 Q And then continuing onto the top of the
2 page. Through -- through D. So the substitute
3 provisions that included EPA having several
4 options including to cancel the registrations.

5 A Okay. I'm trying to keep straight what
6 Bayer is recommending. It's a little confusing
7 because it's not on track changes versus what we
8 wanted.

9 Q Sure. So I believe on page 200028 the
10 draft says part six of the draft pre-registration
11 agreement would be entirely replaced with the
12 following language. So is it your understanding
13 that this was Bayer's proposal?

14 A Yes.

15 Q Thank you. And continuing on page
16 200029 Bayer was proposing to entirely delete
17 paragraph 7 of EPA's draft, which was the
18 expiration provision we talked about a minute ago,
19 correct?

20 A Correct.

21 Q Turning to the next page, 20030, could
22 you state for the record the date of the document,

1 the author, and to whom it is addressed?

2 A Sure. This is July 29, 2008 and the
3 author is Carmen Rodia, and it's to Danielle
4 Laroche from Bayer.

5 Q And is -- Mr. Rodia is with EPA is he
6 not?

7 A Yes.

8 Q And he worked at this time also?

9 A Yes.

10 Q So six days later, on July 29, EPA wrote
11 back to Bayer. And I'd like to ask you to look at
12 the page that's marked 200033. And toward the
13 bottom of that page under 7(c), this is the first
14 time we see the one week voluntary cancellation
15 provision, correct?

16 A The one --

17 Q Yes. Thank you. And take a minute, but
18 to my eye the EPA proposal no longer contained an
19 expiration provision. Can you confirm that?

20 A I need to look at it.

21 Q Yeah, take your time.

22 A What I get from that is it talks about a

1 time limit for registration on the top of page 34.

2 Q And so that's different than the
3 expiration provision that we talked about a moment
4 ago that was in EPA's --

5 A Yes.

6 Q Thank you. Thanks. Okay. A little bit
7 later in the Exhibit, toward the very end, pages
8 20062 to 20065, could you turn -- turn to that?
9 And this is the July 31, 2008 signed version of
10 the Letter that this -- we were looking at in
11 draft over the last few minutes, is it not?

12 A Yes.

13 Q Now turning to page 20063 to 20064,
14 paragraphs 6 and 8. Take a moment to look at
15 those.

16 A Okay.

17 Q And 6(b) and 8(b) are identical in text
18 other than references to the two different
19 registrants Nichino and Bayer. Is that -- that
20 correct?

21 A Yes.

22 Q And so looking at 8(b), which would be

1 the same as 6(b) other than the names of the
2 registrants, that states that EPA shall complete
3 its review of the entire required data set and
4 will consider any additional data supporting
5 information. Is that accurate?

6 A Yes.

7 Q And then it goes on to say that EPA
8 scientists and Bayer scientists -- and I'm reading
9 form 8(b) now -- shall engage in dialogue about
10 the data and the Agency's conclusion. Is that
11 accurate?

12 A Yes.

13 Q Thank you. Now, looking at 6(d), as in
14 dog, and 8(d), both of which are on 20064, are
15 those parallel provisions just with the only
16 difference being the names of the registrants?

17 A Yes.

18 Q And so looking at 8(d) as representative
19 it states that after reviewing the data as
20 discussed in 6(b) and 8(b) if EPA wishes to demand
21 cancellation it must first make a determination
22 that further registration of the Flubendiamide

1 technical product or end use products will result
2 in unreasonable adverse effects.

3 A Correct.

4 Q And the final conditions did not contain
5 an expiration condition did they?

6 A I need to look at the --

7 Q Sure, take -- yes, take your time.

8 A Did you say expiration or --

9 Q Expiration.

10 A That's not an expiration.

11 Q Thank you. Okay, let's turn back to
12 your testimony at Exhibit RD10, and staying with
13 the 2008 time period let's look at your testimony
14 at 200098. And we talked about this a minute ago.
15 You mentioned that you discussed the matter with
16 your staff who were involved and who did that
17 include?

18 A That included Carmen Rodia. It included
19 Maryann Johnson, who was the branch chief at that
20 time. It included Richard Gebken.

21 Q And would all of those people be at
22 positions that report to your level -- the

1 director of registration?

2 A Yes, within my position.

3 Q And did you speak with anyone from that
4 time at your level or above who was at EPA in 2008
5 at your level or above.

6 A No.

7 Q And you spoke a minute ago about your
8 having reviewed many of the key decision documents
9 for 2008, and we talked about the ones that were
10 provided by the parties in this case. Do you
11 recall whether you reviewed the Health Effects
12 Division's assessment of human health impact for
13 2008?

14 A Their assessment? I did not.

15 Q And that would have been the risk
16 assessment that took into account safety to
17 agricultural workers?

18 A Yes.

19 Q Did you review that portion of it?

20 A The risk assessment, no.

21 Q And how about -- would that have taken
22 into account safety of infants and children of the

1 compound?

2 A Yes.

3 Q Did you review that at risk assessment?

4 A That risk assessment, no.

5 Q That particular Health Effects Division
6 risk assessment still stands today, does it not?

7 A Yes.

8 Q There haven't been any changes to that
9 or a new assessment done, have there?

10 A Well, since '08 there are new uses
11 granted so they probably would have been up to
12 date for this new system of assessments.

13 Q Do you know if any of those changed the
14 favorable conclusions in them?

15 A I don't believe they did.

16 Q Thank you. Okay, let's turn now to RD5.

17 A R --

18 Q RD5, yes. And this is your January 29,
19 2016, recordation cancel of currently registered
20 provide flubendiamide, correct?

21 A Correct.

22 Q And our questions here will go to the

1 process, not the substance of, the risk benefit
2 decision that was made.

3 Well, I understand from the face of the
4 document at RD5 that you signed the recommendation
5 to cancel flubendiamide registrations, correct?

6 A Yes.

7 Q Did you draft this memorandum?

8 A No.

9 Q Who drafted it?

10 A It was a combination of our staff, as
11 well as our scientists and portions of legal
12 counsel.

13 Q And when you mention scientists, are you
14 referring there to the Effects Division?

15 A Correct.

16 Q And what about the --

17 A RE? We used their report and they
18 refute the document and edit.

19 Q And what about the Health Effects
20 Division?

21 A No.

22 Q Did OPP Management brief you in it?

1 A Yes.

2 Q And what about OCSS SPT Management?

3 A Right. I don't know if they saw it.

4 Q You confirmed earlier that you were at
5 the December 2016 meeting with the assistant
6 administrator. That was an internal EPA meeting,
7 correct? And you were also at the December 15th
8 meeting that the assistant administrator held with
9 the CEOs and the two registrants.

10 A Correct.

11 Q And quite a lot of people in the room
12 were also there.

13 A Yes.

14 Q At the meeting, the assistant
15 administrator stated that if it had been his
16 decision he would not have registered
17 flubendiamide in 2008, correct?

18 A I have heard him say that.

19 Q Thank you. And at that meeting he also
20 stated, didn't he, that in his opinion persistence
21 alone would be a reason to cancel flubendiamide.

22 A I don't know those are his exact words,

1 but he did say he was extremely concerned with
2 persistence.

3 Q Thank you. Is it your opinion that
4 under the preliminary acceptance letter, the 2008
5 letter, that EPA was required to make a decision
6 on whether flubendiamide meets the unreasonable
7 adverse effects standard for registration?

8 A Yes.

9 Q And the preliminary acceptance letter in
10 paragraph 6(d) and 8(d) that we talked about
11 required an affirmative determination that further
12 registrations would cause unreasonable adverse
13 effects before EPA could demand cancellation.

14 A Correct.

15 Q The preliminary acceptance letter was
16 silent on the way that EPA should memorialize that
17 decision -- is that -- is my understanding
18 correct?

19 A Correct.

20 Q And it was silent on the way that EPA
21 was to communicate the decision to the registrants
22 also.

1 A Correct. But can I check that real
2 quick?

3 Q Oh, sure. Please. That was RE -- it's
4 at the back of -- it's at the back of RE4.

5 A Which one?

6 Q RE4. It's the final few pages that have
7 the signatures on them.

8 A Thank you. Correct.

9 Q But we do know that in this case, EPA
10 did prepare RD5, which was your decision
11 recommendation. Even though EPA wasn't required
12 to do that, they chose to do that. Is that
13 correct?

14 A Correct.

15 Q And the preliminary acceptance letter
16 itself only required EPA to notify the registrants
17 of the decision, not to explain it -- if I'm
18 reading that RD4 correctly.

19 A Correct.

20 Q Could EPA have reached an unreasonable
21 adverse effects determination based on an issue or
22 a concern that EPA had not previously discussed

1 with the registrants based on the letter?

2 A My interpretation says we must have
3 measured dialogue after -- during the process.

4 Q So, that would include discussion of any
5 issue or concern between scientists.

6 A Yes.

7 Q Let's turn now to the existing facts
8 issue, and we'll look at your testimony at RE10.
9 And that page is 200106. At the top of the page,
10 the first full paragraph, you state that "I made
11 the determination regarding how to handle the
12 existing stocks of flubendiamide with the OCSPP
13 (sic) management team". And you confirmed that
14 this morning.

15 A Yes.

16 Q So, I have just a few questions that
17 will help ensure clarity of the record on basis
18 for the existing stocks decision.

19 The EPA did not ask the registrants for
20 information about the amount of flubendiamide in
21 the hands of users, did it?

22 A That's correct.

1 Q And EPA did not ask the registrants for
2 information on the amount flubendiamide in the
3 hands of retailers.

4 A Correct.

5 Q Or for information on the amount of
6 flubendiamide in the hands of distributors.

7 A Correct.

8 Q Or the amount of flubendiamide in the
9 hands of the registrants.

10 A Correct.

11 Q And EPA did not ask about nor did it
12 know that Nichino had stopped ordering
13 flubendiamide by the time of its decision.

14 A Correct.

15 Q And it did not ask about nor did it know
16 the status of Bayer's orders.

17 A Correct.

18 Q EPA did not ask the registrants about
19 whether all the existing stocks under EPA's
20 proposal that would need to be returned to the
21 registrants or that are in the hands of
22 registrants would be disposed of in the

1 environment.

2 A No.

3 Q Or what the environmental impact of that
4 would be?

5 A Correct.

6 Q EPA did not request information on the
7 benefits to growers to using those existing
8 stocks?

9 A On the existing stocks? Correct.

10 Q And EPA did not consider the impact on
11 growers who depend on flubendiamide in developing
12 the existing stocks for those proposal.

13 A That's correct.

14 Q EPA decided to allow end users to use
15 whatever flubendiamide is in their possession
16 based on your understanding that the benefit of
17 getting it out of the marketplace was less than
18 the risk of transporting it to a disposal
19 facility. Is that correct?

20 A That was one.

21 Q And do you believe that there's very
22 little flubendiamide in the hands of end users?

1 A I don't know how much is in the hands of
2 end users, but I have read some of the testimony
3 that indicated that users tend not to hide the
4 product until they know they need it.

5 Q Thank you. And just to be clear, that
6 was the testimony in this case after the
7 cancellation decision after the existing stocks.

8 A Right.

9 Q So, at the time that EPA made that
10 assumption, what was the basis for your
11 understanding that there would be very little
12 material in the hands of the end users?

13 A This is not a -- this is a mature
14 chemical, so it's not heavily produced.

15 Q And can you correlate that to your
16 conclusion that there wouldn't be much material in
17 the hands of the end user?

18 A I think what we said from the hands of
19 the end user, the growers who already have it, the
20 overriding factor was if you have it within
21 containers, there's a bigger risk of spill or
22 exposure, and also it's very difficult to know

1 which grower has it. So, there's an
2 identification process.

3 Q So, none of that had to do with any
4 benefit to the growers to using the product.

5 A No.

6 Q And EPA reserved the right to change its
7 mind and prevent further usage of flubendiamide if
8 it learned that the end users had obtained
9 significant quantities after the notice came out,
10 correct?

11 A I believe so.

12 Q And just to be clear, the EPA proposed
13 to prohibit further sale by retailers and
14 distributors unrelated to the registrants?

15 A Correct.

16 Q And that was to punish the registrants?

17 A The rationale we put in was we did not
18 want to reward additional production. Production
19 can continue now our firm can keep running versus
20 had we received the irrevocable voluntary
21 cancellation, production would have ceased. So
22 those existing stocks and shipments would be

1 increasing at the retail outlet now.

2 Q So, it had to do with the registrants
3 but not with the impact on the retailers.

4 A Right, it was a registrant bonus.

5 Q Just picking up on your comment, now,
6 about the timing. You also mentioned that in your
7 testimony on 200116 that EPA would have moved
8 quickly to publish a notice about the voluntary
9 cancellation had the registrants made a voluntary
10 cancellation.

11 A Correct.

12 Q And just talking about what "quickly"
13 is, I think we've all been experiencing holding a
14 hearing, entertaining a decision within 75 days or
15 97 days. Would you say that that has been a quick
16 process?

17 A This hearing has been relatively quick,
18 yes.

19 Q And in the context of preparing and
20 getting the Federal Register Notice out and
21 published, is "quick" for EPA 45 days?

22 A In my testimony, I anticipated we put

1 the matter quickly because there is a standard
2 voluntary cancellation request and they could have
3 been held and issued almost in a matter of a week.

4 Q And published in the Federal Register --

5 A Published -- well, probably would be in
6 two weeks, so.

7 Q In your original testimony you stated
8 that the end of the hearing process would be
9 August 1st, and you later changed it to July 6,
10 correct?

11 A Correct.

12 Q After 7 1/2 years of registration, the
13 difference between a cancellation notice in, I
14 think you said, March or April and June or July,
15 whichever the date, is not a large difference is
16 it?

17 A It depends on the season -- when you are
18 at the height of the agricultural season it can
19 make a big difference.

20 Q And what are you relying on to state
21 that opinion with regard to flubendiamide?

22 A From all my interactions over the years

1 with industry when they're looking to get that new
2 use registered or get a new active ingredient
3 registered they generally need to have that before
4 so that they can do the marketing and the
5 production and the buying and the orders. So,
6 it's all my years of interacting with industry on
7 my making decisions in the timeframe they need.

8 Q And usually it's before January in order
9 to work with all the different players.

10 A Yes. Usually those are for things that
11 are not registered yet.

12 Q Do you have a different answer for items
13 that are registered? Is the --

14 A The production line?

15 Q The production and distribution and
16 contracts and --

17 A That's probably more of a team if it's
18 been registered for a model.

19 Q But would it also need to occur before
20 January?

21 A That I don't know.

22 Q Okay. Let's turn now to page 200105,

1 your testimony, RE10. And right before the
2 existing stocks provision, you make a statement,
3 "We did not receive a voluntary cancellation
4 request by February 5th or thereafter and
5 subsequently informed the registrants because the
6 registrants had not submitted requests for
7 voluntary cancellation and failed to comply with
8 conditional registration, the flubendiamide
9 products identified in the Notice of Intent to
10 Cancel are subject to cancellation under FIFRA
11 "6(b)." And you confirmed that statement earlier
12 this morning.

13 A Yes.

14 Q One of the experiences that you
15 mentioned in your vitae that you had at EPA that
16 formed the basis for your being offered as an
17 expert witness was your experience as branch chief
18 in the Special Review and Re-registration
19 Division, correct?

20 A Correct.

21 Q And in that capacity, you managed the
22 risk management process for the Rodenticide

1 Cluster, which involved a 2008 risk management
2 decision for handling of Rodenticides. And that
3 included the Rodenticide registrations of Reckitt
4 Benckiser that ultimately were the subject of the
5 cancellation proceeding.

6 A Yes.

7 Q Okay. I'd like to hand you a new cross
8 examination Exhibit. This is the February 5th,
9 2013 Federal Register Notice. And we'll show it
10 to your council first and then -- and this will be
11 marked as PBNX 124.

12 Could you identify for the record the
13 date and subject of this Federal Register Notice?

14 A Yes. February 5th, 2013, and its
15 Rodenticides; Notice of Intent to Cancel
16 Registrations of, and Notice of Denial of
17 Applications for, Certain Rodenticide Bait
18 Products.

19 Q So, this was in 2013, which would have
20 been five years after the 2008 risk management
21 decision for the Rodenticide posture that we
22 talked about a moment ago?

1 A Correct.

2 Q Before EPA issued the notice of intent
3 to cancel further Rodenticides, EPA chose a
4 different way to try to enforce the risk
5 management decision, did they not?

6 A Yes.

7 Q Instead of pursuing cancellation, it
8 declared that the registrations were misbranding
9 as of a certain date, if I remember correctly?

