

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

BEFORE:

SUSAN L. BIRO
Administrative Law Judge
Chief Administrative Law Judge
Office of Administrative Law Judges
United States Environmental Protection
Agency
1200 Pennsylvania Ave., N.W.
MC 1900R
Washington, DC 20460

1 APPEARANCES:

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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 JUDGE BIRO: Good morning, everyone.

3 Please be seated. We're going on the record in
4 the matter of Bayer CropScience 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, both of Bayer, and Jeffrey
5 Johnson from Nichino, who is the CEO and also
6 corporate representative for 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 JUDGE BIRO: Okay, welcome everyone.
16 Could you pronounce your last name for me one more
17 time?

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

20 JUDGE BIRO: Okay. I'm apologizing in
21 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 JUDGE BIRO: Great. We are here today
9 to hold a hearing on Petitioners' request for a
10 hearing in response to EPA's Notice of Intent to
11 Cancel four conditional pesticide registrations
12 involving the ingredient Flubendiamide under
13 6(b) of the Federal Insecticide, Fungicide, and
14 Rodenticide Act, FIFRA.

15 Prior to this hearing we issued -- my
16 office issued, I issued, two orders of substance
17 and I received yesterday Petitioners' Objection to
18 our Rulings in that case. You have reserved all
19 of your rights to appeal those rulings and I will
20 have a standing, you know, objections on behalf of
21 both parties to any ruling made in this case today
22 in which you take umbrage, you'd like to take up

1 on appeal so you don't have to concern yourself
2 with that.

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

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

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

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

7 MS. SZMUSZKOVICZ: We have no
8 preliminary matters at this time.

9 JUDGE BIRO: Thank you. The EPA is
10 going first. Thank you.

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

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

17 A week later, instead of submitting the
18 required voluntary cancellation request,
19 registrants informed EPA that they would not
20 comply. We sent registrants a Notice of Intent to
21 Cancel Flubendiamide products on February 29, 2016
22 under FIFRA ° 6(e). That Section provides for a

1 limited expedited hearing. The statutory
2 provision also states that the only matters for
3 resolution at hearing are whether the conditions
4 have been satisfied within the time provided and
5 that the Administrator's determination with
6 respect to the disposition of existing stocks is
7 consistent with FIFRA.

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

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

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

15 Thank you.

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

22 First, the terms of EPA's 2008

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

1 risk of adverse effects.

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

12 Third, in addition to the unique Letter
13 and the unique EPA implementation, to our
14 knowledge this is the first time that FIFRA § 6(b)
15 hearing has been convened under FIFRA.

16 The registrants wish to emphasize up
17 front that regardless of their disagreements and
18 concerns over the process that EPA followed here,
19 had the science shown that Flubendiamide does not
20 meet the FIFRA registration standard the
21 registrants would have withdrawn the products from
22 the marketplace.

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

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

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

22 On the second issue, existing stocks,

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

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

1 proposal be challenged for being too onerous.
2 Registrants respectfully submit that this is not
3 consistent with FIFRA, which is itself a
4 risk-benefit law.

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

16 As you know, the parties view this case
17 very differently. For the registrants this is an
18 extreme example of EPA elevating a political
19 objective over science. The circumstances are so
20 stark that the registrants found it necessary to
21 take the unusual step of requesting review.
22 Neither registrant has ever undertaken anything

1 like this before. It is extraordinary, especially
2 considering that it involves challenging the very
3 Agency that holds so much power over the
4 registrants' livelihood.

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

16 Thank you for your attention and
17 consideration of the registrants' evidence.

18 JUDGE BIRO: Thank you. Okay, Ms.
19 Goerke, do you want to call your first witness.

20 MS. GOERKE: Yes, thank you. I'd like
21 to call Susan Lewis. Do you prefer if I stand
22 here or do you have a preference?

1 JUDGE BIRO: Yes. If you could stand to
2 the right.

3 MS. GOERKE: Okay.

4 Whereupon,

5 SUSAN LEWIS

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

8 DIRECT EXAMINATION

9 BY MS. GOERKE:

10 Q Good morning.

11 A Good morning.

12 Q Would you please state your name and
13 current title for the record?

14 A Susan Torregrosa Lewis, and I'm Director
15 of Registration Division in the Office of
16 Pesticide Programs.

17 Q I would like to draw your attention to
18 your written testimony. I don't know if it's
19 helpful to have it on the screen or I can just
20 pull it up from a Respondent Exhibit list. It is
21 Item Number 10. If you want I can pull that up.
22 If you can. Do you have your --

1 SPEAKER: Yes.

2 MS. GOERKE: Yes. Exhibit 10.

3 Respondent Exhibit 10.

4 BY MS. GOERKE:

5 Q Do you see that?

6 A I do.

7 Q Is that the -- is this testimony that
8 you have prepared for this hearing?

9 A It is.

10 Q Are there any changes that you would
11 like to make to this testimony?

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

15 Q And for the court reporter's benefit --
16 excuse me -- that is Bates stamp page 200106.

17 A That first full paragraph, second line,
18 the typo says OCSSP and which should end with
19 CSPP.

20 Q Thank you. Is this a true and correct
21 copy to the best of your knowledge and belief of
22 your testimony?

1 A Yes.

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

6 MS. SZMUSZKOVICZ: No objection, Your
7 Honor.

8 MS. GOERKE: Additionally I have a --

9 JUDGE BIRO: Exhibit 10 is admitted into
10 the record.

11 BY MS. GOERKE:

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

19 A Yes.

20 Q Are you familiar with the items that are
21 marked RE1 through 9?

22 A I am.

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

5 JUDGE BIRO: Is there any objection?

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

10 JUDGE BIRO: So you don't object or you
11 do?

12 MS. SZMUSZKOVICZ: We do not object, but
13 we ask for rulings on the scope of all the
14 Exhibits that would be entered, and so if there
15 are objections that we have not heard from EPA,
16 which it advised us it reserved the right to do,
17 we wanted to be able to just ensure that there is
18 a consistency on the type of Exhibits that are
19 admitted into evidence. If EPA indicates -- can
20 represent now it has no further objections to our
21 Exhibits then we would have no further objections.

22 JUDGE BIRO: Do you need time to talk

1 about that now?

2 MS. SZMUSZKOVICZ: It would -- if we
3 could take a minute to do that, Your Honor, that
4 would be -- that would be --

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

11 JUDGE BIRO: Okay. So without
12 objection, then Respondent's Exhibits 1-9 are
13 admitted into the record.

14 MS. GOERKE: Thank you, your Honor. I
15 don't have any further introductory remarks for
16 Ms. Lewis.

17 CROSS-EXAMINATION

18 BY MS. SZMUSZKOVICZ:

19 Q Good morning.

20 A Good morning.

21 Q We've met, but for the record I wanted
22 to introduce myself. My name is Kathy

1 Szmuszkovicz and in this matter I'm representing
2 Bayer CropScience, one of the registrants. Thank
3 you for being here.

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

9 A Correct.

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

15 A Yes.

16 Q So some of my questions will be about
17 the facts and some will be about the opinions you
18 offer and the basis of the opinions that you
19 offered. Many of my questions will call for a yes
20 or no answer. And I would ask that you answer
21 either yes or no. If the EPA legal team believes
22 that further explanation is necessary they will be

1 able to follow up with additional questions once
2 we are done with our conversation.

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

10 A Okay.

11 Q Have you had an opportunity to look at
12 this and confirm whether it is your curriculum
13 vitae?

14 A It is.

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

18 A Correct.

19 Q And before that for two years, between
20 1987 and '89 you coordinated scientific and
21 regulatory assessment for fungicides, correct?

22 A Correct.

1 Q And am I understanding correctly that by
2 stating that you coordinated those assessments you
3 were not the person responsible for preparing the
4 scientific and regulatory assessments in the first
5 instance?

6 A Correct.

7 Q Thank you. And then to round out your
8 experience at EPA, for seven years, from 1980 to
9 1987 you were a staff member on the data call-in
10 team, which identified human health data
11 requirements for older pesticides and determined
12 how EPA would process registrants' responses, such
13 as commitments to generate data, requests for low
14 volume and minor use waivers, amendments to label
15 uses, time extensions, and cancellations. Is that
16 accurate?

17 A Yes.

18 Q In terms of your education would you
19 please tell the Tribunal what university you
20 attended and what degree you obtained?

21 A Sure. Virginia Tech and I have a degree
22 in business administration.

1 Q Do you have any degrees in science?

2 A No.

3 Q And you have been in no scientific role
4 within EPA?

5 A Correct.

6 Q Did you -- were you in any scientific
7 positions -- did you act as a scientist in any of
8 your positions at EPA?

9 A No.

10 Q Also, just from a foundational
11 standpoint I'd like to ask you a few questions
12 about the documents that you reviewed. And so
13 first of all there were the 9 Exhibits that you
14 sponsored. And did you review each of those
15 Exhibits?

16 A Yes.

17 Q I'd like to ask you to turn to
18 Respondents' Exhibit which contains several 2008
19 emails between EPA and Bayer.

20 And there should be a notebook on -- you
21 have the notebook. Did you review any other EPA
22 emails or emails between EPA and the registrants,

1 or the applicants at that time, from that time
2 period?

3 A From 2008 I --

4 Q For --

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

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

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

11 Q And so --

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

13 Q Thank you. And then these -- I take it
14 these were selected from amongst those? Did you
15 do the selection?

16 A No.

17 Q Now I'd like to ask you to turn to the
18 registrants' Exhibits. And there is a list at the
19 front of Volume I of those Exhibits.

20 A Okay.

21 Q Thank you.

22 A All right.

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

3 A Mm-hmm.

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

13 A I have seen that, yes.

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

18 A The extension request I have seen.

19 Q Okay. The extension request? Which
20 numbers would those be?

21 A The letters granting. I -- I don't
22 recall specific, but I am aware that every time

1 that we granted an extension there was an initial
2 record of that.

3 Q Thank you.

4 A So the ones that happened while I was
5 there were definitely ones I had seen.

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

10 A Yes.

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

13 A Yes.

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

19 A I've seen that.

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

1 A I read that, yes.

2 Q Thank you. And then we move back into
3 2015 and 2016 documents, from 22 to 26. Those are
4 all current.

5 A Yes.

6 Q Would you take a look and see if you
7 read those.

8 A I believe that your number 23 was one of
9 our Exhibits.

10 Q Okay.

11 A I have read probably portions of some of
12 the others.

13 Q Okay. Thank you. And then moving to
14 Number 27, that was the 2008 EFED risk assessment.
15 Did you review that?

16 A Yes.

17 Q And there are several other 2010
18 documents here, risk assessments, ecological risk
19 assessments, 28 and 29. Do you remember reading
20 those?

21 A I am familiar but I did not read those
22 at that time.

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

3 A Yes.

4 Q Okay. And 31, 32 are both EPA documents
5 from 2016.

6 A Yes.

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

9 A That DER, no.

10 Q Okay. Okay. And the next document is
11 also a DER from 2011.

12 A No.

13 Q 35, the EFED review of water monitoring.

14 A I'm familiar with it, yes.

15 Q And EPA's EFED review in 2015, that's
16 PBNX 36.

17 A That I'm uncertain.

18 Q Okay. And then the next group, 37-51,
19 have been excluded from this proceeding by Judge
20 Biro's Order. So we will skip over those. 52 is
21 the same as RE 9, so we know you reviewed that.
22 And then the PBNX 80 through 115 have been

1 excluded under Judge Biro's order. Did you review
2 PBNX 116, the verified written statement of
3 Charlotte Sanson?

4 A Yes.

5 Q And PBNX 117, the verified statement of
6 Lee Hall?

7 A Yes.

8 Q And PBNX 118, the verified statement of
9 Jeffrey Johnson?

10 A Nichino?

11 Q Yes.

12 A Yes.

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

18 A Yes.

19 Q And did you review either or both of
20 those?

21 A The first one I reviewed. The second
22 one which just happened I have not reviewed.

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

3 A Briefly, yes.

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

8 A Yes.

9 Q In terms of other sources that you
10 relied on for your testimony, on page 200095 of
11 your testimony, that's Exhibit 10 -- the small
12 number is on the right.

13 A Yeah.

14 Q It's page 2 in the large numbers, 200095
15 in the small.

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

17 Q It ends in 95 in the smaller numbers.

18 A Okay.

19 Q And right before the background section
20 you mention that you're relying in part on
21 discussions with your staff in the Registration
22 Division. Correct?

1 A Correct.

2 Q And you're relying in part on
3 discussions with staff in the Environmental Fate
4 and Effects Division. Correct?

5 A Yes.

6 Q And you're relying in part on
7 discussions with staff in the Biological and
8 Economic Analysis Division.

9 A Yes.

10 Q And this list does not include
11 discussions with staff in the Health Effects
12 Division?

13 A That's correct.

14 Q And that's the division that looks at
15 human health impacts?

16 A Yes.

17 Q Okay. And you were present, were you
18 not, at the internal EPA meeting that took place
19 on December 16, the day after EPA met with the
20 CEOs of the two registrants?

21 A Is this with Jim Jones?

22 Q Yes.

1 A I was there.

2 Q Thank you. And do you -- naturally took
3 those discussions into account also?

4 A Yes.

5 Q Is there anything else that you relied
6 on to prepare your testimony?

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

9 Q Thank you. I'd like to ask you to turn
10 back to Respondent's Exhibit 4, the 2008 emails.
11 And you mentioned a moment ago that you had
12 reviewed all the emails in this Exhibit.

13 A Yes.

14 Q I'd like to ask you to start on page --
15 the very first page. It's -- for the record it's
16 200020. And this is an email from EPA to Bayer,
17 is it not?

18 A It is.

19 Q And could you state for the record what
20 the date of the email is?

21 A July 17, 2008.

22 Q Thank you. And asking you now to turn

1 your attention to the following pages that run
2 from 20021 to 200025. They -- these pages include
3 EPA's July 17, 2008 draft of a Preliminary
4 Acceptance Letter for Flubendiamide, do they not?

5 A Correct.

6 Q Okay. And turn your attention to page
7 200024, paragraph 6. In this paragraph EPA
8 suggested that the registrant, at this point it
9 appears that it's just referring to Bayer, submit
10 an irrevocable request for voluntary cancellation
11 within 60 days of the date EPA granted the
12 registration. Is that -- is that correct?

13 A Yes.

14 Q And the EPA proposed that it would
15 decide at a future date whether to accept that
16 request. Is that correct?

17 A Can you repeat that again?

18 Q Sure. EPA -- in paragraph 6 EPA was not
19 suggesting that the voluntary cancellation request
20 would become immediately effective in 60 days?

21 A That's correct.

22 Q At some point in the future, at least

1 not until sometime in July 2013, EPA would decide
2 whether to accept the cancellation request?

3 A Correct.

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

5 A Yes.

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

16 A Could you give the number please?

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

19 A I see, yes.

20 Q Do you need a minute to read it?

21 A Yes.

22 Q Okay. So what I read into the record

1 was exactly what it said here, it was not an
2 interpretation.

3 A Mm-hmm.

4 Q And you're familiar with that paragraph?

5 A Yes.

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

12 A Yes.

13 Q Okay. Okay. Turning now to the next
14 page, 200026, could you identify for the record
15 what this document is?

16 A Yes. This appears to be -- it's dated
17 July 23, 2008 and it's an email from their --
18 their response back to their -- our initial
19 proposal of the preliminary acceptance letter.

20 Q Thank you. And turn your attention to
21 page 200028. This is part of Bayer's July 23,
22 2008 response. And three paragraphs from the

1 bottom you see that Bayer suggested deleting all
2 of paragraph 6, which we discussed a moment ago.

3 A Yes.

4 Q And then reading -- continuing on to
5 200028 to 200029, Bayer suggested that if after
6 review of the data and scientific discussion
7 between EPA and Bayer, EPA would have several
8 options, one of which would have been for EPA to
9 cancel the registrations. Would you take a moment
10 to look at that --

11 A Sure.

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

13 A This is on the top of 29?

14 Q Yes. Starting -- starting on 28 right
15 underneath where it says "Bayer CropScience
16 understands and agrees".

17 A Yes.

18 Q And then continuing onto the top of the
19 page. Through -- through D. So the substitute
20 provisions included EPA having several options
21 including to cancel the registrations.

22 A Okay. I'm trying to keep straight what

1 Bayer is recommending. It's a little confusing
2 because it's not on track changes versus what we
3 wanted.

4 Q Sure. So I believe on page 200028 the
5 draft says paragraph 6 of the draft
6 pre-registration agreement would be entirely
7 replaced with the following language. So is it
8 your understanding that this was Bayer's proposal?

9 A Yes.

10 Q Thank you. And continuing on page
11 200029 Bayer was proposing to entirely delete
12 paragraph 7 of EPA's draft, which was the
13 expiration provision we talked about a minute ago,
14 correct?