10 A The misbranding -- I believe that was an
11 option that we were considering.

12 Q And the record then has challenged that
13 option in the report. Do you remember that?

14 A Yes.

15 Q And the report found that the
16 misbranding approach was unlawful and required EPA
17 to proceed under FIFRA §6 with cancellation. Do
18 you remember that?

19 A I do, correct.

20 Q And prior to the delay in EPA issuing
21 this notice of intent to cancel in 2013 was caused
22 by EPA's choice of a different option as the first

1 option as the first option. Would that be a fair
2 --

3 MS. GOERKE: Excuse me, Your Honor. I
4 want to object on relevance grounds. I don't see
5 where bringing in previous notices of cancellation
6 has to do with the one at hand.

7 MS. SZMUSZKOVICZ: One of the main
8 issues here, and it's directly addressed in your
9 rulings is whether there is a choice of options,
10 and Ms. Lewis has been offered as an expert on the
11 registration decision-making process, and the
12 decision-making process here contrasted -- and
13 the entire process contrasted with this -- has
14 been brought into the case, and it's discussed in
15 Ms. Lewis' testimony. I have just a small number
16 of questions to ask on this topic.

17 ARBITRATOR BIRO: What is in her
18 testimony?

19 MS. SZMUSZKOVICZ: The EPA
20 decision-making about not having received a
21 voluntary cancellation request in choosing to
22 issue notice of intent to keep us all under FIFRA

1 °6(b). It's at page 200105. The EPA briefs also
2 discussed this.

3 ARBITRATOR BIRO: I'm still not
4 connecting all the dots on how it's relevant to
5 this action.

6 MS. SZMUSZKOVICZ: In this particular
7 action, the record then has an action. There was
8 the issue of timing. 2005 decision versus 2013
9 was an intent to cancel. Also there were 12
10 registrations, six of which were unconditional,
11 six were conditional, and all of them were
12 addressed in the context of one FIFRA °6(b). So,
13 we can proffer if you would find it less laborious
14 than going through the process of questioning. We
15 have all the documents that we entered into the
16 record and I think you know what the documents
17 are. EPA produced their list as well.

18 ARBITRATOR BIRO: Okay, I'm going to
19 sustain the objection and let you make an offer of
20 proof.

21 MS. SZMUSZKOVICZ: Okay. Would you let
22 me do that right now?

1 ARBITRATOR BIRO: Sure.

2 MS. SZMUSZKOVICZ: I'd like to make an
3 offer of proof for the February 5, 2013 Federal
4 Registry Notice and a series of six registration
5 approval letters for the Reckitt Benckiser
6 registrations. Six of the registrations mentioned
7 in the Registry Notice, the documents under face
8 indicate that they were products conditionally
9 registered under FIFRA 3(b)(c)(7) and all
10 reference subject to cancellation under 6(b). In
11 the end, Ms. Lewis was offered as the fact and
12 expert witness in an administrative proceeding.
13 She did not appear to the registrants withdrawn --
14 their registrations -- but all of the
15 registrations were handled in the context of that
16 proceeding. The case caption shows the numbers,
17 and the registration marks which show the numbers,
18 and the Federal Register shows the numbers. You
19 can mark those under separate exhibits.

20 ARBITRATOR BIRO: Okay. There's some
21 stuff that in this instance -- maybe you were both
22 conditional or unconditional registration. The

1 Agency used a 6(b) proceeding to cancel the
2 registrations.

3 MS. SZMUSZKOVICZ: That's correct. All
4 of the registrations.

5 ARBITRATOR BIRO: Well, okay.

6 MS. SZMUSZKOVICZ: May I confer with
7 counsel for just one moment?

8 ARBITRATOR BIRO: You may.

9 MS. SZMUSZKOVICZ: This brief pause is
10 taking a lot of time, so thank you for indulging
11 me.

12 ARBITRATOR BIRO: Would you like to take
13 a recess?

14 MS. SZMUSZKOVICZ: If maybe, just a
15 short, a short break, yeah, just about five
16 minutes?

17 ARBITRATOR BIRO: Okay.

18 MS. SZMUSZKOVICZ: Thank you.

19 BAILIFF: All rise.

20 (Recess)

21 ARBITRATOR BIRO: Thank you. You may
22 proceed.

1 MS. SZMUSZKOVICZ: Thank you. Just for
2 clarity of the record, I will proffer we had
3 marked as PBNX 124, the February 5, 2013 Federal
4 Register Notice and I referenced the notices of
5 pesticide registration for six Reckitt Benckiser
6 rodenticide products that were listed in that
7 Federal Registry Notice and we marked that as PBNX
8 125. And I also reference the case caption from
9 the Reckitt Benckiser section 6(b) hearing and we
10 had a demonstrative we were going to use that
11 we've marked as PBNX 126, for that, the purpose of
12 this joint case caption. And I believe that
13 copies of those exhibits have been, are, will be
14 provided to EPA counsel and have been provided to
15 Mr. Wright.

16 ARBITRATOR BIRO: Okay.

17 BY MS. SZMUSZKOVICZ:

18 Q And just one or two questions, Ms.
19 Lewis, just picking up on your testimony at
20 200105, in that paragraph right before it says
21 Existing Stocks. So that's RE10.

22 A Okay.

1 Q And this is the provision where you
2 explained it. Not that we see the volunteer
3 cancellation request EPA decided to proceed with
4 cancellation under FIFRA section 6(e).

5 A Correct.

6 Q We were speaking a little bit earlier
7 this morning about the different documents that
8 are going to be reviewed in the record and EPA's
9 brief opposing the registrant's request for an
10 accelerated decision in asking for a 6(b) hearing?

11 A Yes.

12 Q Do you recall that?

13 A I do.

14 Q And in that brief, and I can provide it
15 to you and have you look at if that would be
16 helpful, EPA took the position that it does have
17 alternative ways of approaching cancellation. It
18 selected 6(e) in this case. Is that correct? We
19 can look at it together if that would be helpful.

20 A I don't know if 6(e) is the appropriate
21 grounds for that.

22 Q Yes. That was the determination by EPA.

1 A Okay.

2 MS. SZMUSZKOVICZ: All right. I would
3 like to ask to mark the PBNX 127.

4 BY MS. SZMUSZKOVICZ:

5 Q Ms. Lewis, the pages that are marked
6 PBNX 127 are pages out of the EPA's opposition to
7 the registrant's motion for an accelerated
8 decision. And we have the full decision available
9 too, if there is any part of it that you want to
10 --

11 A Okay.

12 Q -- want to reference. This was just to
13 save a little paper. And I'd ask you to turn to
14 PBN 1778.

15 A Okay.

16 Q And the highlighted portion, which was
17 in EPA's brief and could you just read that
18 highlighted portion into the record?

19 A Yes.

20 MS. GOERKE: Excuse me, Your Honor. I
21 have to object to this. I mean what is being read
22 into the record is primarily legal argument that

1 has already been decided by this tribunal. I
2 don't see the relevance of having the witness
3 speak to certain portions of respondent's legal
4 motions in this case.

5 ARBITRATOR BIRO: Well, we'll see.
6 Overruled. Go ahead.

7 BY MS. SZMUSZKOVICZ:

8 Q Would you, would you read it into the
9 record, and then I just have a follow up question
10 for you about it.

11 A Yes. "Although once EPA determines a
12 condition has not been met it has an obligation to
13 issue a notice of intent to cancel under FIFRA °
14 6(e), EPA may use discretionary authority to first
15 resolve its concerns through other methods such as
16 cancellation under 6(b). FIFRA provides a variety
17 of grounds for cancelling a pesticide product, and
18 gives EPA the discretion to choose which to
19 exercise when there appear to be alternative
20 grounds for cancellation."

21 Q And, and in your opinion as an expert on
22 the decision making process, do you agree with

1 that statement?

2 A Yes.

3 Q Thank you. Ms. Lewis, we just have a
4 few more questions and during the break we were
5 able to resolve and eliminate more questions. Do
6 you recall the meetings that were held on January
7 6th at EPA with the registrants?

8 A Yes.

9 Q There were a series of meetings that you
10 presided over. These were distinct from the
11 meetings with Jim Jones in December.

12 A Correct.

13 Q And you were the highest ranking EPA
14 official at those meetings?

15 A In my head, I don't know if the director
16 was there or not, but yes.

17 Q Okay. From your workgroup?

18 A From my group, yes.

19 Q And in the morning EPA presented
20 scientific information to the registrants?

21 A Correct.

22 Q And then in the afternoon, there was a

1 non-science discussion.

2 A Correct.

3 Q And the registrants were appealing to
4 you based on a variety of grounds such as level
5 playing field, transparency, et cetera. Is that a
6 fair --

7 A Yes.

8 Q -- characterization?

9 A Yes, that's fair.

10 Q And you were patient in that meeting
11 with the registrants and heard their statements.
12 At some point in the afternoon, you were candid
13 with the registrants and you said this decision to
14 cancel is political. It's out of my hands.

15 A I don't recall saying that. I think
16 what I may have said is this is a very high level
17 decision.

18 Q Thank you. Ms. Lewis, are you aware
19 that the Center for Food Safety wrote a letter to
20 EPA dated February 11, 2016 demanding that EPA
21 take four specific actions on flubendiamide?

22 A I know they -- I don't have that in

1 front of me, but I am aware, all right.

2 Q All right. And are you also aware that
3 Mr. Housenger, the director of EPA's Office of
4 Pesticide Programs wrote a response to the Center
5 for Food Safety?

6 A I don't recall that.

7 Q Okay. I'd like to present your counsel
8 and then show you a document that we will mark as
9 PBNX 128. Please take a moment to look at this
10 letter.

11 A Okay.

12 Q Thank you. Could you read it into the
13 record what the date of the letter is?

14 A March 28, 2016.

15 Q And could you state for the record, who
16 the signatory of the letter is?

17 A Jack E. Housenger, Director of Office of
18 Pesticide Programs.

19 Q And what would your relationship to him
20 be in a professional sense?

21 A Mr. Housenger is my colleague.

22 Q And the letter is directed to the Center

1 for Food Safety, is it not?

2 A Yes.

3 Q And on its face, it appears to be a
4 response to the Center for Food Safety's February
5 11, 2016 letter. Is that correct?

6 A Correct.

7 Q I know you just had a couple of minutes
8 to look at the letter. Did this refresh you as to
9 whether you had seen it before, or is this the
10 first time you're reading it?

11 A I, I, this does not ring a bell, but it
12 doesn't mean that I haven't seen it, okay.

13 Q That's fine. Turning to the bottom of
14 PBN1910, the first page of the letter, Mr.
15 Housenger's responding to the Center for Food
16 Safety and saying that the agency carefully
17 considered the options available to the agency and
18 believes the cancellation option that was
19 determined is the appropriate way to expeditiously
20 resolve this matter. And, would that be a fair
21 characterization of the process, we carefully
22 considered the options?

1 A Yes.

2 Q And then, continuing on the next page,
3 PBN19177, at the top of the page, Mr. Housenger
4 says that without going into detail he would note
5 that these options neither raise unnecessary legal
6 risks or require significant amounts of time and
7 agency resources when compared with the section
8 6(e) hearing process we're pursuing. Do you agree
9 with that statement?

10 A I -- I agree with the length of time.
11 I'm a little uncertain about the legal risks
12 portion, but the -- the time line, most
13 definitely.

14 Q Thank you.

15 MS. SZMUSZKOVICZ: We have no further
16 questions for Ms. Lewis, thank you, Ms. Lewis.

17 MS. GOERKE: Your Honor, my
18 understanding was you would have questions. Was
19 that at the conclusion of my question?

20 ARBITRATOR BIRO: You have to finish all
21 your questions first.

22 MS. GOERKE: Okay. Okay.

1 ARBITRATOR BIRO: And see if I still
2 have questions.

3 MS. GOERKE: Okay.

4 REDIRECT EXAMINATION

5 BY MS. GOERKE:

6 Q All right. Thank you, Ms. Lewis. I
7 guess we will just start with the last thing that
8 just came before us.

9 A Okay.

10 Q Which was the letter that was just
11 presented to you, that was PBNX128. I would just
12 like to clarify, the document speaks for itself,
13 but in the portion that you were looking at at the
14 bottom of PBN1910, when it speaks to the three
15 actions I just wish to clarify the top three that
16 are on the first page of 1910. Would you
17 articulate what they are?

18 A Yes. Declare the flubendiamide
19 registrations to be expired; two, alternatively
20 declare "imminent hazard" and suspend the
21 registration; and three, issue a Stop Sale, Use or
22 Removal Order to promptly end the use of

1 flubendiamide.

2 Q And just to add clarification to the
3 transcript on the record, for the totality of this
4 is you may have not been extremely familiar, could
5 you read the paragraph that please begins PBN
6 1911, as to your demand. Could you read that in
7 its entirety, please?

8 A Yes. "As to your demand that EPA cease
9 issuing conditional registrations, my short answer
10 is that Congress adopted the provisions in section
11 3(c)(7) of FIFRA in order to allow EPA to issue
12 conditional registrations when the agency makes
13 the finding required by that section, and we will
14 continue to use that authority in the appropriate
15 circumstances. Having said that, I will also note
16 that we expect registrants to comply with
17 conditions of registration and that such
18 compliance is an important factor for us to
19 continue issuing conditional registrations. We
20 are deeply concerned that the flubendiamide
21 registrants accepted a registration with important
22 conditions and later elected not to comply with

1 those conditions. We hope and expect that this
2 refusal to comply with registration conditions is
3 a very isolated example; if it is not, we may have
4 to revisit the circumstances under which we issued
5 conditional registrations."

6 Q Thank you. When you spoke earlier in
7 your cross examination, you were mentioning the,
8 when you were familiarizing yourself with what
9 occurred since you were not in a position when the
10 original determination was made in 2008, and you
11 indicated that you had not spoken with people at
12 your level or above. Could you explain why you
13 did not?

14 A Yes. The division director at the time,
15 Ms. Lois Rossi has retired and she now works, I
16 believe some of her clients are industry. So that
17 conversation did not seem appropriate. The office
18 director, Debra Edwards, Dr. Edwards) Edwards, has
19 since retired and also works with industry. So I
20 chose to go with what was on the record as our
21 decision document, which was what was signed in
22 the rationale.

1 Q Thank you. Turning to the meetings that
2 were raised on the cross examination. To your
3 knowledge, do you know why Jim Jones would have
4 said he would not register flubendiamide in 2000?

5 A My belief of that conversation was Jim
6 Jones was extremely concerned with a persistent
7 and toxic chemical.

8 MS. SZMUSZKOVICZ: Objection. We ask
9 that be stricken from the record as it goes to the
10 risk benefit issue.

11 MS. GOERKE: I believe that the issues
12 about process and what occurred at those meetings
13 were specifically placed at issue by the cross
14 examination that went to what happened at those
15 meetings. I wanted to clarify that.

16 ARBITRATOR BIRO: We're not going to
17 open the door to that whole issue. I'm going to
18 strike that from the record. Go ahead.

19 BY MS. GOERKE:

20 Q Do you think that turning to the stocks
21 that you may have been aware of, do you think that
22 farmers usually hold significant quantities of

1 pesticide? Do they, do they typically use
2 pesticides shortly after they've purchased them?

3 A It depends on the pesticide. Ones they
4 know they're going to need and use them every
5 year, they may buy them and use it, but typically
6 farmers are not going to want to invest the money
7 until they know they need to use them.

8 Q And why do you expect that that would be
9 the case?

10 A Because it depends on the pest pressure
11 every year. We also consulted with our experts in
12 the biological analysis division, and I believe
13 they generally thought it wouldn't be expensive.

14 MS. SZMUSZKOVICZ: Another objection,
15 we'd ask to move to strike. This is all testimony
16 that EPA took the position was not a part of the
17 consideration, it should not be part of the
18 hearing. We're a little confused now about
19 hearing a different side of the story.

20 MS. GOERKE: Well, considering it was
21 similarly raised about what our understanding was
22 about what stops were available at the time she

1 made her decision, I wish for her to clarify what
2 she was asked on cross examination.

3 ARBITRATOR BIRO: Overruled. Go ahead.

4 BY MS. GOERKE:

5 Q Turning to your remarks that you did not
6 consult with HED, could you explain why that was?

7 A The issue on human health was not a
8 concern or a factor in this decision in that there
9 were no risks or concerns. It did play into the
10 benefits considerations because it had a favorable
11 profile for human health and workers, but nothing
12 had changed and our position on that hadn't
13 changed.