15 A Correct.

16 Q Turning to the next page, 20030, could
17 you state for the record the date of the document,
18 the author, and to whom it is addressed?

19 A Sure. This is July 29, 2008 and the
20 author is Carmen Rodia, and it's to Danielle
21 Larochelle from Bayer.

22 Q And is -- Mr. Rodia is with EPA is he

1 not?

2 A Yes.

3 Q And he worked there at this time also?

4 A Yes.

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

11 A The one week, yes.

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

15 A I need to look at it.

16 Q Yeah, take your time.

17 A What I get from that is it talks about a
18 time limit for registration on the top of page 34.

19 Q And so that's different than the
20 expiration provision that we talked about a moment
21 ago that was in EPA's draft.

22 A Yes.

1 Q Thank you. Thanks. Okay. A little bit
2 later in the Exhibit, toward the very end, pages
3 200062 to 200065, could you turn -- turn to that?
4 And this is the July 31, 2008 signed version of
5 the Letter that this -- we were looking at in
6 draft over the last few minutes, is it not?

7 A Yes.

8 Q Now turning to page 200063 to 200064,
9 paragraphs 6 and 8. Take a moment to look at
10 those.

11 A Okay.

12 Q And 6(b) and 8(b) are identical in text
13 other than references to the two different
14 registrants Nichino and Bayer. Is that -- that
15 correct?

16 A Yes.

17 Q And so looking at 8(b), which would be
18 the same as 6(b) other than the names of the
19 registrants, that states that EPA shall complete
20 its review of the entire required data set and
21 will consider any additional data and supporting
22 information. Is that accurate?

1 A Yes.

2 Q And then it goes on to say that EPA
3 scientists and Bayer scientists -- and I'm reading
4 from 8(b) now -- shall engage in dialogue about
5 the data and the Agency's conclusion. Is that
6 accurate?

7 A Yes.

8 Q Thank you. Now, looking at 6(d), as in
9 dog, and 8(d), both of which are on 200064, are
10 those parallel provisions just with the only
11 difference being the names of the registrants?

12 A Yes.

13 Q And so looking at 8(d) as representative
14 it states that after reviewing the data as
15 discussed in 6(b) and 8(b) if EPA wishes to demand
16 cancellation it must first make a determination
17 that further registration of the Flubendiamide
18 technical product or end use products will result
19 in unreasonable adverse effects.

20 A Correct.

21 Q And the final conditions did not contain
22 an expiration condition did they?

1 A I need to look at the --

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

3 A Did you say expiration or --

4 Q Expiration.

5 A That's not an expiration.

6 Q Thank you. Okay, let's turn back to
7 your testimony at Exhibit RE10, and staying with
8 the 2008 time period let's look at your testimony
9 at 200098. And we talked about this a minute ago.
10 You mentioned that you discussed the matter with
11 your staff who were involved and who did that
12 include?

13 A That included Carmen Rodia. It included
14 Marion Johnson, who was the branch chief at that
15 time. It included Richard Gebken.

16 Q And would all of those people be at
17 positions that report to your level -- the
18 director of registration?

19 A Yes, within my position.

20 Q And did you speak with anyone from that
21 time at your level or above who was at EPA in 2008
22 at your level or above.

1 A No.

2 Q And you spoke a minute ago about your
3 having reviewed many of the key decision documents
4 from 2008, and we talked about the ones that were
5 provided by the parties in this case. Do you
6 recall whether you reviewed the Health Effects
7 Division's assessment of human health impact from
8 2008?

9 A Their assessment? I did not.

10 Q And that would have been the risk
11 assessment that took into account safety to
12 agricultural workers?

13 A Yes.

14 Q Did you review that portion of it?

15 A The risk assessment, no.

16 Q And how about -- would that have taken
17 into account safety to infants and children of the
18 compound?

19 A Yes.

20 Q Did you review that HED risk assessment?

21 A That risk assessment, no.

22 Q That particular Health Effects Division

1 risk assessment still stands today, does it not?

2 A Yes.

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

5 A Well, since '08 there are new uses
6 granted so it probably would have been updated for
7 these new uses of assessments.

8 Q Do you know if any of those changed the
9 favorable conclusions in them?

10 A I don't believe they did.

11 Q Thank you. Okay, let's turn now to RE5.

12 A R --

13 Q RE5, yes. And this is your January 29,
14 2016, recommendation to cancel all currently
15 registered flubendiamide products, correct?

16 A Correct.

17 Q And our questions here will go to the
18 process, not the substance of, the risk benefit
19 decision that was made.

20 Well, I understand from the face of the
21 document at RE5 that you signed the recommendation
22 to cancel flubendiamide registrations, correct?

1 A Yes.

2 Q Did you draft this memorandum?

3 A No.

4 Q Who drafted it?

5 A It was a combination of our staff, as
6 well as our scientists and portions of legal
7 counsel.

8 Q And when you mention scientists, are you
9 referring there to the Environmental Fate and
10 Effects Division?

11 A Correct.

12 Q And what about BEAD?

13 A BEAD? We used their report and they
14 reviewed the document and edited it.

15 Q And what about the Health Effects
16 Division?

17 A No.

18 Q Did OPP Management weigh in on it?

19 A Yes.

20 Q And what about OCSPP Management?

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

22 Q You confirmed earlier that you were at

1 the December 16 meeting with the assistant
2 administrator. That was an internal EPA meeting,
3 correct? And you were also at the December 15th
4 meeting that the assistant administrator held with
5 the CEOs and the two registrants.

6 A Correct.

7 Q And quite a lot of people in the room
8 were also there.

9 A Yes.

10 Q At the meeting, the assistant
11 administrator stated that if it had been his
12 decision he would not have registered
13 flubendiamide in 2008, correct?

14 A I have heard him say that.

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

18 A I don't know those are his exact words,
19 but he did say he was extremely concerned with
20 persistence.

21 Q Thank you. Is it your opinion that
22 under the preliminary acceptance letter, the 2008

1 letter, that EPA was required to make a decision
2 on whether flubendiamide meets the unreasonable
3 adverse effects standard for registration?

4 A Yes.

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

10 A Correct.

11 Q The preliminary acceptance letter was
12 silent on the way that EPA should memorialize that
13 decision -- is that -- is my understanding
14 correct?

15 A Correct.

16 Q And it was silent on the way that EPA
17 was to communicate the decision to the registrants
18 also.

19 A Correct. But can I check that real
20 quick?

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

1 A Which one?

2 Q RE4. It's the final few pages that have
3 the signatures on them.

4 A Thank you. Correct.

5 Q But we do know that in this case, EPA
6 did prepare RE5, which was your decision
7 recommendation. Even though EPA wasn't required
8 to do that, they chose to do that. Is that
9 correct?

10 A Correct.

11 Q And the preliminary acceptance letter
12 itself only required EPA to notify the registrants
13 of the decision, not to explain it -- if I'm
14 reading that RE4 correctly.

15 A Correct.

16 Q Could EPA have reached an unreasonable
17 adverse effects determination based on an issue or
18 a concern that EPA had not previously discussed
19 with the registrants based on the letter?

20 A My interpretation says we must have
21 measured dialogue after -- during the process.

22 Q So, that would include discussion of any

1 issue or concern between scientists.

2 A Yes.

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

11 A Yes.

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

15 The EPA did not ask the registrants for
16 information about the amount of flubendiamide in
17 the hands of users, did it?

18 A That's correct.

19 Q And EPA did not ask the registrants for
20 information on the amount of flubendiamide in the
21 hands of retailers.

22 A Correct.

1 Q Or for information on the amount of
2 flubendiamide in the hands of distributors.

3 A Correct.

4 Q Or the amount of flubendiamide in the
5 hands of the registrants.

6 A Correct.

7 Q And EPA did not ask about nor did it
8 know that Nichino had stopped ordering
9 flubendiamide by the time of its decision.

10 A Correct.

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

13 A Correct.

14 Q EPA did not ask the registrants about
15 whether all the existing stocks under EPA's
16 proposal that would need to be returned to the
17 registrants or that are in the hands of
18 registrants would be disposed of in the
19 environment.

20 A No.

21 Q Or what the environmental impact of that
22 would be?

1 A Correct.

2 Q EPA did not request information on the
3 benefits to growers to using those existing
4 stocks?

5 A On the existing stocks? Correct.

6 Q And EPA did not consider the impact on
7 growers who depend on flubendiamide in developing
8 the existing stocks for the proposal.

9 A That's correct.

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

16 A That was one.

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

19 A I don't know how much is in the hands of
20 end users, but I have read some of the testimony
21 that indicated that users tend not to buy the
22 product until they know they need it.

1 Q Thank you. And just to be clear, that
2 was the testimony in this case after the
3 cancellation decision after the existing stocks.

4 A Right.

5 Q So, at the time that EPA made that
6 assumption, what was the basis for your
7 understanding that there would be very little
8 material in the hands of the end users?

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

11 Q And can you correlate that to your
12 conclusion that there wouldn't be much material in
13 the hands of the end user?

14 A I think what we said from the hands of
15 the end user, the growers who already have it, the
16 overriding factor was if you have it within
17 containers, there's a bigger risk of spill or
18 exposure, and also it's very difficult to know
19 which grower has it. So, there's an
20 identification process.

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

1 A No.

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

7 A I believe so.

8 Q And just to be clear, the EPA proposed
9 to prohibit further sale by retailers and
10 distributors unrelated to the registrants?

11 A Correct.

12 Q And that was to punish the registrants?

13 A The rationale we put in was we did not
14 want to reward additional production. Production
15 can continue now, or can keep running, versus had
16 we received the irrevocable voluntary
17 cancellation, production would have ceased. So
18 those existing stocks and shipments would be
19 increasing at the retail outlet now.

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

22 A Right, it was a registrant bonus.

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

7 A Correct.

8 Q And just talking about what "quickly"
9 is, I think we've all been experiencing holding a
10 hearing, entering a decision within 75 days or 97
11 days. Would you say that that has been a quick
12 process?

13 A This hearing has been relatively quick,
14 yes.

15 Q And in the context of preparing and
16 getting the Federal Register Notice out and
17 published, is "quick" for EPA 45 days?

18 A In my testimony, I anticipated we would
19 act quickly because there is a standard voluntary
20 cancellation request and they could have been held
21 and issued almost in a matter of a week.

22 Q And published in the Federal Register --

1 A Published -- well, probably would be in
2 two weeks, so.

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

7 A Correct.

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

13 A It depends on the season -- when you are
14 at the height of the agricultural season it can
15 make a big difference.

16 Q And what are you relying on to state
17 that opinion with regard to flubendiamide?

18 A From all my interactions over the years
19 with industry when they're looking to get that new
20 use registered or get a new active ingredient
21 registered they generally need to have that before
22 January so that they can do the marketing and the

1 production and the buying and the orders. So,
2 it's all my years of interacting with industry on
3 my making decisions in the timeframe they need.

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

6 A Yes. Usually those are for things that
7 are not registered yet.

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

10 A The production line?

11 Q The production and distribution and
12 contracts and --

13 A That's probably more time if it's been
14 registered for a while.

15 Q But would it also need to occur before
16 January?

17 A That I don't know.

18 Q Okay. Let's turn now to page 200105,
19 your testimony, RE10. And right before the
20 existing stocks provision, you make a statement,
21 "We did not receive a voluntary cancellation
22 request by February 5th or thereafter and

1 subsequently informed the registrants because the
2 registrants had not submitted requests for
3 voluntary cancellation and failed to comply with
4 conditional registration, the flubendiamide
5 products identified in the Notice of Intent to
6 Cancel are subject to cancellation under FIFRA
7 section 6(e)." And you confirmed that statement
8 earlier this morning.

9 A Yes.

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

16 A Correct.

17 Q And in that capacity, you managed the
18 risk management process for the Rodenticide
19 Cluster, which involved a 2008 risk management
20 decision for handling of Rodenticides. And that
21 included the Rodenticide registrations of Reckitt
22 Benckiser that ultimately were the subject of the

1 cancellation proceeding.

2 A Yes.

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

8 Could you identify for the record the
9 date and subject of this Federal Register Notice?

10 A Yes. February 5th, 2013, and it's
11 Rodenticides; Notice of Intent to Cancel
12 Registrations of, and Notice of Denial of
13 Applications for, Certain Rodenticide Bait
14 Products.

15 Q So, this was in 2013, which would have
16 been five years after the 2008 risk management
17 decision for the Rodenticide cluster that we
18 talked about a moment ago?

19 A Correct.

20 Q Before EPA issued the notice of intent
21 to cancel further Rodenticides, EPA chose a
22 different way to try to enforce the risk

1 management decision, did they not?

2 A Yes.

3 Q Instead of pursuing cancellation, it
4 declared that the registrations were misbranded as
5 of a certain date, if I remember correctly?

6 A The misbranding -- I believe that was an
7 option that we were considering.

8 Q And Reckitt Bensicker then challenged
9 that option in court. Do you remember that?

10 A Yes.

11 Q And the court found that the misbranding
12 approach was unlawful and required EPA to proceed
13 under FIFRA ° 6 with cancellation. Do you
14 remember that?

15 A I do, correct.

16 Q And part of the delay in EPA issuing
17 this notice of intent to cancel in 2013 was caused
18 by EPA's choice of a different option as the first
19 option. Would that be a fair --

20 MS. GOERKE: Excuse me, Your Honor. I
21 want to object on relevance grounds. I don't see
22 where bringing in previous notices of cancellation

1 has to do with the one at hand.

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

12 JUDGE BIRO: What is in her testimony?

13 MS. SZMUSZKOVICZ: The EPA
14 decision-making about not having received a
15 voluntary cancellation request in choosing to
16 issue notice of intent to cancel under FIFRA °
17 6(e). It's at page 200105. The EPA briefs also
18 discussed this.

19 JUDGE BIRO: I'm still not connecting
20 all the dots on how it's relevant to this action.

21 MS. SZMUSZKOVICZ: In this particular
22 action, the Agency took action in response to the

1 registrants' letter. There was the issue of
2 timing in EPA's other 2008 decision versus its
3 2013 notice of intent to cancel. Also there were
4 12 registrations, six of which were unconditional,
5 six were conditional, and all of them were
6 addressed in the context of one FIFRA ° 6(b). So,
7 we can proffer if you would find it less laborious
8 than going through the process of questioning. We
9 have all the documents that we can enter into the
10 record and can state what the documents are. EPA
11 has its copies as well.

12 JUDGE BIRO: Okay, I'm going to sustain
13 the objection and let you make an offer of proof.

14 MS. SZMUSZKOVICZ: Okay. Would you let
15 me do that right now?

16 JUDGE BIRO: Sure.

17 MS. SZMUSZKOVICZ: I'd like to make an
18 offer of proof for the February 5, 2013 Federal
19 Register Notice and a series of six registration
20 approval letters for the Reckitt Benckiser
21 registrations. For 6 of the registrations
22 mentioned in the Register Notice, the documents on

1 their face indicate that they were products
2 conditionally registered under FIFRA ° 3(c)(7) and
3 all registrations were subject to cancellation
4 under 6(b). In the end, Ms. Lewis was offered as
5 the fact and expert witness in an administrative
6 proceeding. She did not appear as the registrants
7 withdrew -- their registrations -- but all of the
8 registrations were handled in the context of that
9 proceeding. The case caption shows the numbers,
10 and the registration letters which show the
11 numbers, and the Federal Register shows the
12 numbers. We can mark those under separate
13 exhibits.

14 JUDGE BIRO: Okay. There's some stuff
15 that in this instance -- maybe you were both
16 conditional or unconditional registration. The
17 Agency used a 6(b) proceeding to cancel the
18 registrations.

19 MS. SZMUSZKOVICZ: That's correct. All
20 of the registrations.

21 JUDGE BIRO: Well, okay.

22 MS. SZMUSZKOVICZ: May I confer with

1 counsel for just one moment?

2 JUDGE BIRO: You may.

3 MS. SZMUSZKOVICZ: This brief pause is
4 saving a lot of time, so thank you for indulging
5 me.

6 JUDGE BIRO: Would you like to take a
7 recess?

8 MS. SZMUSZKOVICZ: If maybe, just a
9 short, a short break, yeah, just about five
10 minutes?

11 JUDGE BIRO: Okay.

12 MS. SZMUSZKOVICZ: Thank you.

13 MR. WRIGHT: All rise.

14 (Recess)

15 JUDGE BIRO: Thank you. You may proceed.

16 MS. SZMUSZKOVICZ: Thank you. Just for
17 clarity of the record, I will proffer we had
18 marked as PBNX 124, the February 5, 2013 Federal
19 Register Notice and I referenced the notices of
20 pesticide registration for six Reckitt Benckiser
21 rodenticide products that were listed in that
22 Federal Register Notice and we marked that as PBNX

1 125. And I also reference the case caption from
2 the Reckitt Benckiser ° 6(b) hearing and we had a
3 demonstrative we were going to use that we've
4 marked as PBNX 126, for that, the purpose of this
5 case caption. And I believe that copies of those
6 exhibits have been, are, will be provided to EPA
7 counsel and have been provided to Mr. Wright.