14 Q And also regarding questions that you
15 have received pursuant to the rodenticide
16 cancellation, isn't -- do you recollect -- wasn't
17 that just a registration that was not, you did not
18 have an issue with conditions of registration in
19 that case?

20 MS. SZMUSZKOVICZ: Objection. Leading.

21 ARBITRATOR BIRO: Sustained.

22 BY MS. GOERKE:

1 Q Can you explain your understanding of
2 rodenticides and how that may have differed since
3 that was raised in the previous process --

4 A Yes, my recollection of rodenticides
5 when I was the branch chief was that these
6 products have been registered for a very long
7 time, they came under our re-registration review
8 program. We concluded that there was unreasonable
9 adverse effects. I -- I didn't recall but it
10 looks like some of them had been conditionally
11 registered, but certainly not all. We've pursued
12 this, the -- the long discussion since we
13 processed. So there were those. To my
14 recollection, there weren't very specific
15 requirements in those, for one thing. Additional
16 registration, I would say we would cancel.

17 Q After your discussion with staff, why
18 was the voluntary cancellation provision included
19 within the original PAL that we discussed?

20 A The agency was concerned with the
21 persistence and toxicity of this chemical. Uh, the
22 registrant believed that our models were

1 conservative and that they could do additional
2 data to disprove our models.

3 MS. GOERKE: I have no further
4 questions, Your Honor. I'm sorry. I didn't mean to
5 cut the witness off.

6 THE WITNESS: I just wanted to add that
7 from my viewing of what transpired then, having a
8 date certain and irrevocable voluntary
9 cancellation request was very important to know
10 that if we reached an unreasonable adverse effects
11 after reviewing the data, that we knew that this
12 could be withdrawn.

13 MS. GOERKE: Thank you. No further
14 questions.

15 ARBITRATOR BIRO: Any re-cross?

16 MS. SZMUSZKOVICZ: No.

17 ARBITRATOR BIRO: Ms. Lewis, I would
18 just like to ask a few questions of you. Do you
19 have a copy of the respondent, which is the
20 agency's exhibits in front of you?

21 THE WITNESS: I do.

22 ARBITRATOR BIRO: Would you turn to

1 agency exhibit number 3?

2 THE WITNESS: Okay.

3 ARBITRATOR BIRO: These are I believe
4 the registrations of the pesticides at issue in
5 this case?

6 THE WITNESS: Yes.

7 ARBITRATOR BIRO: The first one is the
8 registration for the technical formulation of
9 flubendiamide and if you look at page two of it,
10 the second paragraph, which is unnumbered, says to
11 release through shipment of these products
12 constitutes acceptance of conditions of
13 registration as outlined in a preliminary
14 acceptance letter for flubendiamide dated July 31,
15 2008. Is that correct?

16 THE WITNESS: Yes.

17 ARBITRATOR BIRO: Okay. And that is the
18 preliminary acceptance letter, or PAL, that you've
19 been discussing in this matter?

20 THE WITNESS: Yes.

21 ARBITRATOR BIRO: Okay. So if you look
22 at the next registration noted, on the second page

1 of that, would you agree with me it has the same
2 statements?

3 THE WITNESS: Yes.

4 ARBITRATOR BIRO: Now, moving to the
5 third, and look at the second page. And it's a
6 little farther down on this second page, but this
7 is the registration for data and asking if you
8 note a matter of registration. And you'll see it
9 says released for shipment of these products
10 constitutes the acceptance of the conditions of
11 registration as outlined in the preliminary
12 acceptance letter for flubendiamide plus
13 buprofezin, premixed products, dated March 4,
14 2009. Where is that preliminary acceptance
15 letter?

16 THE WITNESS: That date of March 4, 2009
17 was in error. There was no unique acceptance
18 letter for this newer thing. It should have
19 referenced the July 31, 2008. It is my
20 understanding that there is no March 4, 2009
21 condition.

22 ARBITRATOR BIRO: And is there any part

1 on this between when this was issued in 2009, in
2 March 2009 and the notice of cancellation?

3 THE WITNESS: Well, the agency prepared
4 something for the record a few days, last week on
5 this issue, but I'm not aware that it's anywhere
6 in the record.

7 ARBITRATOR BIRO: Okay. So there is no
8 different preliminary acceptance letter for this
9 combination product?

10 THE WITNESS: No.

11 ARBITRATOR BIRO: Would you look at the
12 next registration. This is for Nichino America
13 and Turismo, it's the name of the product. And
14 again, on the second page, it references a March
15 4, 2009 preliminary acceptance letter. Is that
16 correct?

17 THE WITNESS: It does reference it, and
18 I believe again, that does not exist. It should
19 have been the conditions from the July 31, '08.

20 ARBITRATOR BIRO: And in terms of
21 documents that clarify that issue, is there
22 anything?

1 THE WITNESS: There is one document that
2 was prepared last week I believe, for the record,
3 but I don't have it on me.

4 ARBITRATOR BIRO: I'm not interested in
5 that. It's being prepared for litigation. I'm
6 interested in any document between 2009 and before
7 this litigation began.

8 THE WITNESS: Not that I'm aware of, no.
9 This just recently came to my attention.

10 ARBITRATOR BIRO: Is there anything from
11 Nichino or Bayer that confirms their understanding
12 that EPA had, that this was covered under the 2008
13 PAL?

14 THE WITNESS: I'm not aware of any.

15 ARBITRATOR BIRO: Okay. Let me just ask
16 you a couple of other questions. You testified
17 that there was -- you asked the question was
18 registration time limited, or is there an
19 expiration date. I understand that at some point,
20 FIFRA had a five year limitation written into the
21 statute for conditional registration. Is that
22 correct?

1 THE WITNESS: I don't recall that.

2 ARBITRATOR BIRO: Okay. Maybe can you
3 explain to me what a difference is between a
4 conditional registration with a expiration date,
5 and a conditional registration that is time
6 limited.

7 THE WITNESS: My understanding is if we
8 had an expiration date on a registration and we
9 have done these in the past, but on rare
10 occasions, the registration expires regardless of
11 any action we do unless we renew it. So it would
12 be automatic. Sometimes we have products that are
13 registered for about two products that are pet
14 products right now, and they all expire in two
15 years. And based on the review of instant data,
16 and then we can renew it for another two. So my
17 understanding of an expiration date is that it's
18 automatic unless they agency chooses to renew. On
19 a time limited, the way this was written back in
20 '08, it changed a product from expiration to time
21 limited and a request for a voluntary
22 cancellation.

1 ARBITRATOR BIRO: Okay. So --

2 THE WITNESS: Does that make sense?

3 ARBITRATOR BIRO: So, so --

4 THE WITNESS: Expiration date means the
5 product would just be gone after whatever period
6 was set.

7 ARBITRATOR BIRO: If EPA doesn't
8 affirmatively act.

9 THE WITNESS: Correct.

10 ARBITRATOR BIRO: And it has no
11 obligation to take any action by virtue of the
12 registration --

13 THE WITNESS: Correct.

14 ARBITRATOR BIRO: It will expire. Okay.
15 And what happens in those cases to the existing
16 stock?

17 THE WITNESS: We then have to make an
18 existing stocks determination.

19 ARBITRATOR BIRO: And in time limited,
20 it means that EPA has an affirmative obligation to
21 act?

22 THE WITNESS: I believe it's all

1 dependent on how we write the registration notice.
2 We don't do that in any time limited
3 registrations.

4 ARBITRATOR BIRO: Are there other
5 registrations that have this type of provision
6 written in it, as in this registration where it
7 provides for a week or some period of time after
8 notification of a finding of unreasonable adverse
9 effect for voluntary cancellation to be submitted?

10 THE WITNESS: This is the first one I've
11 come across.

12 ARBITRATOR BIRO: So could the agency
13 have expanded this registration and kept that
14 condition going for voluntary cancellation
15 indefinitely?

16 THE WITNESS: I -- I believe we could
17 have if we had imposed added data requirements or
18 additional mitigations to see how that worked.

19 ARBITRATOR BIRO: So as long as the
20 agency was continuing to determine whether or not
21 the pesticide had an unreasonable adverse effect
22 on the environment, in the, in an indefinite

1 sense, then it could continue the conditional
2 registration?

3 THE WITNESS: Yes.

4 ARBITRATOR BIRO: You also used the term
5 measured dialogue. Is that a term of art within
6 the agency?

7 THE WITNESS: No, this was added in to
8 the pre- acceptance letter I believe. And I
9 believe the registrant requested that term. I'm
10 not 100 percent certain on that.

11 ARBITRATOR BIRO: But that's not a term
12 of art that you --

13 THE WITNESS: That's not a term of art
14 that I'm aware of.

15 ARBITRATOR BIRO: I understand that
16 there apparently was a, a meeting sometime in
17 January that lasted apparently all day between the
18 agency and the registrants about these pesticide
19 registrations. Is that correct?

20 THE WITNESS: It was a very lengthy
21 meeting. It was two parts. The morning was with
22 the science, and then the afternoon was a smaller

1 group, more on the -- what I would call the
2 regulatory path for it.

3 ARBITRATOR BIRO: And were the
4 scientists both agency scientists and the
5 registrants' scientists?

6 THE WITNESS: Yes.

7 ARBITRATOR BIRO: At some point, you
8 said you indicated to the registrants that this
9 was an AA level decision. AA stands for associate
10 administrator of the agency?

11 THE WITNESS: Yes. Assistant
12 administrator.

13 ARBITRATOR BIRO: Okay. And that was
14 Jim Jones who you referred to?

15 THE WITNESS: Yes.

16 ARBITRATOR BIRO: And how many levels
17 between you and him are there?

18 THE WITNESS: Just Jack Housenger.

19 ARBITRATOR BIRO: And Jim Jones is the
20 assistant administrator for what office?

21 THE WITNESS: The OCSPP, the Office of
22 Chemical Safety and Pesticide Pollution.

1 ARBITRATOR BIRO: And what's his
2 background?

3 THE WITNESS: Jim, I believe has a
4 master's in public policy. He's not a scientist.
5 And I believe an undergrad degree in economics,
6 so, that's my recollection.

7 ARBITRATOR BIRO: How long has he been
8 at the agency or do you know?

9 THE WITNESS: Over 20 years.

10 ARBITRATOR BIRO: In this position?

11 THE WITNESS: No, I believe he used to
12 actually have my job so he's only been the last
13 couple of years in -- in the political levels.
14 But he had been branch chief within registration,
15 then registration division director and then I
16 believe office director of SSI programs.

17 ARBITRATOR BIRO: Do you know that the
18 agency received any other letters, other than the
19 letter that was sent from Food Safety regarding
20 handling flubendiamide?

21 THE WITNESS: I don't know specifically
22 if we have or haven't.

1 ARBITRATOR BIRO: Okay. I have no
2 further questions. Ms. Goerke, do you have any
3 questions you would like to follow up with?

4 MS. GOERKE: I didn't know if you wanted
5 me to clarify for Ms. Lewis, or clarification of
6 the record where there is a tie-in of the
7 preliminary acceptance letter that would be
8 integrated into the registrations Vetica and
9 Turismo registrations. There is documentation to
10 that effect that is record currently. Would you
11 like me to direct your attention to it?

12 ARBITRATOR BIRO: Sure.

13 MS. GOERKE: That is, those -- the
14 letters that went from EPA to the registrants that
15 are petitioner exhibits 11, 13, 14, 15 and 16,
16 each of those letters lists all the registrations
17 including Turismo and Vetica. And each of those
18 letters states that all of the original conditions
19 that apply that were identified in the preliminary
20 acceptance letter of July 31, 2008, were
21 applicable. So as Ms. Lewis indicated, it was her
22 understanding that that was a typographical error

1 and there was no further communication that is in
2 the record that discusses that except for those
3 letters, which directs their attention to that.

4 MS. SZMUSZKOVICZ: I'm not sure the
5 numbers were actually what you intended.

6 ARBITRATOR BIRO: It was petitioner's
7 exhibits 11, and 13, and 16?

8 MS. GOERKE: Oh, not 14, sorry.

9 ARBITRATOR BIRO: Okay, 13, 15 and 16?

10 MS. GOERKE: Yes.

11 MS. SZMUSZKOVICZ: And, not 11, which is
12 -- which is an email.

13 MS. GOERKE: I'm sorry, it was 10. I'm
14 sorry it was 10. Sorry.

15 ARBITRATOR BIRO: Okay. Exhibits 10, 13
16 and 15 and 16?

17 MS. GOERKE: Yes.

18 ARBITRATOR BIRO: Okay. Are there any
19 additional questions?

20 MS. SZMUSZKOVICZ: No, Your Honor, no
21 questions, thank you.

22 ARBITRATOR BIRO: Thank you, Ms. Lewis,

1 you may step down. Would you like to call your
2 next witness?

3 MS. GOERKE: The respondent has no
4 further witnesses.

5 ARBITRATOR BIRO: Oh, do you rest?

6 MS. GOERKE: Yes, Your Honor.

7 ARBITRATOR BIRO: If you'd like to call
8 your next witness?

9 MS. GOERKE: The respondent has no
10 further witnesses.

11 ARBITRATOR BIRO: Do you rest?

12 MS. GOERKE: Yes, Your Honor.

13 ARBITRATOR BIRO: Would you like to take
14 a break? What would you like to do?

15 MS. SZMUSZKOVICZ: I think we can go
16 forward, unless the witness -- I could just ask
17 the witness if we could --

18 ARBITRATOR BIRO: Sure.

19 (Discussion off the record)

20 MS. SZMUSZKOVICZ: I would like to call
21 the Registrant's first witness, Ms. Charlotte
22 Sanson.

1 ARBITRATOR BIRO: Before we begin with
2 Ms. Sanson's testimony, what about these exhibits
3 marked for identification, are we able to move
4 them into the record?

5 MS. SZMUSZKOVICZ: We would like to,
6 Your Honor, and so they will be exhibits PBNX 124
7 to 128, I believe.

8 ARBITRATOR BIRO: 124 through 126, I
9 think we can get it to the offer of proof. 123 is
10 Ms. Lewis' CV? Would you like to put that into
11 the evidence?

12 MS. SZMUSZKOVICZ: Yes. Thank you.

13 ARBITRATOR BIRO: Are there any
14 objections?

15 MS. GOERKE: No.

16 ARBITRATOR BIRO: Okay. 123, PBNX 123
17 being admitted in the record without objection;
18 124 to 126 is not admitted but will be held for an
19 offer of proof; 127 is the portion of respondent's
20 opposition to Bayer's motion for accelerated
21 decision. Would you like to move that into the
22 record?

1 MS. SZMUSZKOVICZ: Yes.

2 ARBITRATOR BIRO: Are there any
3 objection?

4 MS. GOERKE: No.

5 ARBITRATOR BIRO: PBNX 127 is admitted
6 into the record without objection; 128 is a letter
7 dated March 28, 2016 from EPA to Mr. Jenkins with
8 the Center for Food Safety, we'll also move that
9 into the record.

10 MS. SZMUSZKOVICZ: You'll put that on
11 the record.

12 ARBITRATOR BIRO: Any objection?

13 MS. GOERKE: No, Your Honor.

14 ARBITRATOR BIRO: Okay. PBX 128 into
15 the record. Okay. So we are going to swear her.
16 Whereupon,

17 CHARLOTTE SANSON

18 was called as a witness and, having been first
19 duly sworn, was examined and testified as follows:

20 DIRECT EXAMINATION

21 BY MS. SZMUSZKOVICZ:

22 Q Thank you, Ms. Sanson.

1 A Okay.

2 Q Could you state for the record what your
3 current position is?

4 A I'm Director of Federal Registration for
5 Bayer CropScience.

6 Q Thank you. And would you turn to Volume
7 4 of the registrant's exhibits, the petitioner's
8 exhibits. And please turn to Exhibit PBNX 116, if
9 you would? Could you state for the record what
10 that exhibit is?

11 A This is my verified written statement.

12 Q Are there any changes, additions or
13 edits that you'd like to make today?

14 A No.

15 Q Could you take a moment to just confirm
16 that you are very happy with the statement that we
17 prepared?

18 A Yes.

19 MS. SZMUSZKOVICZ: Your Honor, with Ms.
20 Sansou's testimony she's sponsored the following
21 Petitioner Exhibits, PBNX 7 through 21, 26, 33, 49
22 and 52, we would like to admit into evidence.

1 ARBITRATOR BIRO: Any objection?

2 MS. GOERKE: No.

3 ARBITRATOR BIRO: Okay. PBNX, will be
4 given 116, as well as 7 through 21, 26, 33, 49 and
5 52, are entered into the record without objection.