8 JUDGE BIRO: Okay.

9 BY MS. SZMUSZKOVICZ:

10 Q And just one or two questions, Ms.
11 Lewis, just picking up on your testimony at
12 200105, in that paragraph right before it says
13 Existing Stocks. So that's RE10.

14 A Okay.

15 Q And this is the provision where you
16 explained it. Note that because we have not seen
17 the voluntary cancellation request EPA decided to
18 proceed with cancellation under FIFRA ° 6(e).

19 A Correct.

20 Q We were speaking a little bit earlier
21 this morning about the different documents that
22 you reviewed in the record and EPA's brief

1 opposing the registrants' request for an
2 accelerated decision in asking for a 6(b) hearing?

3 A Yes.

4 Q Do you recall that?

5 A I do.

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

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

14 Q Yes. That was the determination by EPA.

15 A Okay.

16 MS. SZMUSZKOVICZ: All right. I would
17 like to ask to mark this as PBNX 127.

18 BY MS. SZMUSZKOVICZ:

19 Q Ms. Lewis, the pages that are marked
20 PBNX 127 are pages out of the EPA's opposition to
21 the registrants' motion for an accelerated
22 decision. And we have the full opposition

1 available too, if there is any part of it that you
2 want to --

3 A Okay.

4 Q -- want to reference. This was just to
5 save a little paper. And I'd ask you to turn to
6 PBN 1778.

7 A Okay.

8 Q And the highlighted portion, which was
9 in EPA's brief and could you just read that
10 highlighted portion into the record?

11 A Yes.

12 MS. GOERKE: Excuse me, Your Honor. I
13 have to object to this. I mean what is being read
14 into the record is primarily legal argument that
15 has already been decided by this tribunal. I
16 don't see the relevance of having the witness
17 speak to certain portions of respondent's legal
18 motions in this case.

19 JUDGE BIRO: Well, we'll see.

20 Overruled. Go ahead.

21 BY MS. SZMUSZKOVICZ:

22 Q Would you, would you read it into the

1 record, and then I just have a follow up question
2 for you about it.

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

13 Q And, and in your opinion as an expert on
14 the decision making process, do you agree with
15 that statement?

16 A Yes.

17 Q Thank you. Ms. Lewis, we just have a
18 few more questions and during the break we were
19 able to resolve and eliminate more questions. Do
20 you recall the meetings that were held on January
21 6th at EPA with the registrants?

22 A Yes.

1 Q There was a series of meetings that you
2 presided over. These were distinct from the
3 meetings with Jim Jones in December.

4 A Correct.

5 Q And you were the highest ranking EPA
6 official at those meetings?

7 A In my head, I don't know if the other
8 directors were there or not, but yes.

9 Q Okay. From your workgroup?

10 A From my group, yes.

11 Q And in the morning EPA presented
12 scientific information to the registrants?

13 A Correct.

14 Q And then in the afternoon, there was a
15 non-science discussion.

16 A Correct.

17 Q And the registrants were appealing to
18 you based on a variety of grounds such as level
19 playing field, transparency, et cetera. Is that a
20 fair --

21 A Yes.

22 Q -- characterization?

1 A Yes, that's fair.

2 Q And you were patient in that meeting
3 with the registrants and heard their statements.
4 At some point in the afternoon, you were candid
5 with the registrants and you said this decision to
6 cancel is political. It's out of my hands.

7 A I don't recall saying that. I think
8 what I may have said is this is a very high level
9 decision.

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

14 A I know they -- I don't have that in
15 front of me, but I am aware, all right.

16 Q All right. And are you also aware that
17 Mr. Housenger, the director of EPA's Office of
18 Pesticide Programs wrote a response to the Center
19 for Food Safety?

20 A I don't recall that.

21 Q Okay. I'd like to present your counsel
22 and then show you a document that we will mark as

1 PBNX 128. Please take a moment to look at this
2 letter.

3 A Okay.

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

6 A March 28, 2016.

7 Q And could you state for the record, who
8 the signatory of the letter is?

9 A Jack E. Housenger, Director of Office of
10 Pesticide Programs.

11 Q And what would your relationship to him
12 be in a professional sense?

13 A Mr. Housenger is my manager.

14 Q And the letter is directed to the Center
15 for Food Safety, is it not?

16 A Yes.

17 Q And on its face, it appears to be a
18 response to the Center for Food Safety's February
19 11, 2016 letter. Is that correct?

20 A Correct.

21 Q I know you just had a couple of minutes
22 to look at the letter. Did this refresh you as to

1 whether you had seen it before, or is this the
2 first time you're reading it?

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

5 Q That's fine. Turning to the bottom of
6 PBN1910, the first page of the letter, Mr.
7 Housenger's responding to the Center for Food
8 Safety and saying that the agency carefully
9 considered the options available to the agency and
10 believes the cancellation option that was
11 determined is the appropriate way to expeditiously
12 resolve this matter. And, would that be a fair
13 characterization of the process, we carefully
14 considered the options?

15 A Yes.

16 Q And then, continuing on the next page,
17 PBN1911, at the top of the page, Mr. Housenger
18 says that without going into detail he would note
19 that these options either raise unnecessary legal
20 risks or require significant amounts of time and
21 agency resources when compared with the ° 6(e)
22 hearing process we're pursuing. Do you agree with

1 that statement?

2 A I -- I agree with the length of time.
3 I'm a little uncertain about the legal risks
4 portion, but the -- the time line, most
5 definitely.

6 Q Thank you.

7 MS. SZMUSZKOVICZ: We have no further
8 questions for Ms. Lewis, thank you, Ms. Lewis.

9 MS. GOERKE: Your Honor, my
10 understanding was you would have questions. Was
11 that at the conclusion of my questions?

12 JUDGE BIRO: You have to finish all your
13 questions first.

14 MS. GOERKE: Okay. Okay.

15 JUDGE BIRO: And see if I still have
16 questions.

17 MS. GOERKE: Okay.

18 REDIRECT EXAMINATION

19 BY MS. GOERKE:

20 Q All right. Thank you, Ms. Lewis. I
21 guess we will just start with the last thing that
22 just came before us.

1 A Okay.

2 Q Which was the letter that was just
3 presented to you, that was PBNX128. I would just
4 like to clarify, the document speaks for itself,
5 but in the portion that you were looking at at the
6 bottom of PBN1910, when it speaks to the three
7 actions I just wish to clarify the top three that
8 are on the first page of PBN1910. Would you
9 articulate what they are?

10 A Yes. Declare the flubendiamide
11 registrations to be expired; two, alternatively
12 declare "imminent hazard" and suspend the
13 registration; and three, issue a Stop Sale, Use or
14 Removal Order to promptly end the use of
15 flubendiamide.

16 Q And just to add clarification to the
17 transcript on the record, for the totality of this
18 is you may have not been extremely familiar, could
19 you please read the paragraph that begins PBN
20 1911, as to your demand. Could you read that in
21 its entirety, please?

22 A Yes. "As to your demand that EPA cease

1 issuing conditional registrations, my short answer
2 is that Congress adopted the provisions in °
3 3(c)(7) of FIFRA in order to allow EPA to issue
4 conditional registrations when the agency makes
5 the finding required by that section, and we will
6 continue to use that authority in the appropriate
7 circumstances. Having said that, I will also note
8 that we expect registrants to comply with
9 conditions of registration and that such
10 compliance is an important factor for us to
11 continue issuing conditional registrations. We
12 are deeply concerned that the flubendiamide
13 registrants accepted a registration with important
14 conditions and later elected not to comply with
15 those conditions. We hope and expect that this
16 refusal to comply with registration conditions is
17 a very isolated example; if it is not, we may have
18 to revisit the circumstances under which we issued
19 conditional registrations."

20 Q Thank you. When you spoke earlier in
21 your cross examination, you were mentioning the,
22 when you were familiarizing yourself with what

1 occurred since you were not in a position when the
2 original determination was made in 2008, and you
3 indicated that you had not spoken with people at
4 your level or above. Could you explain why you
5 did not?

6 A Yes. The division director at the time,
7 Ms. Lois Rossi has retired and she now works, I
8 believe some of her clients are industry. So that
9 conversation did not seem appropriate. The office
10 director, Debra Edwards, Dr. Edwards, has since
11 retired and also works with industry. So I chose
12 to go with what was on the record as our decision
13 document, which was what was signed in the
14 rationale.

15 Q Thank you. Turning to the meetings that
16 were raised on the cross examination. To your
17 knowledge, do you know why Jim Jones would have
18 said he would not register flubendiamide in 2008?

19 A My belief of that conversation was Jim
20 Jones was extremely concerned with a persistent
21 and toxic chemical.

22 MS. SZMUSZKOVICZ: Objection. We ask

1 that be stricken from the record as it goes to the
2 risk benefit issue.

3 MS. GOERKE: I believe that the issues
4 about process and what occurred at those meetings
5 were specifically placed at issue by the cross
6 examination that went to what happened at those
7 meetings. I wanted to clarify that.

8 JUDGE BIRO: We're not going to open the
9 door to that whole issue. I'm going to strike
10 that from the record. Go ahead.

11 BY MS. GOERKE:

12 Q Do you think that turning to the stocks
13 that you may have been aware of, do you think that
14 farmers usually hold significant quantities of
15 pesticide? Do they, do they typically use
16 pesticides shortly after they've purchased them?

17 A It depends on the pesticide. Ones they
18 know they're going to need and use them every
19 year, they may buy them and use it, but typically
20 farmers are not going to want to invest the money
21 until they know they need to use them.

22 Q And why do you expect that that would be

1 the case?

2 A Because it depends on the pest pressure
3 every year. We also consulted with our experts in
4 the Biological and Economic Analysis Division, and
5 I believe they generally thought it wouldn't be
6 extensive.

7 MS. SZMUSZKOVICZ: Another objection,
8 we'd ask to move to strike. This is all testimony
9 that EPA took the position was not a part of the
10 consideration, it should not be part of the
11 hearing. We're a little confused now about
12 hearing a different side of the story.

13 MS. GOERKE: Well, considering it was
14 similarly raised about what our understanding was
15 about what stocks were available at the time she
16 made her decision, I wish for her to clarify what
17 she was asked on cross examination.

18 JUDGE BIRO: Overruled. Go ahead.

19 BY MS. GOERKE:

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

22 A The issue on human health was not a

1 concern or a factor in this decision in that there
2 were no risks or concerns. It did play into the
3 benefits considerations because it had a favorable
4 profile for human health and workers, but nothing
5 had changed and our position on that hadn't
6 changed.

7 Q And also regarding questions that you
8 have received pursuant to the rodenticide
9 cancellation, isn't -- do you recollect -- wasn't
10 that just a registration that was not, you did not
11 have an issue with conditions of registration in
12 that case?

13 MS. SZMUSZKOVICZ: Objection. Leading.

14 JUDGE BIRO: Sustained.

15 BY MS. GOERKE:

16 Q Can you explain your understanding of
17 rodenticides and how that may have differed since
18 that was raised in the previous process --

19 A Yes, my recollection of rodenticides
20 when I was the branch chief was that these
21 products have been registered for a very long
22 time, they came under our re-registration review

1 program. We concluded that there was unreasonable
2 adverse effects. I -- I didn't recall but it
3 looks like some of them had been conditionally
4 registered, but certainly not all. We've pursued
5 this, the -- the long discussion since we
6 processed. So there were those. To my
7 recollection, there weren't very specific
8 requirements in those, for one thing. Additional
9 registration, I would say we would cancel.

10 Q After your discussion with staff, why
11 was the voluntary cancellation provision included
12 within the original PAL that we discussed?

13 A The agency was concerned with the
14 persistence and toxicity of this chemical. Uh, the
15 registrant believed that our models were
16 conservative and that they could do additional
17 data to disprove our models.

18 MS. GOERKE: I have no further
19 questions, Your Honor. I'm sorry. I didn't mean to
20 cut the witness off.

21 THE WITNESS: I just wanted to add that
22 from my viewing of what transpired then, having a

1 date certain and irrevocable voluntary
2 cancellation request was very important to know
3 that if we reached an unreasonable adverse effects
4 after reviewing the data, that we knew that this
5 could be withdrawn.

6 MS. GOERKE: Thank you. No further
7 questions.

8 JUDGE BIRO: Any re-cross?

9 MS. SZMUSZKOVICZ: No.

10 JUDGE BIRO: Ms. Lewis, I would just
11 like to ask a few questions of you. Do you have a
12 copy of the respondent, which is the agency's,
13 exhibits in front of you?

14 THE WITNESS: I do.

15 JUDGE BIRO: Would you turn to agency
16 exhibit number 3?

17 THE WITNESS: Okay.

18 JUDGE BIRO: These are I believe the
19 registrations of the pesticides at issue in this
20 case?

21 THE WITNESS: Yes.

22 JUDGE BIRO: The first one is the

1 registration for the technical formulation of
2 flubendiamide and if you look at page two of it,
3 the second paragraph, which is unnumbered, says to
4 release through shipment of these products
5 constitutes acceptance of conditions of
6 registration as outlined in a preliminary
7 acceptance letter for flubendiamide dated July 31,
8 2008. Is that correct?

9 THE WITNESS: Yes.

10 JUDGE BIRO: Okay. And that is the
11 preliminary acceptance letter, or PAL, that you've
12 been discussing in this matter?

13 THE WITNESS: Yes.

14 JUDGE BIRO: Okay. So if you look at
15 the next registration noted, on the second page of
16 that, would you agree with me it has the same
17 statements?

18 THE WITNESS: Yes.

19 JUDGE BIRO: Now, moving to the third,
20 and look at the second page. And it's a little
21 farther down on this second page, but this is the
22 registration for data and asking if you note a

1 matter of registration. And you'll see it says
2 release for shipment of these products constitutes
3 the acceptance of the conditions of registration
4 as outlined in the preliminary acceptance letter
5 for flubendiamide plus buprofezin, premixed
6 products, dated March 4, 2009. Where is that
7 preliminary acceptance letter?

8 THE WITNESS: That date of March 4, 2009
9 was in error. There was no unique acceptance
10 letter for this newer thing. It should have
11 referenced the July 31, 2008. It is my
12 understanding that there is no March 4, 2009
13 condition.

14 JUDGE BIRO: And is there any part on
15 this between when this was issued in 2009, in
16 March 2009 and the notice of cancellation?

17 THE WITNESS: Well, the agency prepared
18 something for the record a few days, last week on
19 this issue, but I'm not aware that it's anywhere
20 in the record.

21 JUDGE BIRO: Okay. So there is no
22 different preliminary acceptance letter for this

1 combination product?

2 THE WITNESS: No.

3 JUDGE BIRO: Would you look at the next
4 registration. This is for Nichino America and
5 Turismo, it's the name of the product. And
6 again, on the second page, it references a March
7 4, 2009 preliminary acceptance letter. Is that
8 correct?

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

12 JUDGE BIRO: And in terms of documents
13 that clarify that issue, is there anything?

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

17 JUDGE BIRO: I'm not interested in that.
18 It's being prepared for litigation. I'm
19 interested in any document between 2009 and before
20 this litigation began.

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

1 JUDGE BIRO: Is there anything from
2 Nichino or Bayer that confirms their understanding
3 that EPA had, that this was covered under the 2008
4 PAL?

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

6 JUDGE BIRO: Okay. Let me just ask you
7 a couple of other questions. You testified that
8 there was -- you were asked the question was
9 registration time limited, or is there an
10 expiration date. I understand that at some point,
11 FIFRA had a five year limitation written into the
12 statute for conditional registration. Is that
13 correct?

14 THE WITNESS: I don't recall that.

15 JUDGE BIRO: Okay. Maybe can you
16 explain to me what a difference is between a
17 conditional registration with a expiration date,
18 and a conditional registration that is time
19 limited.

20 THE WITNESS: My understanding is if we
21 had an expiration date on a registration and we
22 have done these in the past, but on rare

1 occasions, the registration expires regardless of
2 any action we do unless we renew it. So it would
3 be automatic. Sometimes we have products that are
4 registered for about two years that are pet
5 products right now, and they all expire in two
6 years. And based on the review of incident data,
7 and then we can renew it for another two. So my
8 understanding of an expiration date is that it's
9 automatic unless they agency chooses to renew. On
10 a time limited, the way this was written back in
11 '08, it changed a product from expiration to time
12 limited and a request for a voluntary
13 cancellation.