6 MS. SZMUSZKOVICZ: Thank you. We'll
7 turn Ms. Sanson over to cross examination at this
8 time.

9 CROSS-EXAMINATON

10 BY MS. GOERKE:

11 Q Ms. Sanson, you've heard Ms. Lewis'
12 testimony here this morning, correct.

13 A Yes.

14 Q And similar to Ms. Lewis, you were not
15 in a position there when the terms and conditions
16 were developed for this registration,
17 flubendiamide. Is that correct?

18 A That's correct.

19 Q And you similarly -- you've been
20 informed via documentation or staff for your
21 testimony today?

22 A Yes.

1 Q Acknowledged? Thank you. So, as
2 Bayer's -- in your written testimony you stated
3 you are currently the Director of Registration for
4 Bayer, have you -- you do have an opportunity to
5 come before the Agency on a relatively frequent
6 basis, or infrequently?

7 A On a relatively frequent basis.

8 Q And when you come before the Agency, who
9 would you typically interact with, either staff,
10 or management?

11 A I typically interact with, depending on
12 the issue at hand, you know, of course, you know,
13 Ms. Lewis, or any of her direct reports, or
14 anybody within the registration commission, as
15 well as scientists, again, depending on the issue.

16 Q Would you agree that it's important for
17 all the managerial staff, just the regular staff,
18 to be able to trust the representations that are
19 made when you meet with them?

20 A I would say so, yes.

21 Q And that so the Agency would be
22 dependent on such representations?

1 A Yes.

2 Q I would like to turn your attention to
3 the Respondent Exhibit binder, that's the one up
4 there. Respondent's exhibit No. 3. Once you find
5 that. And what is that?

6 A Now this is the Notice of Pesticide
7 Registration, dated August 1, 2008, and it's a
8 conditional registration for NNI-0001 Technical.

9 Q And it's your understanding that this is
10 a conditional registration?

11 A It's a conditional registration.

12 Q And moving down to the portion of the
13 registration, where it indicates this product is
14 conditionally registered in accordance with the
15 FIFRA section 3(c)(7). Is that something that you
16 would have typically seen previously?

17 A Yes.

18 Q On the Registration Notice, and on the
19 next page 200015, after number 2 where it says
20 submit two (2) copies, it indicates here that your
21 release for shipment of these products constitutes
22 acceptance; is that also something that you've

1 similarly seen on the Registration Notices?

2 A Yes.

3 Q And I notice what also refers to the
4 Preliminary Acceptance Letter, in discussing it
5 earlier today, I have to turn your attention to
6 the Preliminary Acceptance Letter that's
7 integrated into that Registration Notice. And
8 that is available to Respondent Exhibit 2. If you
9 could look at that, Exhibit 2, look at page -- the
10 PALS that are listed here. Look at 8, beginning
11 at 8(b), the EPA will complete its review. To
12 your knowledge has the EPA completed all of its
13 review of all the data submitted by Bayer?

14 A EPA did review everything that was
15 submitted.

16 Q And you indicated in your testimony that
17 all of the data was submitted. Is that correct?

18 A The data required here was submitted,
19 however we still have ongoing water monitoring
20 studies in progress. They'll be a constant --
21 they're still being -- that could be submitted to
22 EPA.

1 Q But that was voluntarily submitted.
2 That wasn't submitted, it was under the terms of
3 the registration. That was not a requirement of
4 the conditional registration.

5 A The water monitoring studies that were
6 being conducted presently?

7 Q The ones that were being conducted
8 presently that you referenced in your testimony
9 that all of the data conditions that were required
10 have been submitted presently --

11 A That's correct.

12 Q -- so that is correct. All of the
13 conditions have been -- the data conditions --

14 A Mm-hmm.

15 Q -- but you indicate all the data
16 conditions, but similarly, listed under (d), would
17 you indicate that similarly is listed as a
18 condition within the registration? You get an
19 opportunity to read that.

20 A Okay, so the question is?

21 Q The question is, is that similarly
22 listed in the PAL as a condition of registration?

1 A Yes.

2 Q And this particular condition is the
3 voluntary cancellation condition, correct?

4 A Yes.

5 Q And when did you first learn about this
6 condition?

7 A When I first learned about this
8 condition --

9 Q Yes.

10 A -- was last year when we had submitted
11 the results of the water monitoring data, and it
12 was brought to our attention that EPA was pursuing
13 this condition.

14 Q So you had not previously been aware of
15 the condition --

16 A No.

17 Q -- this condition. And turning your
18 attention to 8 (c) listed right above that --
19 excuse me, 8(b), the last sentence of 8(b), could
20 you read that sentence?

21 A "EPA scientists and Bayer scientists, as
22 agents for Nichino, shall engage in dialogue about

1 the data and the Agency's conclusions."

2 Q Does that -- is there anything either in
3 that provision or any provision under 8 that
4 states that the science must be approved by Bayer
5 and Nichino scientists?

6 A Well, this isn't predicated by the
7 emails that were discussions that happened before
8 this letter was issued. That statement was based
9 on the fact that there would be discussion between
10 the Bayer scientists and EPA scientists and I
11 think in reference to measured dialogue that Ms.
12 Lewis discussed in her testimony, and that's
13 what's meant by this statement here.

14 Q Yes, but even if it says the dialogue,
15 the measured dialogue, there is nothing to
16 indicate that Bayer must approve of EPA's science,
17 was there?

18 A Approved, no, but we did expect that the
19 science will be discussed and figured out in a
20 fair manner, and that real water monitoring data
21 would be reviewed for what it is, and also the
22 theoretical model that's discussed here.

1 Q But at the same time, similarly, it
2 doesn't require that there be approval by Bayer.

3 A Well, I wouldn't say that we would
4 approve of the conclusions. We had --

5 Q Made here.

6 A -- a disagreement on the conclusions.

7 Q I know, but that's not for the hearing,
8 but the question was there is nothing explicitly
9 stating a process that needs to go further than
10 the dialogue.

11 A Well, it's a typical yes or no answer,
12 given this particular case. I think it warrants
13 more discussion.

14 Q But what the answer would be, and it's
15 not there.

16 A It's not there.

17 Q It's not there. So in terms of that
18 back and forth, the emails that were developed
19 that was our Respondent Exhibit 4, are you
20 generally familiar with those emails?

21 A Generally.

22 Q Generally familiar with those emails.

1 And, based on your familiarity with those emails,
2 was there any recommendation that was put forward
3 that was indicative there or any of your clear
4 knowledge of correspondence that may have occurred
5 that requested that EPA put further process into
6 the preliminary acceptance letter?

7 A I think it would be helpful to actually
8 take a look at the email --

9 Q Sure, please do. Yes, starting on page
10 220; take your time.

11 A Exhibit 4?

12 Q Yes.

13 A Mm-hmm. All right, could you repeat the
14 question?

15 Q Yes. The question was, are you aware of
16 any of -- within the back and forth of the emails
17 or any other information you may be aware that
18 Bayer or Nichino had recommended that there be
19 more process established within the PAL?

20 A I think what was requested was to have a
21 scientific exchange, a discussion on the results
22 of the data that Bayer had a few years to

1 generate, and supported the conditional decision.

2 Q And in your written testimony, you
3 stated that EPA insisted on the term of
4 registration. Do you think it's accurate to say
5 that EPA did not have issue with registration
6 about that provision?

7 A It appears that way based on emails.

8 Q And on page 7 of your written testimony,
9 you had stated that you were not aware of any
10 other provisions EPA seems to be interpreting this
11 one now. Are you saying that EPA has changed
12 their interpretation of what this condition means?

13 A No, what I'm saying is I've never seen
14 conditions of registration established on this.

15 Q But interpreting now, it would seem to
16 indicate that it's potentially changing EPA's
17 interpretation, would you not agree?

18 A I'm not sure if it changes, but I
19 haven't seen that before then.

20 Q Previous to your interactions with the
21 agency in 2016, had you ever indicated to any of
22 the staff or the managers that you envisioned that

1 this condition was unlawful?

2 A I don't know.

3 Q Is it fair to say that EPA would have a
4 reason to know that Bayer would not comply with
5 this condition until Bayer became aware that the
6 condition might be triggered?

7 A Can you repeat that?

8 Q Is it fair to say that EPA would have
9 had no reason to know that Bayer would not comply
10 with the condition until Bayer became aware of the
11 condition that would be triggered?

12 MS. SZMUSZKOVICZ: Objection. Question
13 calls for witness to speculate about what EPA
14 would have thought, and we had the EPA witness
15 here earlier to ask that question of.

16 ARBITRATOR BIRO: Sustained.

17 BY MS. GOERKE:

18 Q So, as a regulatory manager, moving on,
19 would you have preferred to have a registration
20 with the condition that was clear, or would you
21 opt to decline a registration that contained such
22 a term as a voluntary cancellation?

1 A Well, in a matter of conditional
2 registration, there's a lot that was mentioned
3 about all the factors that go into that decision,
4 and to have conditional registration at this point
5 in time for the product was an important option.
6 I think it was a valuable option from the
7 standpoint that the companies had generated
8 millions of dollars, invested millions of dollars
9 and generated support for the registration. We
10 also had commitments. It's just like our other
11 groups whether it's a conditional registration or
12 non-conditional registration there really wasn't
13 much choice to get the product to the market in
14 time.

15 Q There were no additional choices for it
16 to be pursued?

17 A Based on what I hear, it was either a
18 conditional registration or no registration.

19 Q Let's go back to the PAL, which is
20 Exhibit number 2, briefly. And on the last page,
21 which is Bates 200013, there's a paragraph that
22 begins Nichino and Bayer should recognize that if

1 EPA issues this registration. And the next
2 sentence, Any such registration, once release for
3 shipment has occurred, and the sentence that
4 begins, either Nichino or Bayer. Can you please
5 read that sentence, please?

6 A "If either Nichino or Bayer does not
7 agree with any conditions of registration, they
8 should consider any such registration to be null
9 and void. If either Nichino or Bayer notifies EPA
10 that it is unwilling to accept any of those
11 conditions, EPA will commence the appropriate
12 denial process under Section 3(c)(6) of FIFRA."

13 Q That provision or that statement that
14 any such registration to be null and void, what do
15 you take that that to mean?

16 A I take that to mean that if Bayer and
17 Nichino did not agree to the conditions of the
18 registration, there would be no registration.

19 Q And that would be a registration, a
20 complete registration, that would be not --

21 A It would be a non-registration.

22 Q But is it safe to say that you couldn't

1 just take some of the conditions out of your
2 registration, it would be the entire registration?

3 A It was all or nothing? When this is far
4 enough and you take the conditions into your
5 registration.

6 Q Turning to the existing stocks, do you
7 think it's permissible to allow registrants to
8 continue to produce pesticide products and sell
9 those products when it's in violation of the
10 registrant's registration conditions?

11 A Well, 42 --

12 MS. SZMUSZKOVICZ: Objection. Calls for
13 a legal conclusion.

14 MS. GOERKE: We're speaking about the
15 existing stocks policy that we have here, and
16 they're testifying what the agency should -- the
17 written testimony -- to get it whether the agency
18 shouldn't do it with regards to --

19 ARBITRATOR BIRO: To your --

20 MS. GOERKE: -- the existing stocks.

21 ARBITRATOR BIRO: What again?

22 MS. GOERKE: The question was, is it

1 permissible to allow registrants to continue to
2 produce products and sell those products when it
3 is not in compliance with the registration's
4 conditions?

5 ARBITRATOR BIRO: Sustained.

6 MS. SZMUSZKOVICZ: May we ask that the
7 question just be verified as to what conditions?

8 ARBITRATOR BIRO: What conditions are
9 you verifying or you just answered your question.

10 MS. GOERKE: I have no further
11 questions, Your Honor.

12 MS. SZMUSZKOVICZ: Okay, I just have one
13 more. I have just a couple of other questions.

14 ARBITRATOR BIRO: Approved.

15 REDIRECT EXAMINATION

16 BY MS. SZMUSZKOVICZ:

17 Q Ms. Sanson, could you turn back to
18 Respondent's Exhibit 2, please, and Ms. Goerke
19 asked you some questions about 200012, and
20 particularly, paragraph 8(b). I just wanted to
21 make sure the record was clear on questions and
22 answers. Under (e), is it your understanding that

1 EPA was to consider all of data and supporting
2 information whether required or voluntarily
3 submitted by the registrants?

4 A Right, all the data that was submitted
5 whether it was required or voluntary, yes.

6 Q And just to clarify, the water
7 monitoring data that you made reference to, I
8 think you probably remember the data, were those a
9 condition of the original registrations?

10 A Well, that was a condition, I believe it
11 was -- that EPA had requested, and based on that,
12 we went back and did the -- the requirement that
13 was added on was to conduct the water monitoring
14 or conduct water monitoring based on actual use of
15 the product.

16 Q And so those data had been required or
17 voluntarily submitted?

18 A They were required.

19 MS. SZMUSZKOVICZ: Your Honor, I have
20 one point of order also. When we spoke earlier
21 about the exhibits that Ms. Sanson sponsored, I
22 gave you a complete list.

1 ARBITRATOR BIRO: Exhibit 49, I think,
2 on one of the exhibits that was barred by the
3 final decision.

4 MS. SZMUSZKOVICZ: 49? Thank you for
5 the opportunity to talk this through. 49 is not
6 included amongst the exhibits that the parties
7 discussed ought to be excluded as we understood
8 your order. Are you telling us now that as a
9 decision that you have separately made after
10 reviewing our list or have we had a slight
11 misunderstanding?

12 ARBITRATOR BIRO: I think we were
13 providing, I believe, on the email that came from
14 the party. I didn't think it was listed in that
15 email, but I could be mistaken. But can we finish
16 your testimony and let's go over this?

17 MS. SZMUSZKOVICZ: Yes.

18 ARBITRATOR BIRO: Okay.

19 MS. SZMUSZKOVICZ: Okay, so we'll
20 confirm that. The one thing I did want to ask you
21 before I step back is that we went through the
22 exhibits that Ms. Sanson had sponsored. There

1 were some exhibits that the experts sponsored, but
2 which the parties, in reviewing your order,
3 believed were admissible, but they were sponsored
4 by the experts, and we wanted to ask if you would
5 like Ms. Sanson to sponsor those, review those and
6 sponsor those since she is here and she has
7 familiarity with all of the documents?

8 ARBITRATOR BIRO: Well, if there's no
9 objection to the admission, then we don't have to
10 do that.

11 MS. SZMUSZKOVICZ: All right.

12 ARBITRATOR BIRO: Do you feel any
13 objections?

14 MS. GOERKE: No, there is no objection.
15 But my understanding when that was conveyed was
16 that that wasn't to go to the substantive merits,
17 that was just to go to the agency's process, so
18 maybe that can be clarified as well.

19 MS. SZMUSZKOVICZ: Yes, we're offering
20 these within the judge's ruling and to the extent
21 there's any dispute over that, we can make an
22 offer of proof.

1 ARBITRATOR BIRO: Okay, so what exhibits
2 are those?

3 MS. SZMUSZKOVICZ: Those would be PBNX
4 22 through 25, 27 through 32, and 34 through 36.

5 ARBITRATOR BIRO: Okay, and we have no
6 objections?

7 MS. GOERKE: No.

8 ARBITRATOR BIRO: Okay. PBNX 22 through
9 25, 27 through 32, 34 through 36 are admitted into
10 the record to the extent they're consistent with
11 the prior first order, okay.

12 MS. SZMUSZKOVICZ: Thank you, Your
13 Honor. We have no further questions.

14 ARBITRATOR BIRO: Would you look into --

15 MS. SZMUSZKOVICZ: Yes.

16 ARBITRATOR BIRO: -- and go ahead with
17 49. Okay, but do you have any re-cross?

18 MS. GOERKE: No, Your Honor.

19 ARBITRATOR BIRO: Okay. I'd like to ask
20 a couple of questions. Who is Margaret -- I want
21 to say Cherny --

22 THE WITNESS: Margaret Cherny.

1 ARBITRATOR BIRO: -- Cherny, who signed
2 the PAL.

3 THE WITNESS: Well, currently, she's
4 retired from Bayer. At the time, she was the Vice
5 President of Regulatory Affairs at Bayer.

6 ARBITRATOR BIRO: Is that your current
7 position or --

8 THE WITNESS: That would be my manager's
9 predecessor.

10 ARBITRATOR BIRO: Okay. And would you
11 agree that at the time that this conditional
12 registration was being issued, the parties
13 understood -- and by the parties, I mean EPA and
14 Bayer and Nichino -- understood that there was a
15 sense of known unknown, meaning that they knew
16 they did not know what the full ramifications were
17 of using flubendiamide in the water?