14 JUDGE BIRO: Okay. So --

15 THE WITNESS: Does that make sense?

16 JUDGE BIRO: So, so --

17 THE WITNESS: Expiration date means the
18 product would just be gone after whatever period
19 was set.

20 JUDGE BIRO: If EPA doesn't
21 affirmatively act.

22 THE WITNESS: Correct.

1 JUDGE BIRO: And it has no obligation to
2 take any action by virtue of the registration --

3 THE WITNESS: Correct.

4 JUDGE BIRO: It will expire. Okay. And
5 what happens in those cases to the existing stock?

6 THE WITNESS: We then have to make an
7 existing stocks determination.

8 JUDGE BIRO: And in time limited, it
9 means that EPA has an affirmative obligation to
10 act?

11 THE WITNESS: I believe it's all
12 dependent on how we write the registration notice.
13 We don't do that many time limited registrations.

14 JUDGE BIRO: Are there other
15 registrations that have this type of provision
16 written in it, as in this registration where it
17 provides for a week or some period of time after
18 notification of a finding of unreasonable adverse
19 effect for voluntary cancellation to be submitted?

20 THE WITNESS: This is the first one I've
21 come across.

22 JUDGE BIRO: So could the agency have

1 expanded this registration and kept that condition
2 going for voluntary cancellation indefinitely?

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

6 JUDGE BIRO: So as long as the agency
7 was continuing to determine whether or not the
8 pesticide had an unreasonable adverse effect on
9 the environment, in the, in an indefinite sense,
10 then it could continue the conditional
11 registration?

12 THE WITNESS: Yes.

13 JUDGE BIRO: You also used the term
14 measured dialogue. Is that a term of art within
15 the agency?

16 THE WITNESS: No, this was added in to
17 the pre- acceptance letter I believe. And I
18 believe the registrant requested that term. I'm
19 not 100 percent certain on that.

20 JUDGE BIRO: But that's not a term of
21 art that you --

22 THE WITNESS: That's not a term of art

1 that I'm aware of.

2 JUDGE BIRO: I understand that there
3 apparently was a, a meeting sometime in January
4 that lasted apparently all day between the agency
5 and the registrants about these pesticide
6 registrations. Is that correct?

7 THE WITNESS: It was a very lengthy
8 meeting. It was two parts. The morning was with
9 the scientists, and then the afternoon was a
10 smaller group, more on the -- what I would call
11 the regulatory path for it.

12 JUDGE BIRO: And were the scientists
13 both agency scientists and the registrants'
14 scientists?

15 THE WITNESS: Yes.

16 JUDGE BIRO: At some point, you said you
17 indicated to the registrants that this was an AA
18 level decision. AA stands for associate
19 administrator of the agency?

20 THE WITNESS: Yes. Assistant
21 administrator.

22 JUDGE BIRO: Okay. And that was Jim

1 Jones who you referred to?

2 THE WITNESS: Yes.

3 JUDGE BIRO: And how many levels between
4 you and him are there?

5 THE WITNESS: Just Jack Housenger.

6 JUDGE BIRO: And Jim Jones is the
7 assistant administrator for what office?

8 THE WITNESS: The OCSPP, the Office of
9 Chemical Safety and Pollution Prevention.

10 JUDGE BIRO: And what's his background?

11 THE WITNESS: Jim, I believe has a
12 master's in public policy. He's not a scientist.
13 And I believe an undergrad degree in economics,
14 so, that's my recollection.

15 JUDGE BIRO: How long has he been at the
16 agency or do you know?

17 THE WITNESS: Over 20 years.

18 JUDGE BIRO: In this position?

19 THE WITNESS: No, I believe he used to
20 actually have my job so he's only been the last
21 couple of years in -- in the political levels.
22 But he had been branch chief within registration,

1 then registration division director and then I
2 believe office director of OPP programs.

3 JUDGE BIRO: Do you know that the agency
4 received any other letters, other than the letter
5 that was sent from Food Safety regarding handling
6 flubendiamide?

7 THE WITNESS: I don't know specifically
8 if we have or haven't.

9 JUDGE BIRO: Okay. I have no further
10 questions. Ms. Goerke, do you have any questions
11 you would like to follow up with?

12 MS. GOERKE: I didn't know if you wanted
13 me to clarify for Ms. Lewis, for clarification of
14 the record where there is a tie-in of the
15 preliminary acceptance letter that would be
16 integrated into the registrations Vetica and
17 Tourismo registrations. There is documentation to
18 that effect that is in the record currently.
19 Would you like me to direct your attention to it?

20 JUDGE BIRO: Sure.

21 MS. GOERKE: That is, those -- the
22 letters that went from EPA to the registrants that

1 are petitioners' exhibits 11, 13, 14, 15 and 16,
2 each of those letters lists all the registrations
3 including Turismo and Vetica. And each of those
4 letters states that all of the original conditions
5 that apply that were identified in the preliminary
6 acceptance letter of July 31, 2008, were
7 applicable. So as Ms. Lewis indicated, it was her
8 understanding that that was a typographical error
9 and there was no further communication that is in
10 the record that discusses that except for those
11 letters, which directs their attention to that.

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

14 JUDGE BIRO: It was petitioner's
15 exhibits 11, and 13, and 16?

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

17 JUDGE BIRO: Okay, 13, 15 and 16?

18 MS. GOERKE: Yes.

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

21 MS. GOERKE: I'm sorry, it was 10. I'm
22 sorry it was 10. Sorry.

1 JUDGE BIRO: Okay. Exhibits 10, 12, 13
2 and 15 and 16?

3 MS. GOERKE: Yes.

4 JUDGE BIRO: Okay. Are there any
5 additional questions?

6 MS. SZMUSZKOVICZ: No, Your Honor, no
7 questions, thank you.

8 JUDGE BIRO: Thank you, Ms. Lewis, you
9 may step down. Would you like to call your next
10 witness?

11 MS. GOERKE: The respondent has no
12 further witnesses.

13 JUDGE BIRO: Oh, do you rest?

14 MS. GOERKE: Yes, Your Honor.

15 JUDGE BIRO: Would you like to take a
16 break? What would you like to do?

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

20 JUDGE BIRO: Sure.

21 (Discussion off the record)

22 MS. SZMUSZKOVICZ: I would like to call

1 the Registrants' first witness, Ms. Charlotte
2 Sanson.

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

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

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

14 MS. SZMUSZKOVICZ: Yes. Thank you.

15 JUDGE BIRO: Are there any objections?

16 MS. GOERKE: No.

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

1 record?

2 MS. SZMUSZKOVICZ: Yes.

3 JUDGE BIRO: Are there any objection?

4 MS. GOERKE: No.

5 JUDGE BIRO: PBNX 127 is admitted into
6 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: Yes, we'll put that
11 on the record.

12 JUDGE BIRO: Any objection?

13 MS. GOERKE: No, Your Honor.

14 JUDGE BIRO: Okay. PBX 128 into the
15 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 registrants' exhibits, the petitioners'
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 this is a true and correct copy of the
17 statement you prepared?

18 A Yes.

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

1 JUDGE BIRO: Any objection?

2 MS. GOERKE: No.

3 JUDGE BIRO: Okay. PBNX, will be given
4 116, as well as 7 through 21, 26, 33, 49 and 52,
5 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 Division, as well
15 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 ° 3(c)(7). Is that something that you would
16 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 200012
10 the conditions that are listed here. Look at 8,
11 beginning at 8(b), the EPA will complete its
12 review. To your knowledge has the EPA completed
13 all of its review of all the data submitted by
14 Bayer?

15 A EPA did review everything that was
16 submitted.

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

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

1 submitted to EPA.

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

6 A The water monitoring studies that are
7 being conducted presently?

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

12 A That's correct.

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

15 A Mm-hmm.

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

21 A Okay, so the question is?

22 Q The question is, is that similarly

1 listed in the PAL as a condition of registration?

2 A Yes.

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

5 A Yes.

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

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

10 Q Yes.

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

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

17 A No.

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

22 A "EPA scientists and Bayer scientists, as

1 agents for Nichino, shall engage in dialogue about
2 the data and the Agency's conclusions."

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

7 A Well, this is predicated by the emails
8 that were discussions that happened before this
9 letter was issued. That statement was based on
10 the fact that there would be discussion between
11 the Bayer scientists and EPA scientists and I
12 think in reference to measured dialogue that Ms.
13 Lewis discussed in her testimony, and that's
14 what's meant by this statement here.

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

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

1 the theoretical model that's discussed here.

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

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

6 Q Made here.

7 A -- a disagreement on the conclusions.

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

12 A Well, it's not a typical yes or no
13 answer, given this particular case. I think it
14 warrants more discussion.

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

17 A It's not there.

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

22 A Generally.

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

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

10 Q Sure, please do. Yes, starting on page
11 220; take your time.

12 A Exhibit 4?

13 Q Yes.

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

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

21 A I think what was requested was to have a
22 scientific exchange, a discussion on the results

1 of the data that Bayer had a few years to
2 generate, and supported the conditional decision.