18 THE WITNESS: Well, based on the data
19 that was originally submitted in the application,
20 EPA had identified an area of uncertainty in terms
21 of, if in the event that the product ends in a
22 farm pond, for example, based on normal

1 application by a farmer. If it ends in water,
2 what is the risk to these aquatic organisms. I
3 think they -- when they fully evaluated the data
4 and as you probably saw in the documents, there
5 was a very favorable profile known in the
6 environment, and it was a small area of
7 uncertainty that they had relative to these
8 aquatic organisms, so Bayer agreed to generate the
9 additional data requirements that the EPA
10 identified followed by the water monitoring in the
11 event that that would be necessary based on the
12 vegetative buffer strips did not adequately
13 prevent the material from entering the water. So
14 I know it states that this is not unusual when EPA
15 identifies areas of uncertainty if they can make
16 use of their conclusions that use of the product
17 would not result in unreasonable adverse effects
18 while the conditional data is being generated. I
19 think that's quite normal.

20 ARBITRATOR BIRO: So did Bayer agree
21 that there was an uncertainty as to that issue, or
22 is your impression that, at that time, Bayer

1 thought that there was no uncertainty?

2 THE WITNESS: Based on what I've read of
3 the history, I think maybe they weren't certain
4 either. I think they felt fairly confident that
5 let's go ahead and run the water monitoring and
6 see what the results turn out to be, and I think,
7 usually, there's fair enough confidence that it's
8 going to turn out to be okay. But, clearly, the
9 science has demonstrated a risk that wasn't
10 outweighed by the benefits, that would have been
11 the right thing to do, and I don't think Bayer
12 would have gone forward with pursuing a long-term
13 cancellation.

14 ARBITRATOR BIRO: So in 2008, both Bayer
15 and EPA were uncertain, to some extent, what the
16 long-term effects were of the pesticide use. Is
17 that correct?

18 THE WITNESS: I would say that's
19 probably correct.

20 ARBITRATOR BIRO: And the first thing
21 they had to do, as you mentioned, is a vegetative
22 buffer study. Is that correct?

1 THE WITNESS: Yes.

2 ARBITRATOR BIRO: And Bayer did the
3 vegetative buffer study.

4 THE WITNESS: Yes.

5 ARBITRATOR BIRO: And they submitted
6 their results to EPA.

7 THE WITNESS: Yes.

8 ARBITRATOR BIRO: And I understand from
9 looking through the record that, apparently, EPA
10 found some modeling errors, statistical error in
11 the results submitted. Is that also your
12 understanding?

13 THE WITNESS: I'm afraid I can't
14 adequately answer that question.

15 ARBITRATOR BIRO: Okay.

16 THE WITNESS: I understand the power
17 strip was effective to some degree, meaning 40
18 percent, 50 percent, somewhere in that range, but
19 other than that, I don't have knowledge of the
20 statistics that were used.

21 ARBITRATOR BIRO: But, in any event, it
22 did not resolve the uncertainty regarding the

1 long-term consequences of using this pesticide
2 such that EPA was willing to grant an
3 unconditional registration at that point.

4 THE WITNESS: Well, that's why the water
5 monitoring was required as a result, yes.

6 ARBITRATOR BIRO: Exactly. Okay, so
7 then the water monitoring studies began, and that
8 was about 2010? Is that correct?

9 THE WITNESS: I think so.

10 ARBITRATOR BIRO: Okay. And the water
11 monitoring studies went on from 2010 until when?

12 THE WITNESS: Well, my understanding was
13 that the water monitoring studies are still
14 ongoing; we've never stopped, but we did submit
15 the data last year up to that point in time
16 because of the commitment that Bayer had made to
17 submit the studies, submit results of the study by
18 -- I don't remember the exact date, I think it was
19 the end of December 2014, but we as -- not that
20 EPA asked -- but we continue to do the monitorings
21 because we feel it's necessary to.

22 ARBITRATOR BIRO: Okay, but initially,

1 at least according to the preliminary acceptance
2 letter, the monitoring studies, water monitoring
3 studies, were going to take about two years. Is
4 that correct?

5 THE WITNESS: I think so.

6 ARBITRATOR BIRO: Okay, and instead,
7 they went on for about five years now. Is that
8 correct?

9 THE WITNESS: Yes.

10 ARBITRATOR BIRO: And is it a same
11 ongoing study or a series of studies?

12 THE WITNESS: I believe it's the same
13 locations that were the same locations, the same
14 studies.

15 ARBITRATOR BIRO: And is it being
16 conducted in the same way or has it changed how
17 you're conducting?

18 THE WITNESS: As far as being -- yes,
19 but for -- I don't want to speculate.

20 ARBITRATOR BIRO: And, at this point in
21 time, is it the situation that Bayer believed that
22 the long-term ramifications of this product are

1 known, or they believe they are still unknown?

2 THE WITNESS: Well, I believe, based on
3 the results of the data that's been gathered to
4 date, we can see that the actual concentrations of
5 the compound and its metabolite are well below the
6 level of concern the EPA identified, and I think
7 our data shows that it's not increasing over time,
8 it's the modeling -- the theoretical computer
9 modeling -- that EPA scientists have done, that
10 shows that they're looking at real world data,
11 which is, when a company generates real world
12 data, its specs can be evaluated for what it
13 shows, and it certainly shows there's no increase
14 -- based on 7 years of conducting the studies, and
15 even with the endpoint of 70 times below where it
16 was originally upon which all of our discussions
17 had been based, all our science discussions, and
18 we're still a little bit concerned, based on
19 actual use of the product.

20 ARBITRATOR BIRO: But you have to fill
21 what EPA has asked for, in your opinion.

22 THE WITNESS: Yes.

1 ARBITRATOR BIRO: And EPA has evaluated
2 it, and in your -- is that correct, EPA evaluated
3 all the data you submitted?

4 THE WITNESS: They have, yes.

5 ARBITRATOR BIRO: And you've had
6 meetings with them regarding that data, is that
7 correct?

8 THE WITNESS: Yes.

9 ARBITRATOR BIRO: Okay. And, in your
10 opinion and Bayer's opinion and Nichino's opinion,
11 the data shows you should get an unconditional
12 registration, is that correct?

13 THE WITNESS: We feel it supports an
14 unconditional registration.

15 ARBITRATOR BIRO: And EPA and their
16 scientists believe that the registration should be
17 cancelled, is that correct?

18 THE WITNESS: Yes. But I could also add
19 that there was a second provision in there where
20 there were three options in the letter,
21 unconditional registration, continued registration
22 with continued conditions, or a cancellation, and

1 last year, we thought we were working at number 2,
2 because even up through August EPA didn't think
3 that they intended to continue the conditional
4 registration and provided lists of additional data
5 requirements that should be considered while we
6 continued the scientific discussions, and that
7 happened through August, I believe it was, and
8 then because they're still in those discussions,
9 that the expiration date was moved out to
10 December, and that's when suddenly we found out
11 that the science opinions of EPA, they're
12 assessing us in decision endpoint that was driving
13 those discussions was suddenly lower, 70 times,
14 although it was, and it changed everything, and it
15 just wasn't transparent to us. There was no
16 communication to us that that was going to happen.

17 ARBITRATOR BIRO: Okay, so you thought
18 at some point you'd be able to negotiate a middle
19 ground where you'd be able to continue a
20 conditional registration with perhaps some new
21 conditions.

22 THE WITNESS: Correct.

1 ARBITRATOR BIRO: Okay. But EPA made
2 its own judgment based on the scientists that this
3 should be cancelled. Is that correct?

4 THE WITNESS: I would say it was a
5 scientific, but more of a political decision.

6 ARBITRATOR BIRO: Okay. Did my
7 questions raise any questions?

8 MS. SZMUSZKOVICZ: No.

9 MS. GOERKE: No.

10 ARBITRATOR BIRO: Okay, thank you very
11 much.

12 THE WITNESS: Thank you.

13 ARBITRATOR BIRO: All right, can we go
14 back and look at Exhibit 49 before we proceed?
15 And in the email that our office received from Mr.
16 Barker, it indicated that PBNX Exhibits 37 through
17 51, the parties had agreed to exclude based on the
18 prior order.

19 MS. SZMUSZKOVICZ: I think the confusion
20 arose because Ms. Sanson also commented on that
21 exhibit in her testimony, so I will confirm that,
22 but you know --

1 ARBITRATOR BIRO: Okay. All right. So
2 where are we?

3 MS. SZMUSZKOVICZ: Thank you for
4 pointing it out, so that exhibit was referenced in
5 Ms. Sanson's testimony, at page 13, and a section
6 of her testimony under your order would be --

7 ARBITRATOR BIRO: Excluded.

8 MS. SZMUSZKOVICZ: -- excluded, and so
9 it would be included in our offer to proof. So I
10 apologize for the confusion there.

11 ARBITRATOR BIRO: Okay. So we are going
12 to withdraw that from being admitted into the
13 record. Okay.

14 MS. SZMUSZKOVICZ: Thanks, Your Honor.

15 ARBITRATOR BIRO: Would you like to
16 break for lunch or would you like to proceed?

17 MS. SZMUSZKOVICZ: It would be great to
18 wait for the --

19 ARBITRATOR BIRO: Okay. It's 11:30. Do
20 you think you can be back within an hour?

21 MS. SZMUSZKOVICZ: Yes.

22 ARBITRATOR BIRO: Okay. Well, we stand

1 to recess till 12:30. Thank you.

2 BAILIFF: All rise.

3 (Whereupon, at 11:32 p.m., a

4 luncheon recess was taken.)

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1 A F T E R N O O N S E S S I O N

2 (12:35 p.m.)

3 ARBITRATOR BIRO: Okay. We are going
4 back on record. In the case of Bayer CropScience.
5 When we left off -- let's see. Okay, you've
6 switched places. Okay, fine. Mr. Barker?

7 MR. BARKER: Yes.

8 ARBITRATOR BIRO: Would you like to call
9 your next witness?

10 MR. BARKER: Yes. I would like to very
11 well call Lee Hall.

12 Whereupon,

13 LEE HALL

14 was called as a witness and, having been first
15 duly sworn, was examined and testified as follows:

16 DIRECT EXAMINATION

17 BY MR. BARKER:

18 Q Good afternoon, Mr. Hall.

19 A Good afternoon.

20 Q I'm going to ask you to turn to Exhibit
21 117, which is Volume 4 of the petitioner's
22 exhibits.

1 A Okay. I'm there.

2 Q Could you state for the record what that
3 copy is?

4 A It's a verified witness statement, of
5 Lee Hall, we have Bayer CropScience and Nichino
6 America.

7 Q And that is your written testimony.
8 Correct?

9 A That is correct.

10 Q Do you have any changes, additions or
11 edits to make to your testimony?

12 A No. I do not.

13 Q Would you take a moment to confirm and
14 to say, it's a true and correct copy of the
15 testimony you prepared?

16 A Yes. It appears so.

17 Q Thank you.

18 MR. BARKER: Your Honor, I would like to
19 move Mr. Hall's written testimony into the record
20 as evidence?

21 ARBITRATOR BIRO: Is there any
22 objection?

1 MS. GOERKE: No.

2 ARBITRATOR BIRO: Petitioner's Exhibit
3 117 is admitted into the record without objection.

4 MR. BARKER: We have no further
5 questions at this time.

6 ARBITRATOR BIRO: Please proceed.

7 MS. GOERKE: Thank you, Your Honor.

8 CROSS-EXAMINATION

9 BY MS. GOERKE:

10 Q Good afternoon, Mr. Hall.

11 A Good afternoon.

12 Q In your testimony you were seeking the
13 existing stocks treatment that you referred to as
14 a non-standard existing stock treatment which
15 would be allowing sale and distribution to clear
16 the channel of trade. Is that correct?

17 A Yes. And it's standard procedure, as
18 I've experienced with products, and the lab
19 cleared the channel with 18 to 24 months.

20 Q That is what you were seeking for the
21 Agency should it proceed to approve the diagram.
22 Is that correct?

1 A Yes. If there is a determination that
2 if the product is to be cancelled that at that
3 point a reasonable standard of procedures would
4 apply.

5 Q So, is it correct, that you were seeking
6 the same existing stocks treatment, and you did
7 not inquire for permission as a company that would
8 have submitted a voluntary cancellation request?

9 A Could you repeat the question?

10 Q Sure. So you are seeking here, the same
11 existing stock's treatment, and you did not apply
12 the conditions of registration as a company that
13 has submitted a voluntary cancellation request?

14 MR. BARKER: Objection; lacking
15 foundation.

16 MS. GOERKE: It's in his written
17 testimony, Your Honor --

18 ARBITRATOR BIRO: Overruled. Go ahead.

19 BY MS. GOERKE:

20 A Could you -- could you repeat the
21 question?

22 Q Sure. Sure. So, what you are seeking

1 in this treatment for existing stocks for
2 flubendiamide you are seeking the same treatment,
3 when you did not comply with conditions where a
4 condition of registration has not submitted a
5 voluntary cancelation request which is a standard
6 -- the standard treatment for existing stocks?

7 A I'm not sure I can answer that as a yes
8 or no question or answer. We thought that we did
9 meet the conditions for registration. That's why
10 we are here.

11 Q So even though you were moving forward
12 as if that condition was not required. You're
13 seeking the same policies as if you did comply
14 with all conditions?

15 ARBITRATOR BIRO: Asked and answered.
16 Move on.

17 BY MS. GOERKE:

18 Q And as a practical matter, would it be
19 your admission that is basically rewarding Bayer
20 for not conforming with the conditions of
21 registration?

22 A I'm not sure that I'm understanding

1 exactly the question. Again, it's not a yes or no
2 answer. We did comply with conditions of
3 registration, so we should be allowed to for those
4 products.

5 Q So it's your testimony today that you
6 have complied with all conditions of registration?

7 A Yes.

8 MS. GOERKE: No further questions, Your
9 Honor.

10 ARBITRATOR BIRO: Any redirect?

11 MR. BARKER: No, Your Honor.

12 ARBITRATOR BIRO: Mr. Hall, can I ask
13 just a couple of questions.

14 THE WITNESS: Okay.

15 ARBITRATOR BIRO: How many registrations
16 does Bayer have, pesticide registrations?

17 THE WITNESS: I've been -- it will be
18 hard for me to answer that question, numerous.

19 ARBITRATOR BIRO: Give me a ball park,
20 1,000, 10,000, 100,000?

21 THE WITNESS: Individual registrations,
22 I would guess more than 250.

1 ARBITRATOR BIRO: Two hundred and fifty?

2 THE WITNESS: That would be a good

3 guess, Your Honor.

4 ARBITRATOR BIRO: And one of those that
5 you, I believe, voluntarily cancelled, was for one
6 of the products involving flubendiamide, and I'm
7 trying to remember what the name of it was.

8 THE WITNESS: The name of the product is
9 Synapse.

10 ARBITRATOR BIRO: Synapse, right.

11 THE WITNESS: Yes.

12 ARBITRATOR BIRO: That's right. When
13 you voluntarily cancelled that, what were the
14 terms regarding existing stocks?

15 THE WITNESS: I don't recall that there
16 were negotiations around existing stocks, we
17 phased that product out because of some
18 formulation issues, inconsistency in formulation,
19 and made the products not reliable in terms of
20 presenting a quality product to end user. So we
21 phased that product out, and after the product had
22 cleared the channel of trade then we submitted for

1 an involuntary cancellation to remove that product
2 from the market.

3 ARBITRATOR BIRO: Have you had other
4 products that have been involuntarily cancelled?

5 THE WITNESS: Not that I can recall.
6 But I am not an expert on the history of what
7 products have been cancelled, what they are.

8 ARBITRATOR BIRO: So when you are
9 talking about your standard experience, is that
10 with just pesticide registrations where you
11 voluntarily cancel?

12 THE WITNESS: And many times we'll do a
13 label change, we were either adding labels or uses
14 or removing uses from a label, there's a standard
15 practice of 18 to 24 months to let that product
16 clear the channel, instead of having to bring it
17 all back and relabel it. So those were -- from my
18 experience from a standard procedure.

19 ARBITRATOR BIRO: Okay. All right. Did
20 my questions raise any questions for you, Mr.
21 Barker.

22 MR. BARKER: No, Your Honor.

1 ARBITRATOR BIRO: Okay. Ms. Goerke?

2 MS. GOERKE: No, Your Honor.

3 ARBITRATOR BIRO: Thank you so much, Mr.

4 Hall.

5 THE WITNESS: Okay.

6 ARBITRATOR BIRO: Hello, Mr. Eisenberg?

7 MR. EISENBERG: Hello. Good afternoon.

8 I'm going to get a hold of Jeffrey Johnson.

9 Whereupon,

10 JEFFREY JOHNSON

11 was called as a witness and, having been first

12 duly sworn, was examined and testified as follows:

13 DIRECT EXAMINATION

14 BY MR. EISENBERG:

15 Q Good afternoon, Mr. Johnson.

16 A Good afternoon.

17 Q Please state you full name and title for

18 the record.

19 A Jeffrey R. Johnson, President of Nichino

20 America.

21 Q And for record, this is the fourth

22 binder, PBNX 118?

1 A Yes.

2 Q Do you recognize this document?

3 A Yes.

4 Q And what was this?

5 A It's a verified written statement of
6 Jeffrey Johnson, on behalf of Bayer CropScience LP
7 and Nichino America.

8 Q And take a moment and look through it.
9 And Mr. Johnson, is anything you have in your
10 testimony that you wish to change?

11 A No.

12 Q Is this a true and accurate copy of your
13 written testimony?

14 A I believe so.

15 MR. EISENBERG: Your Honor, the
16 petitioners offer PBNX 118 in evidence.

17 ARBITRATOR BIRO: Is there any
18 objection?

19 MS. GOERKE: No, Your Honor.

20 ARBITRATOR BIRO: Okay. PBNX 118 is
21 admitted into the record without objection.

22 MR. EISENBERG: We have no further

1 questions at this time.

2 ARBITRATOR BIRO: Okay. Ms. Goerke?

3 MS. GOERKE: My co-counsel will ask the
4 questions this time.

5 ARBITRATOR BIRO: Of course.

6 MR. PERLIS: Thank you, Your Honor.

7 CROSS-EXAMINATION

8 BY MR. PERLIS:

9 Q Mr. Johnson?

10 A Yes.

11 Q As president of Nichino, what is your
12 involvement with Nichino of said products?

13 A All products?

14 Q The pesticide products.

15 A I am at arm's length in terms of
16 overseeing the process within the company, or
17 working for a parent company, and working on
18 studies that are required by the EPA. The field
19 development studies, efficacy studies, formulation
20 work. So my staff that reports to me are in those
21 different disciplines, and as we have new compound
22 that is discovered and moved forward through the

1 registration process, and I work with our national
2 team to move it through. So, I'm not intimately
3 involved with all the details on the regulatory
4 side.

5 Q How often did you get a record of the
6 developmental studies?

7 A I, myself, have only been to the EPA
8 probably less than 10 times, and that includes
9 having meetings with CropLife America Board, so
10 that's usually my staff that has those meetings
11 with EPA officials.

12 Q And does your staff meet regularly with
13 EPA officials on pesticides matters?

14 A Yes.

15 Q What involvement if any, did you have in
16 the discussions with Bayer or EPA to related to
17 the initial registrations of flubendiamide?

18 A The initial registrations I had
19 personally no involvement in those discussion, and
20 the licensing agreement that was made between our
21 parent company, Nohyaku and Bayer CropScience was
22 actually in principle, principally developed

1 before Nichino America even became a company here
2 in the U.S. So, the fact that Nichino America
3 became the holder of the registration was the
4 reason why we have the licensing agreement with
5 Bayer, and because Nichino America initially was
6 not marketing flubendiamide products under that
7 agreement, I wasn't really much involved at all
8 with those discussions.

9 Q Did you have any involvement or any
10 internal discussions at Nichino related to the
11 initial registrations of flubendiamide in 2008?

12 A In 2008?

13 Q Yes.

14 A Very little. Just a kind of overview
15 from the Vice President of Regulatory at the time,
16 Ken Chisholm, who is now retired, and he would
17 inform me of some of the communications with
18 Bayer, and update on the progress of the
19 registration, but very general information.

20 Q And were you personally involved at all
21 with any of the internal discussions between
22 Nichino and Bayer related to the initial

1 registration of flubendiamide again in 2008?

2 A No.

3 Q Now, I'd like to turn your attention to
4 the condition that's at the heart of this
5 proceeding. Would you agree that the following is
6 a fair characterization of a condition if after
7 scientific discussions with Bayer and Nichino, if
8 EPA still determines that flubendiamide causes
9 unreasonable adverse effects on the environment,
10 and notifies Nichino about the termination,
11 Nichino must submit a voluntary request for
12 cancellation within seven days. Is that a correct
13 characterization?

14 A A fair characterization of?

15 Q Of the condition that's at issue in this
16 proceeding.

17 A It sounds like it is.

18 Q Can you tell me when you first became
19 aware of the condition?

20 A I believe it was sometime in the summer,
21 July or August. I was aware only that it was
22 conditional registration, which from my experience

1 with Nichino America, all of our registrations
2 have been conditional, so I never really thought
3 there was anything unusual, until the discussions
4 started to occur in July and August, and it
5 appeared that the extension of the registration
6 may be jeopardy, that came to my attention that
7 this certain voluntary cancellation clause was in
8 that conditional registration.

9 Q So I take it then, you have no personal
10 knowledge of why Nichino accepted the condition?

11 A Not at the time. I can comment as to
12 why I believe it was accepted, and after spending
13 over at least 65 million in the U.S., in over 10
14 years to bring a product to market it was a
15 decision that I think that made economic sense at
16 the time. And all was done under good faith to do
17 the work, understand that Bayer was going to do
18 the work to clarify some of the concerns that
19 existed at the time, and we, again, with all of
20 our conditional registrations we've had to do
21 additional work, do additional studies for
22 different compounds, and so it was not an unusual

1 aspect, only that this voluntary cancelation
2 clause was in there. That was the most unusual
3 thing.

4 Q Well, I take it Nichino was aware of
5 that -- Do you know if Nichino was aware of that
6 condition in 2008?

7 A I believe the regulatory -- yes.

8 Q Now I take it you know Charlotte Sanson.

9 A Only through these goings on.

10 Q She has testified that EPA essentially
11 coerced Bayer into accepting the condition. Do
12 you agree with her testimony at this point? Did
13 you feel that Nichino was coerced in accepting the
14 condition?

15 MR. EISENBERG: Objection. I think that
16 mischaracterizes the --

17 ARBITRATOR BIRO: Sustained.

18 MR. PERLIS: I'm sorry, it's
19 mischaracterizing Ms. Sanson's testimony?

20 ARBITRATOR BIRO: Yes.

21 MR. EISENBERG: Yes.

22 MR. PERLIS: Fair enough. Let me

1 rephrase it.

2 BY MR. PERLIS:

3 Q Ms. Sanson testified that Bayer was
4 expected to accept the provision for
5 registrations. Do you agree with that?

6 A Yes.

7 Q And did Nichino feel the same way?

8 A Yes.

9 Q So, is it then your testimony that
10 Nichino recognizes that the Agency would not issue
11 those registrations without Nichino's acceptance
12 to the conditions?

13 A Yes.

14 Q Was it Nichino's intention to comply
15 with the condition when it was accepted for
16 registration?

17 A Yes.

18 Q Okay. And are familiar with Jack
19 Housenger's letter of January 24th, 2016 in which
20 he asked both Bayer and Nichino about the
21 registrations?

22 A Yes. Not every word, but --

1 Q But in the broader sense. Did Nichino
2 in fact request voluntary cancelation like the one
3 mentioned in Mr. Housenger's letter?

4 A Well, we did not believe that the
5 cancellation clause had really been triggered. So
6 that's why we --

7 MR. PERLIS: Excuse me, Your Honor. Can
8 I ask the witness to respond to the questions that
9 I asked him, because he --

10 MR. EISENBERG: I believe he just did.

11 BY MR. PERLIS:

12 Q I believe that question called for a yes
13 or no answer; did Nichino send a voluntary
14 cancellation request, if you want to ask him why
15 that's fine, you can do that later but -- The
16 question I asked was, did Nichino send a voluntary
17 cancellation request? Do you believe that to the
18 best of your knowledge?

19 A I don't believe we did.

20 Q So, to summarize, Nichino's registration
21 based on the commitment, you accept that Nichino
22 would not have a registration before that time

1 limit, and then Nichino failed to live up to the
2 commitment --

3 MR. EISENBERG: Objection. I would ask
4 that clarify what you mean by commitment, because
5 the whole dispute in here is about the scope of
6 the condition. So is the commitment a voluntary
7 cancellation, or is it --

8 THE WITNESS: Yes.

9 MR. EISENBERG: Or is it the entire
10 condition?

11 MR. PERLIS: It's a voluntary
12 cancellation.

13 THE WITNESS: If I'm understanding your
14 question, it was the commitment was to the
15 condition -- conditional registration.

16 BY MR. PERLIS:

17 Q Now, are you familiar with the letter
18 from Dana Sargent, it's Respondent's Exhibit 7,
19 that responded to Jack Housenger's request to
20 submit voluntary cancellation?

21 A I'm aware of the letter.

22 Q Okay. Could I ask you to open -- you

1 should have copies of the respondent's exhibits.

2 A Which?

3 Q This one book with all the respondent's
4 exhibits in it.

5 A Okay. This one here.

6 Q Could you turn that to Exhibit 7.

7 A Okay.

8 Q Can I ask you to read 2 and 3 to
9 yourself and then I'll ask some questions?

10 A Pages 2 and 3?

11 Q Yes, I actually think it starts -- the
12 questions I'm going to ask start at the middle of
13 page 2, after where says third and most
14 significantly.

15 A Okay.

16 Q Now you will agree that Ms. Sargent, in
17 the paragraphs that I asked you to look at,
18 suggesting that there is a significant scientific
19 disagreement between the registrants and the EPA
20 regarding the safety of flubendiamide?

21 A Yes.

22 Q Does it say anywhere in there, that the

1 registrants are taking the position that they did
2 not have an opportunity to discuss the science
3 with EPA? Did you notice that at all in your
4 reading?

5 A Well I -- I think the indication is
6 that, particularly on the second page, fourth
7 paragraph, the EPA abruptly shifting course and
8 expressed its intent to discount the real world
9 monitoring data is an indication of one of the
10 issues that we've had, and where the scientific
11 discussions started to fall apart, so to speak.

12 Q I appreciate that there was a gap, and a
13 fairly significant gap between the parties on the
14 science but does it say anywhere there that EPA
15 did not discuss the science with Bayer and
16 Nichino. I'm just asking in this letter, does it
17 say anything that would appear that Nichino did
18 not have an opportunity to discuss the science
19 with EPA?

20 A I don't believe it says that there was
21 no opportunity to discuss the science.

22 Q All right. Thank you. Now can you tell

1 me why Nichino decided not to keep its commitment
2 to cancel the registrations, when asked to do so
3 by Mr. Housenger?

4 A Again, I think that we did not feel that
5 the condition of cancellation was triggered,
6 because the scientific discussions, although there
7 were discussions ongoing, broke down and some of
8 the most relevant points in terms of the
9 degridates and their persistence, or potential
10 persistence were being ignored. In my
11 understanding. I not a scientist, I'm not a
12 regulatory official and I was available at two
13 meetings, the October -- I'm sorry, December 15th
14 and January 6th meeting. And at that stage the
15 scientific discussions were a bit at loggerheads,
16 I guess you would say.

17 Q I think that's fair to say but turning
18 your attention to the condition itself, and I can
19 direct you to that if you don't remember this, but
20 is the condition worded in such a way that Bayer
21 and Nichino would have to agree with the Agency's
22 scientific determination in order to trigger the

1 voluntary cancellation request?

2 A I think our understanding of it was that
3 there would be good-faith back and forth dialogue
4 to reach a sound scientific conclusion. And that
5 as responsible corporate citizens if that
6 conclusion were negative then we would agree to
7 voluntarily cancel the product, but we don't
8 believe that we got to the point to have that
9 scientific discussion concluded, and that's one of
10 the reasons why we requested the hearing.

11 Q Okay. And do you agree that there is
12 nothing in Ms. Sargent's letter that suggests
13 that there hasn't been an opportunity to discuss
14 the science? That it was not in issue as that
15 time, was it?

16 MR. EISENBERG: Objection. I believe
17 that question has already been asked and answered.

18 ARBITRATOR BIRO: Sustained.

19 BY MR. PERLIS:

20 Q Very well. I believe I've asked you
21 this before, and I'm just trying to make sure that
22 we're on the same page before I move on to another

1 series of questions. You are aware of the EPA, I
2 take it you are aware that the EPA has frequent
3 interactions with pesticide applications, during
4 the application process?

5 A I'm sorry. I couldn't hear you, sir.

6 Q Are you aware that the EPA has frequent
7 interactions with pesticide applicants during the
8 application process?

9 A Yes.

10 Q Would you think it important to a
11 regulatory agency like EPA that it can be
12 confident that it can rely on the integrity of the
13 companies that it deals with --

14 MR. EISENBERG: Objection; calls for
15 speculation about the Agency.

16 MR. PERLIS: Your Honor, I asked him
17 whether he thinks it is important, I'm not asking
18 him whether he's correct in his thought.

19 ARBITRATOR BIRO: Overruled. Go ahead.

20 THE WITNESS: Yes.

21 MR. EISENBERG: Could you at least --
22 can you repeat the question then? Thank you.

1 BY MR. PERLIS:

2 Q Would you think it important to a
3 regulatory agency like, EPA that it can be
4 confident that it can rely on the integrity of the
5 companies it deals with?

6 A Yes. And likewise we rely on EPA as
7 well, in the same way.

8 MR. PERLIS: I'm sorry. I'm going to
9 ask you some yes or no questions and I'd ask to
10 please answer only the question I'm asking. Thank
11 you.

12 BY MR. PERLIS:

13 Q Again, in your opinion, do you think if
14 EPA cannot rely on the integrity of the pesticide
15 registrants and applicants that might have a
16 negative impact on the losses incurred?

17 A If the -- can you repeat the question?
18 If the EPA cannot --

19 Q Yes. If the EPA cannot rely on the
20 integrity of the pesticide registrants and
21 applicants would that have a negative effect on
22 the losses incurred? Let me break that a little

1 more. If we could not rely on the integrity of
2 pesticide registrants and applicants might it
3 negatively affect the ability of Nichino to get
4 the registration?

5 A I think integrity is important all the
6 way around.

7 Q So the answer to that question is, yes,
8 it would have a negative effect on the losses
9 incurred?

10 MR. EISENBERG: Objection;
11 mischaracterizes his testimony.

12 MR. PERLIS: No. I'm asking the
13 question, and I think he answered yes but then he
14 added an additional part and I'm not sure the
15 question was answered.

16 ARBITRATOR BIRO: Overruled. Go ahead.

17 BY MR. PERLIS:

18 Q So, your short answer is, yes, you agree
19 that if you cannot rely on the integrity of your
20 registrants and applicants that could have a
21 negative effect on the losses incurred?

22 A I'm sorry could you --

1 Q When you use the word --

2 A Yes.

3 Q Thank you. Now, do you think EPA will
4 justifiably be less confident with Nichino in the
5 future?

6 A I don't believe that anything that has
7 happened throughout this process shows a lack of
8 integrity, or a lack of trust, and we've been
9 clear and upfront through this whole process. And
10 we have to be transparent, and we learn by law,
11 and I don't think that there is anything --
12 anything that's been done that should warrant any
13 lack of trust in our company or a lack of
14 integrity in our company.

15 Q Now, going back to the letter that I
16 showed you from Ms. Delaney she listed three
17 reasons for not complying. She believes that EPA
18 was obligated to civil action under section 6(b)
19 if they wanted to cancel these registrations.
20 Does Nichino agree with those?

21 A Yes.

22 Q Now, if the condition were not

1 believable that wouldn't have affected your
2 ability to comply with the condition, would it?

3 MR. EISENBERG: Objection; the question
4 calls for a legal conclusion.

5 ARBITRATOR BIRO: The question was not
6 legal?

7 MR. PERLIS: I'll be happy to rephrase
8 the question.

9 ARBITRATOR BIRO: That's all right.

10 BY MR. PERLIS:

11 Q Are you contending that Nichino could
12 not legally, have complied with the condition that
13 Mr. Housenger asked for cancellation?

14 MR. EISENBERG: The same objection, it
15 still calls for --

16 ARBITRATOR BIRO: Go on.

17 MR. PERLIS: Your Honor, this man is
18 president of the company if they didn't comply --
19 he thinks they were legally prohibited from
20 complying, I'd like to hear that and if they
21 weren't legally prohibited from complying I think
22 he should be in a position to be able to say that

1 as well.

2 ARBITRATOR BIRO: He is not a lawyer, do
3 you want to --

4 MR. PERLIS: I appreciate he is not a
5 lawyer but he -- his knowledge of --

6 ARBITRATOR BIRO: You just want to know
7 whether there was anything that prevented him from
8 complying. Is that correct? Was there anything,
9 in fact, that prevented you from complying or
10 withdrawing your pesticide registration if you
11 wanted to?

12 THE WITNESS: Not if we wanted to, but
13 we felt it was the appropriate thing to do at the
14 time.

15 ARBITRATOR BIRO: Okay. Move on.

16 BY MR. PERLIS:

17 Q Now, if Nichino came in today with an
18 application similar, one that showed promise but
19 in which the Agency saw significant potential
20 risks, and EPA need to rely on the commitment that
21 they made together with respect to that
22 registration, do you think that EPA would be less

1 likely to bring that registration than yours in
2 2008?

3 MR. EISENBERG: Objection; this is the
4 same line.

5 ARBITRATOR BIRO: Sustained.

6 MR. PERLIS: I'm sorry, what's the
7 objection?

8 ARBITRATOR BIRO: You are asking him to
9 suppose on EPA's behalf, on what EPA would have
10 done?

11 MR. PERLIS: Fair enough.

12 BY MR. PERLIS:

13 Q Would you agree, generally, that EPA's
14 pesticide licensing program operated under fair
15 and sensible manner?

16 A Yes.

17 Q Now, in your testimony you state your
18 belief that it will be appropriate for EPA to
19 allow Nichino and Bayer to sell off the stocks
20 after cancellation. Isn't that correct?

21 A Yes.

22 Q Would you agree that cancellation would

1 have occurred sooner here if Bayer and Nichino
2 submitted a voluntary request for cancellation?

3 A Would it have occurred sooner if we had
4 voluntarily cancelled?

5 Q If you voluntarily cancelled in August,
6 for the purpose of this question, that
7 cancellation may occur in this year. The question
8 is, if cancellation had occurred sooner, do you
9 agree that if cancellation would have occurred
10 sooner had you complied with the condition to
11 submit a voluntary cancellation?

12 A I'm not sure I really understand the
13 question.

14 Q All right. Let me ask it this way then.
15 You asked for the voluntary cancellation request
16 by February 5. Isn't that correct?

17 A Correct.

18 Q Now, Ms. Lewis, you may have heard this
19 morning - you heard Ms. Lewis testify?

20 A Yes.

21 Q Her testimony suggested that it could
22 take about a month for the cancellation to be

1 processed. So, if that's true when would the
2 product have been cancelled if you submitted a
3 voluntary cancellation request?

4 A I'm not sure exactly how that would
5 work, or how long it will take, if we did that.

6 Q Okay. Do you have any reason to believe
7 that Ms. Lewis was incorrect when she said that
8 cancellation could have occurred by late March or
9 early April?

10 A Could have occurred --

11 Q Had you requested voluntary cancellation
12 and asked to do so -- her testimony was the
13 cancellation could have occurred by early April.
14 Do you have any reason to believe that's
15 incorrect?

16 A I'm not a regulatory expert, so I --
17 there's always time intervals in weeks or months,
18 so I'm not sure I can answer that one way or the
19 other.

20 Q Okay. But it is fair to say that based
21 on your failures to submit voluntary cancellation,
22 cancellation did not occur in April. Do you agree

1 with that?

2 A Yes.

3 Q And in fact when we do the arithmetic,
4 the cancellation will be unlikely to occur before
5 July.

6 A Whatever the time timeframe of the
7 hearing, let me say that.

8 Q Okay. So, if EPA were to conclude, and
9 I think, Ms. Lewis did conclude, the cancellation
10 was delayed because Nichino and Bayer did not
11 submit the cancellation request, when they were
12 asked to do so. Do you have any reason to
13 disagree with that conclusion, that the
14 cancelation was delayed?

15 A Obviously by requesting a hearing the --
16 any type of cancellation would have to be delayed.

17 Q Okay. Then just to be clear, it's not
18 the request of the hearing that caused the delay,
19 it's the failure to submit the request when asked.
20 Isn't that correct?

21 A Well, from our standpoint, again, we
22 didn't feel that the voluntary cancellation clause

1 was triggered, and that by requesting a hearing
2 that we would eventually talk about this issue,
3 and hopefully clarify the science and keep the
4 registration going.

5 Q Now, do you know what existing stocks
6 are -- do you know the term?

7 A Not -- not as it's quoted in FIFRA, I
8 have a general layman's understanding of existing
9 stocks.

10 Q I'm not trying to take advantage of you,
11 sir, but would you agree that existing stocks are
12 product that has been produced and released for
13 shipment before the date of cancellation? Does
14 that sound right to you?

15 A Yes.

16 Q Do you know what the status is when a
17 pesticide product that is produced and released
18 for shipment after the effective date of
19 cancellation?

20 A I don't know the different terms, but
21 over the years in the industry I know that there
22 has been different ways that the EPA has dealt

1 with existing products that have been cancelled
2 and pulled away from any stocks to be used, all
3 the way to stop sales and returns. So, I'm not
4 sure --

5 Q I'm sorry?

6 A -- what all the terminologies are for
7 those different --

8 Q I'm not asking that as existing stocks
9 -- existing stocks of a product that was produced
10 and released for shipment before the effective
11 date of cancellation. My question is, do you know
12 what the status is in a pesticide product that is
13 produced after the effective date of cancellation?
14 So it's not an existing stock, it was produced
15 later after the cancellation.

16 A I don't know what you would call --

17 Q Okay. I'd like you to assume for the
18 purposes of this next series of questions, that
19 product produced after the pesticide is cancelled
20 is unregistered and can't be sold in a sense. If
21 that were the case would you agree that a company
22 in Nichino's position that complied with this

1 commitment and request of voluntary cancellation
2 might have been unable to sell any product
3 produced after March or early April? And that --
4 well, let's just start with that first question.
5 So would you agree then, if the Agency were able
6 to cancel in April that Nichino would not have
7 been able to sell any product produced after that
8 date?

9 A Yes.

10 Q Okay. Now, would you also agree that as
11 a direct result of Bayer and Nichino not
12 submitting a cancellation request as they
13 promised, they would be able to produce and
14 release for shipment product until let's say
15 sometime in June or July?

16 A I believe under the technicalities of
17 the hearing that that is the case, but that is not
18 the purpose behind our requesting a hearing.

19 Q I wasn't suggesting it was I just want
20 to make sure we're on the same page. So do you
21 agree that Nichino and Bayer would be able produce
22 and release for shipment product that they would

1 not have been able to produce, and they requested
2 voluntary cancellation when asked to do so?

3 A It's my understanding --

4 MR. EISENBERG: Sorry. Objection,
5 another hypothetical.

6 MR. PERLIS: I don't think it's a
7 hypothetical at all. What I'm asking is, and I
8 think I'm entitled to ask a hypothetical question,
9 and I already identified the paramaters to the
10 hypothetical.

11 MR. EISENBERG: I think if you look at
12 Mr. Johnson's direct testimony, it is very
13 narrowly scoped, and you give him, Counsel, a lot
14 of leeway, and not objecting, but we're far beyond
15 the scope of the witness' testimony.

16 ARBITRATOR BIRO: He is an expert
17 witness. Isn't he?

18 MR. EISENBERG: No. He is not.

19 ARBITRATOR BIRO: Okay. Sustained. Go
20 ahead.

21 MR. PERLIS: Your Honor, this witness
22 testified on this stocks provision and I'm trying

1 to restore what he doesn't --

2 ARBITRATOR BIRO: Any questions about
3 personal knowledge that he has, and no more.

4 BY MR. PERLIS:

5 Q Okay. Is it fair to say that you, in
6 your testimony, suggested that it would be
7 appropriate for Bayer and Nichino to be able to
8 sell and distribute all product that they produce
9 before the effective date of the cancellation?

10 A Yes.

11 Q So under your proposal Bayer and Nichino
12 would be able to sell -- would be able to release
13 the shipment and then sell more product than you
14 likely would have been able to produce and release
15 and they complied with the commitment, isn't that
16 true?

17 MR. EISENBERG: Objection. Again, calls
18 for speculation.

19 MR. PERLIS: Your Honor, I don't think
20 that calls for speculation. We've had testimony
21 in this proceeding that cancellations could have
22 been processed --

1 ARBITRATOR BIRO: Overruled, and I think
2 it's been asked and answered.

3 MR. PERLIS: Fair enough. Just two more
4 questions.

5 ARBITRATOR BIRO: All right.

6 BY MR. PERLIS:

7 Q Do you think it's fair and sensible for
8 government to treat companies that don't honor
9 commitments better than companies that do keep
10 their promises?

11 A I think that if you're trying to
12 characterize this situation in that light, it's a
13 misdirected characterization of these discussions
14 and the reason for this hearing.

15 Q I'm not sure that was an answer to the
16 question, but let me try it another way. So
17 imagine if Bayer and Nichino had honored this
18 commitment and the other did not. Would you think
19 it fair for government to treat the company that
20 spurns it better than the company that honored it?

21 MR. EISENBERG: Objection. I mean, the
22 question started with "imagine," given the fact

1 that this is getting very narrow spoken testimony.
2 I don't think it should be up to his imagination.

3 ARBITRATOR BIRO: Sustained.

4 BY MR. PERLIS:

5 Q So just so we're clear, it's your
6 testimony that EPA, in establishing this existing
7 stocks provision, should ignore the fact that you
8 accepted a condition as part of getting the
9 registration and then failing to comply with the
10 commitment. Is that correct?

11 A No, I don't agree with that.

12 Q Do you think EPA should take into
13 account in its existing stocks provision that,
14 from then on, the failure of Nichino and Bayer in
15 its presumption to request cancellation and ask to
16 do so? So, essentially, asking EPA to ignore that
17 fact when establishing new existing stocks
18 provisions?

19 A I think that while we're going through
20 this hearing process that we should be allowed to
21 sell -- continue to manufacture and sell product.

22 Q Well, during this hearing process you

1 are allowed to sell product, that's a result of
2 requesting a hearing, but you're also asking for
3 an existing stocks provision that would be the
4 same whether you requested voluntary cancellation
5 or not. Isn't that correct? Isn't that what
6 you're asking for in your testimony?

7 A I'm not sure what kind of a stocks
8 provision occurs with a voluntary cancellation.

9 Q But you are asking that everything that
10 Bayer and Nichino has produced prior to the date
11 of cancellation, which would be for existing
12 stocks, you are asking that all of those existing
13 stocks, liquidities of existing stocks that were
14 produced during this hearing, should be allowed to
15 be sold under EPA's existing stocks provision,
16 isn't that correct?

17 MR. EISENBERG: Objection, because it
18 mischaracterizes the direct testimony which states
19 that production has already stopped, and this has
20 come up maybe five times in the question. It's
21 part of the basis for objection.

22 MR. PERLIS: Excuse me, but the

1 testimony said the registrants believe -- one of
2 the registrants testified that they were
3 continuing to produce.

4 MR. EISENBERG: This is Nichino's
5 present, and he testified their production
6 stopped, so if you're asking about Bayer's
7 production, then you'd have to ask the Bayer
8 witness, I believe.

9 MR. PERLIS: He also testified that he
10 believes the registrants believed it.

11 ARBITRATOR BIRO: Okay, we're not going
12 to argue back and forth between you, because I am
13 the only one you're supposed to be talking to.
14 The question is whether he feels he should be
15 allowed to continue to sell stocks until a final
16 determination on cancellation is made.

17 MR. PERLIS: No, excuse me. I don't
18 believe that's the question because they could
19 clearly continue to sell products registered. The
20 question was whether he believes it appropriate
21 for the -- I'm sorry, he believes it inappropriate
22 for the agency to take into account the failure to

1 comply with the commitment in establishing
2 existing stocks provision which will be kick in at
3 the end of this proceeding.

4 ARBITRATOR BIRO: Do you understand that
5 question?

6 THE WITNESS: I think I do, but I think
7 it's inappropriate, but I think it was more of a
8 punitive action for, again, complying in what
9 we're doing in legal, and that our view of the
10 conditions of this registration obviously differs,
11 that's why we're here, and that if we go through
12 and then resolve our differences one way or the
13 other, then there shouldn't be any kind of a
14 punitive action after the conclusions.

15 MR. PERLIS: Your Honor, I have no
16 further questions for this witness.

17 ARBITRATOR BIRO: Okay. Mr. Eisenberg,
18 do you have any redirect?

19 MR. EISENBERG: Yes.

20 REDIRECT EXAMINATION

21 BY MR. EISENBERG:

22 Q Mr. Johnson, just to call on this last

1 point on existing stocks, were you to sell your
2 existing stocks, who would you sell them to?

3 A My distributors.

4 Q And who would the distributors sell them
5 to?

6 A To the growers.

7 Q So if you're not permitted to exhaust
8 your existing stocks the product would perish?

9 A Our products in particular in a few
10 areas are highly valued, and if that couldn't
11 happen, if it stopped, then we would have to take
12 everything back and we would have to just waste
13 disposal, which doesn't help anyone, I don't
14 believe.

15 Q Is Nichino manufacturing flubendiamide
16 at this time?

17 A No.

18 Q When did Nichino stop manufacturing
19 flubendiamide?

20 A The last formulation, it was September
21 28th, and I became aware of the more difficult
22 discussions with EPA on the time limit extension

1 for conditional registration. We originally had a
2 production scheduled in August, but we delayed to
3 try to see what was happening with the conditional
4 registration and the hopeful extension of that
5 registration, and as we got into September, at the
6 end of August, into September, there were a lot of
7 very positive developments, emails back and forth
8 with EPA discussing the 3-year extension, talking
9 about the different studies that were being agreed
10 to get that 3-year extension, and at that point,
11 we felt that it looked like the registration would
12 continue, and so we made the decision to make some
13 product in September. We were out at that point.

14 Q If EPA's existing stocks proposal is
15 adopted as currently proposed, where else if
16 anywhere would you sell off Nichino's existing
17 stocks?

18 A Unfortunately, because our products are
19 a formulation of flubendiamide and the focus of
20 it, there's -- that combination does not have a
21 registration anywhere else in the world, so it's
22 not like we could ship it somewhere else, so it's

1 one of the reasons we're being very conservative
2 with our formulation or production to make sure
3 that we're not creating some economic problem for
4 ourselves if any of this does get cancelled
5 potentially in the future.

6 Q I'd like you to turn back to what's in
7 the respondent's binder, Exhibit 7. And to the
8 second page, please. Counsel, I believe, was
9 asking you on cross about how Dana Sargent's
10 provided registrants concerned with EPA's
11 decision, and of course, that questioning asked
12 you if you thought there had been scientific
13 discussions. If you turn to the last paragraph on
14 page 2, where the sentence in the middle starting
15 with "Yet EPA," could you read that to the Court?

16 A This? "Yet EPA, it is now --

17 MR. PERLIS: I'm going to object here.
18 I believe what I asked him was whether there was
19 any discussion that EPA had not had discussions
20 with them, and frankly, I don't think these
21 questions cover that.

22 MR. EISENBERG: The question, and we can

1 go back to the record, I believe the questions
2 were, were there scientific discussions with EPA
3 --

4 ARBITRATOR BIRO: Sustained. I mean,
5 overruled. Go ahead, ask your question.

6 BY MR. EISENBERG:

7 Q So could you please read that into the
8 record?

9 A "Yet EPA is now ignoring that study in
10 favor of a less appropriate study with a different
11 endpoint. Notably, after seven years of
12 flubendiamide use and monitoring, not one of the
13 water monitoring samples that EPA required and
14 that was collected has met or exceeded even this
15 lower endpoint."

16 Q And directing you on to page 3, the
17 paragraph starting "Moreover," would you read that
18 first sentence?

19 A "Moreover, although the unreasonable
20 adverse effects registration standard requires
21 consideration of benefits as well as risks, EPA
22 downplays or ignores the significant benefits

1 flubendiamide provides compared to alternatives,
2 including its excellent safety profile and its
3 targeted control."

4 Q Is that word "ignored" in this place, is
5 that a word to dissociate the scientific
6 discussion?

7 A No, not necessarily. We're being
8 ignored. You said "ignored," right?

9 Q Yes.

10 A Yeah.

11 Q I just want to point you to the last
12 sentence in the letter. Could you read that into
13 the record again for me?

14 A "We remain available to address the
15 science in a transparent and methodical way,
16 consistent with the FIFRA registration standard
17 and process. If this is done as Congress
18 envisioned, the products should remain
19 registered."

20 MR. EISENBERG: We have no further
21 questions.

22 ARBITRATOR BIRO: Thank you, Mr.

1 Eisenberg. Mr. Perlis?

2 MR. PERLIS: Nothing.

3 ARBITRATOR BIRO: Mr. Johnson, I just
4 have a few questions. Maybe you can clarify some
5 things for me. You indicated that -- I think it's
6 Nichino or some company they're affiliated with
7 created flubendiamide. Is that correct?

8 THE WITNESS: That's correct. They're a
9 parent company, Nihon Nohyaku, from Tokyo, Japan,
10 are the original discoverers of flubendiamide.

11 ARBITRATOR BIRO: Okay. And you said
12 that they spent \$65 million to bring that product
13 to market. Is that correct?

14 THE WITNESS: That's just for the U.S.
15 Probably, on a global basis, it's closer to \$200
16 million.

17 ARBITRATOR BIRO: What goes into that
18 cost that you're talking about, bringing it to
19 market in the U.S.?

20 THE WITNESS: Well, there's the original
21 discovery cost in terms of screening compounds and
22 finding activity and finding safety, and then

1 moving them through efficacy trials and doing all
2 the toxicological trials, environmental -- again,
3 I'm not a scientist, I go through my experience in
4 managing over top that area, so there's a
5 considerable amount of work that's done, a lot of
6 man-hours as well that goes into those costs. I
7 think there was recently a survey by Phillips
8 McDougall that shows from discovery to market now
9 it takes roughly 10 years and \$286 million to
10 bring a compound to our marketplace. So when we
11 talk about having choices to get a registration or
12 not get a registration, after spending all that
13 time and money, it's difficult to turn down the
14 conditional registration offers, and, as I said,
15 all of our registrations have been conditional, so
16 there's always unanswered questions, and there has
17 been in the past a very good faith dialogue
18 between our company and EPA to resolve those
19 conditions for all registrations, and this is our
20 first experience with really kind of getting to a
21 point where we kind of hit a brick wall.

22 ARBITRATOR BIRO: When EPA offers you a

1 conditional registration, it's not really a take
2 it or leave it approach, is it? You can turn it
3 down and then file suit, isn't that correct?

4 THE WITNESS: That may be technically
5 correct. I'm not totally aware of all that, how
6 all those laws work. I'd say practically, given
7 the time, the money that you're, as a business
8 person, you're in a situation where you take what
9 you can go with and try to address all the
10 questions that are being asked in good faith,
11 again, and that's really been a fairly normal
12 process for our industry.

13 ARBITRATOR BIRO: Besides Bayer, have
14 you licensed flubendiamide to anybody else?

15 THE WITNESS: No.

16 ARBITRATOR BIRO: So they're the only
17 other company selling the product or selling some
18 combination of the product?

19 THE WITNESS: In the U.S.

20 ARBITRATOR BIRO: How about elsewhere?

21 THE WITNESS: Elsewhere, it's mainly
22 Bayer and there's a couple other smaller companies

1 I'm not quite aware of the names in some other
2 countries, some smaller countries, but it's
3 primarily Bayer and Nihon Nohyaku market the
4 products.

5 ARBITRATOR BIRO: And give me a ballpark
6 number how much has your company made each year
7 from licensing or selling your product with
8 flubendiamide?

9 MR. EISENBERG: Your Honor, just
10 respectfully, I want -- this may touch on some CBI
11 here.

12 ARBITRATOR BIRO: That's why I'm asking
13 for a general ballpark figure. Is that CBI? Do
14 you consider that confidential business
15 information?

16 MS. SZMUSZKOVICZ: One moment.

17 ARBITRATOR BIRO: Okay.

18 (Discussion off the record)

19 MR. EISENBERG: This is not totally
20 available information in the general course.

21 ARBITRATOR BIRO: I was just interested
22 in knowing. Since you're telling me the cost of

1 making it, I'd like to know the cost of the return
2 on the investment, but it's okay. I'll accept him
3 withholding the information. Where do you
4 manufacture flubendiamide?

5 THE WITNESS: Flubendiamide is
6 manufactured in Japan; we had to agree to it.

7 ARBITRATOR BIRO: And your product that
8 you sell?

9 THE WITNESS: We import the active
10 ingredient here and have it formulated --

11 ARBITRATOR BIRO: Here in the United
12 States.

13 THE WITNESS: Yes.

14 ARBITRATOR BIRO: You import it from
15 Japan.

16 THE WITNESS: We import the active
17 ingredient from Japan and then have it formulated
18 into the end use products at a 3rd-party contract
19 normally.

20 ARBITRATOR BIRO: You indicated that
21 your unique product that's a mixture of
22 ingredients is only registered here in the United

1 States. Is there anything that would stop you
2 from applying for registration elsewhere?

3 THE WITNESS: No, we could technically
4 apply for that registration elsewhere. It would
5 take -- depending on the country, it could take
6 many years, but it is possible.

7 ARBITRATOR BIRO: Is EPA's cancellation
8 definitive as to whether any other country will
9 give you a registration?

10 THE WITNESS: Not directly. I believe
11 other regulatory agencies around the world look to
12 the EPA, but it's not directly related.

13 ARBITRATOR BIRO: You talked a lot about
14 why you didn't feel that voluntary cancellation
15 clause was triggered, and I just want to go over
16 that little bit with you. You feel that it wasn't
17 triggered because EPA was making its determination
18 based on an endpoint for toxicity to aquatic
19 invertebrates, different from the endpoint that
20 Bayer scientists thought was appropriate. Is that
21 correct?

22 THE WITNESS: That's one aspect of it,

1 as I understand it.

2 ARBITRATOR BIRO: Well, an aspect that
3 was not -- you would agree that EPA notified you
4 that they had concluded that they found that the
5 product created an unreasonable adverse effect on
6 the environment. Isn't that correct?

7 THE WITNESS: I would agree that they
8 notified us?

9 ARBITRATOR BIRO: Yes.

10 THE WITNESS: In your letter, yes, they
11 did.

12 ARBITRATOR BIRO: Okay. And they did
13 have meetings with Bayer scientists. EPA
14 scientists did have meetings with Bayer scientists
15 discussing the science regarding whether it
16 created an undue -- unreasonable adverse effect on
17 the environment. Isn't that correct?

18 THE WITNESS: There were discussions
19 over time, yes. I'm not sure that they were
20 always fruitful discussions. There was not
21 necessarily agreement around the science, the use
22 of the studies, and it's really, I think, the crux

1 of the issue why we're here that we believed that
2 that discussion got abruptly stopped in late
3 September, early October, because when we were
4 really coming to a point where we were going to
5 extend the registration, redo the water studies,
6 to elucidate and clarify the questions about the
7 data, and the real world water monitoring studies
8 are really the basis for that, and the longer you
9 can run those studies, the more information you
10 can get a clearer picture and you can derive from
11 that rather than just using the model, say.
12 That's a lot of the discussion that kind of broke
13 down.

14 ARBITRATOR BIRO: Right, so that's the
15 real nub of the issue. EPA went on its modeling,
16 you went on what you consider real world data,
17 which is actual data with points taken from the
18 ponds that you were monitoring, and you came to
19 different points in terms of the toxicity levels
20 based on those two sets of data.

21 THE WITNESS: Well, I don't --

22 ARBITRATOR BIRO: Is that not correct?

1 THE WITNESS: That could be a little
2 oversimplification.

3 ARBITRATOR BIRO: Oh, I'm sure it is.

4 THE WITNESS: So the endpoint is a whole
5 other argument in itself, and it got changed late
6 in the game. It was not a transparent discussion
7 at all.

8 ARBITRATOR BIRO: Oh, so that's a
9 different issue from either relying on modeling or
10 real world data?

11 THE WITNESS: No, it feeds into the
12 modeling, but we were in discussions about
13 litigation and taking uses off the label and
14 trying to do things for use label which would
15 actually fit into EPA's models, and we even got
16 down to a very, very truncated label that we
17 believed would pass the model, and then they
18 changed the model.

19 ARBITRATOR BIRO: What do you mean --

20 THE WITNESS: So the goalpost got moved
21 and, at that time, it was apparent to us that it
22 was starting to be more of a political issue and

1 not a science issue.

2 ARBITRATOR BIRO: Everybody keeps using
3 this term "political issue." What do you mean by
4 that?

5 THE WITNESS: Well, I think that when I
6 came into the meeting on December 15th at the EPA,
7 and the assistant administrator came in and sat
8 down and said he personally didn't believe that
9 this compound should have ever been registered,
10 that that was not a good sign in terms of any
11 further discussion. And he never really
12 elucidated why other than he believed it was
13 persistent, and I don't believe that it's
14 necessarily been totally concluded that it's
15 persistent, and if it were concluded that it were
16 persistent, is it toxic, does it have risk versus
17 all benefits. So the tremendous compound, all
18 categories, they're focusing on a very narrow area
19 of concern, and we were addressing those concerns
20 as best we can. And so the science is developing
21 and looking at the water monitoring, so from our
22 standpoint, and particularly in Bayer's case,

1 who's been really doing all this work, we're
2 working in good faith to provide those answers
3 around this concern that, as we are here now,
4 don't believe it's an imminent situation, there's
5 not imminent harm occurring, that we have time to
6 clarify what happens with this compound, and if we
7 find, as was stated earlier, that it looks like
8 there is an issue, then I think the registrants
9 would then move with the voluntary cancellation.
10 But that's why we don't believe we're at that
11 point, and we have a great tool for growers. It's
12 environmentally very good human tox, avian,
13 aquatic tox, except for this one vented organism
14 -- not that they're not important -- but that is
15 still a big question as far as how toxic it can
16 be, and it doesn't appear that it's building up
17 based on water monitoring and the USGS monitoring,
18 so we feel if we get a fair, clear opportunity in
19 a unbiased situation to provide that scientific
20 dialogue, that it would not be viewed as this
21 unreasonable risk. And so that's why we're here.

22 ARBITRATOR BIRO: Okay. I don't want to

1 cut you off, but I would like to get back to my
2 question, which what makes you think it's a
3 political determination? What do you mean by
4 that?

5 THE WITNESS: Well, it just seemed that
6 there was a lot of good faith back and forth
7 dialogue, as we've experienced with our
8 registrations, conditional registrations, in the
9 past, and then suddenly in October, the
10 communications seemed to stop, and almost like a
11 light switch, and then --

12 ARBITRATOR BIRO: So by political, you
13 mean that the agency decided to go in a different
14 direction in terms of its scientific
15 determination?

16 THE WITNESS: I'm not sure if it was
17 scientific or it was more try to make an example
18 out of the compound, try to use it as a way to
19 make policy, because it seemed that no matter what
20 we tried to do to address the scientific concerns,
21 they would move the goalpost. So the impression
22 is from -- my personal impression is that there

1 was someone that reached a conclusion inside the
2 agency and that everything was being backed into
3 that, as much as we tried to address it.

4 ARBITRATOR BIRO: And the conclusion was
5 determining this pesticide, no matter what? What
6 is the end goal of the political consideration you
7 think is in play here?

8 THE WITNESS: Possibly to deem this as a
9 persistent pesticide and had to take it off the
10 market.

11 ARBITRATOR BIRO: To what end?

12 THE WITNESS: To help drive a potential
13 new persistence policy within EPA. And in the
14 December 15th meeting, the assistant administrator
15 also talked about heavily halogenated compounds,
16 was very concerned about those, and that
17 persistence in and of itself should be a reason to
18 not allow the product on the market, regardless of
19 whether there's risk or not. And that's very much
20 against the risk approach that EPA takes.

21 ARBITRATOR BIRO: Okay.

22 THE WITNESS: Or has taken.

1 ARBITRATOR BIRO: Thank you, Mr.
2 Johnson. Mr. Eisenberg, do you have any
3 follow-up questions?

4 MR. EISENBERG: May we have a moment?

5 ARBITRATOR BIRO: Of course.

6 (Recess)

7 MR. EISENBERG: We'd like to try and
8 address the question posed that we though touched
9 on CBI in a way that protects the company's
10 interest so we'll try and phrase it more
11 generally.

12 ARBITRATOR BIRO: Okay.

13 BY MR. EISENBERG:

14 Q Mr. Johnson, you were asked earlier by
15 the Judge whether the company - what the profits
16 were for flubendiamide for your company. I want
17 to ask that a different way. If you still have a
18 concern let us know, but please try to answer in
19 general terms. Looking at the \$65 million that
20 you said - or larger \$200+ figure, would you say
21 the company has recovered its costs through sales
22 of flubendiamide?

1 A That's a difficult question to answer,
2 the reason being the way this business was
3 established is that the revenues don't all run
4 through each general area. So Bayer's business is
5 separate from our business, and our business if it
6 were based just on Nichino America business, no.
7 It would not have paid by back by then. I'm not
8 sure about the Bayer business and its separate
9 licensing arrangements with the parent company and
10 so all I would do is guesstimate.

11 Q Thank you.

12 MR. EISENBERG: We have no further
13 questions.

14 ARBITRATOR BIRO: Mr. Perlis?

15 MR. PERLIS: Just one.

16 RE CROSS EXAMINATION

17 BY MR. PERLIS:

18 Q Has anyone at EPA ever suggested to you
19 that the cancellation here is being based on
20 persistence without regard to any toxicity issues?

21 A No.

22 Q Thank you.

1 MR. PERLIS: I have nothing further,
2 Your Honor.

3 ARBITRATOR BIRO: Thank you, Mr.
4 Johnson, you may step down.

5 Okay. Who's standing up next?

6 MS. SZMUSZKOVICZ: We have no further
7 witnesses and there are no further exhibits. So
8 we would rest.

9 ARBITRATOR BIRO: Let's go over the
10 exhibits we have now before we close so we're all
11 on the same page. For the Agency, the Respondent,
12 I have exhibits No. 1-10.

13 MS. GOERKE: That is correct, Your
14 Honor.

15 ARBITRATOR BIRO: For the petitioner,
16 Bayer, I have Exhibits 7-21, 26, 33, 52, 116-118,
17 123, 127, 128, and then 22-25, 27 through 32, and
18 34 through 36. I'm sorry, they weren't in
19 sequential order, but -- are we all in agreement?

20 MS. SZMUSZKOVICZ: Yes, that's right,
21 and we'll double check.

22 ARBITRATOR BIRO: Okay.

1 MS. GOERKE: I believe that's correct as
2 well.

3 ARBITRATOR BIRO: Okay, and then you can
4 submit a statement of any other documents and
5 testimony you want to submit as part of your offer
6 of proof with your post-hearing brief. I'd be
7 happy to let you do closing statements if you
8 wish, but you certainly don't need to, because I'm
9 going to give you an opportunity to file
10 post-hearing briefs.

11 MS. GOERKE: No.

12 MS. SZMUSZKOVICZ: No.

13 ARBITRATOR BIRO: We're going to wait?
14 Okay, great. So we're anticipating actually not
15 getting a transcript tonight, but we should have a
16 final transcript by Thursday. We would like any
17 motion to conform the transcript to the testimony
18 to be filed by May 16, and it would be lovely if
19 you could get together before you file that and
20 see if you can agree on the changes so we could
21 not wait for any replies and we could rule on that
22 as quickly as possible because of the tight

1 deadline. We'd like post-hearing briefs by May
2 18, and we weren't going to set time for doing
3 reply briefs because of the deadline. If you
4 really feel a need for reply briefs, we'll take
5 them. You can move, tell me some issue that you
6 haven't had a chance to fully brief. Is there any
7 other issue we should discuss before we close for
8 today?

9 MS. SZMUSZKOVICZ: I don't have any
10 issues.

11 MS. GOERKE: None.

12 ARBITRATOR BIRO: All right, thank you
13 very much for your cooperation. I really
14 appreciate it. Have a good evening.

15

16

17 (Whereupon, at 2:00 p.m., the
18 ARBITRATION was adjourned.)

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CERTIFICATE OF NOTARY PUBLIC

COMMONWEALTH OF VIRGINIA

I, Carleton J. Anderson, III, notary public in and for the Commonwealth of Virginia, do hereby certify that the forgoing PROCEEDING was duly recorded and thereafter reduced to print under my direction; that the witnesses were sworn to tell the truth under penalty of perjury; that said transcript is a true record of the testimony given by witnesses; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this proceeding was called; and, furthermore, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

(Signature and Seal on File)

Notary Public, in and for the Commonwealth of Virginia

My Commission Expires: November 30, 2016

Notary Public Number 351998

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