3 Q And in your written testimony, you
4 stated that EPA insisted on the term of
5 registration. Do you think it's accurate to say
6 that EPA would not have issued the registration
7 without that provision?

8 A It appears that way based on the emails.

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

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

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

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

21 Q Previous to your interactions with the
22 agency in 2016, had you ever indicated to any of

1 the staff or the managers that you envisioned that
2 this condition was unlawful?

3 A I don't know.

4 Q Is it fair to say that EPA would have
5 had no reason to know that Bayer would not comply
6 with this condition until Bayer became aware that
7 a condition might be triggered?

8 A Can you repeat that?

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

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

17 JUDGE BIRO: Sustained.

18 BY MS. GOERKE:

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

1 a term as a voluntary cancellation?

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

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

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

20 Q Let's go back to the PAL, which is
21 Exhibit number 2, briefly. And on the last page,
22 which is Bates 200013, there's a paragraph that

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

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

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

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

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

22 A It would be a non-registration.

1 Q But is it safe to say that you couldn't
2 just take some of the conditions out of your
3 registration, it would be the entire registration?

4 A It was all or nothing. EPA ha gone as
5 far as it would and you take the conditions into
6 your registration.

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

12 A Well, 42 --

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

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

20 JUDGE BIRO: To your --

21 MS. GOERKE: -- the existing stocks.

22 JUDGE BIRO: What again?

1 MS. GOERKE: The question was, is it
2 permissible to allow registrants to continue to
3 produce products and sell those products when it
4 is not in compliance with the registration's
5 conditions?

6 JUDGE BIRO: Sustained.

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

9 JUDGE BIRO: What conditions are you
10 verifying? I just sustained your objection.

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

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

15 JUDGE BIRO: Proceed.

16 REDIRECT EXAMINATION

17 BY MS. SZMUSZKOVICZ:

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

1 answers. Under (b), is it your understanding that
2 EPA was to consider all of the data and supporting
3 information whether required or voluntarily
4 submitted by the registrants?

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

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

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

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

19 A They were required.

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

1 gave you a complete list.

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

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

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

18 MS. SZMUSZKOVICZ: Yes.

19 JUDGE BIRO: Okay.

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

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

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

12 MS. SZMUSZKOVICZ: All right.

13 JUDGE BIRO: Do you feel any 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 JUDGE BIRO: Okay, so what exhibits are
2 those?

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

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

7 MS. GOERKE: No.

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

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

14 JUDGE BIRO: Would you look into --

15 MS. SZMUSZKOVICZ: Yes.

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

18 MS. GOERKE: No, Your Honor.

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

22 THE WITNESS: Margaret Cherny.

1 JUDGE BIRO: -- Cherny, who signed the
2 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 JUDGE BIRO: Is that your current
7 position or --

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

10 JUDGE BIRO: Okay. And would you agree
11 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 unknowns, 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 benthic aquatic
3 organisms. I think they -- when they fully
4 evaluated the data and as you probably saw in the
5 documents, there was a very favorable profile
6 known in the environment, and it was a small area
7 of 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 if 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 JUDGE BIRO: So did Bayer agree that
21 there was an uncertainty as to that issue, or is
22 your impression that, at that time, Bayer thought

1 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 if the
9 science had 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 registration.

14 JUDGE BIRO: So in 2008, both Bayer and
15 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 JUDGE BIRO: And the first thing they
21 had to do, as you mentioned, is a vegetative
22 buffer study. Is that correct?

1 THE WITNESS: Yes.

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

4 THE WITNESS: Yes.

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

7 THE WITNESS: Yes.

8 JUDGE 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 JUDGE BIRO: Okay.

16 THE WITNESS: I understand the buffer
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 JUDGE BIRO: But, in any event, it did
22 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 JUDGE BIRO: Exactly. Okay, so then the
7 water monitoring studies began, and that was about
8 2010? Is that correct?

9 THE WITNESS: I think so.

10 JUDGE 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 for stewardship.

22 JUDGE BIRO: Okay, but initially, at

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

9 THE WITNESS: Yes.

10 JUDGE BIRO: And is it a same ongoing
11 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 JUDGE BIRO: And is it being conducted
16 in the same way or has it changed how you're
17 conducting?

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

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

1 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 as the modeling -- the theoretical computer
9 modeling -- that EPA scientists have done, that
10 shows that they're not looking at real world data,
11 which is, when a company generates real world
12 data, it expects it 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 below levels of concern, based on
19 actual use of the product.

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

22 THE WITNESS: Yes.

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

4 THE WITNESS: They have, yes.

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

7 THE WITNESS: Yes.

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

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

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

17 THE WITNESS: Yes. But I could also add
18 that there was a second provision in there where
19 there were three options in the letter,
20 unconditional registration, continued registration
21 with continued conditions, or a cancellation, and
22 last year, we thought we were working at number 2,

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

17 JUDGE BIRO: Okay, so you thought at
18 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 JUDGE BIRO: Okay. But EPA made its own
2 judgment based on the scientists that this should
3 be cancelled. Is that correct?

4 THE WITNESS: I would say it was not
5 scientific, but more of a political decision.

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

8 MS. SZMUSZKOVICZ: No.

9 MS. GOERKE: No.

10 JUDGE BIRO: Okay, thank you very much.

11 THE WITNESS: Thank you.

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

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

22 JUDGE BIRO: Okay. All right. So where

1 are we?

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

6 JUDGE BIRO: Excluded.

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

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

13 MS. SZMUSZKOVICZ: Thanks, Your Honor.

14 JUDGE BIRO: Would you like to break for
15 lunch or would you like to proceed?

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

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

20 MS. SZMUSZKOVICZ: Yes.

21 JUDGE BIRO: Okay. Well, we stand to
22 recess till 12:30. Thank you.

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MR. WRIGHT: All rise.

(Whereupon, at 11:32 a.m., a
luncheon recess was taken.)

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, on behalf of Bayer CropScience and
6 Nichino 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 JUDGE BIRO: Is there any objection?

22 MS. GOERKE: No.

1 JUDGE BIRO: Petitioners' Exhibit 117 is
2 admitted into the record without objection.

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

5 JUDGE BIRO: Please proceed.

6 MS. GOERKE: Thank you, Your Honor.

7 CROSS-EXAMINATION

8 BY MS. GOERKE:

9 Q Good afternoon, Mr. Hall.

10 A Good afternoon.

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

16 A Yes. And it's standard procedure, as
17 I've experienced with products, and they have been
18 allowed to clear the channel within 18 to 24
19 months.

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

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

4 Q So, is it correct, that you were seeking
5 the same existing stocks treatment, when you did
6 not comply with the condition as a company that
7 would have submitted a voluntary cancellation
8 request?

9 A Could you repeat the question?

10 Q Sure. So you are seeking here, the same
11 existing stocks 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 JUDGE 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 JUDGE BIRO: Asked and answered. Move
16 on.

17 BY MS. GOERKE:

18 Q And as a practical matter, would it be
19 your position 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 sell
4 those 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 JUDGE BIRO: Any redirect?

11 MR. BARKER: No, Your Honor.

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

14 THE WITNESS: Okay.

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

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

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

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

1 JUDGE BIRO: Two hundred and fifty?

2 THE WITNESS: That would be a good
3 guess, Your Honor.

4 JUDGE BIRO: And one of those that you,
5 I believe, voluntarily cancelled, was for one of
6 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 JUDGE BIRO: Synapse, right.

11 THE WITNESS: Yes.

12 JUDGE BIRO: That's right. When you
13 voluntarily cancelled that, what were the terms
14 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 that made the products not reliable in terms of
20 presenting a quality product to end users. So we
21 phased that product out, and after the product had
22 cleared the channel of trade then we submitted for

1 a voluntary cancellation to remove that product
2 from the market.

3 JUDGE BIRO: Have you had other products
4 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 JUDGE BIRO: So when you are talking
9 about your standard experience, is that with just
10 pesticide registrations where you voluntarily
11 cancel?

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

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

21 MR. BARKER: No, Your Honor.

22 JUDGE BIRO: Okay. Ms. Goerke?

1 MS. GOERKE: No, Your Honor.

2 JUDGE BIRO: Thank you so much, Mr.

3 Hall.

4 THE WITNESS: Okay.

5 JUDGE BIRO: Hello, Mr. Eisenberg?

6 MR. EISENBERG: Hello. Good afternoon.

7 I would like to call Jeffrey Johnson.

8 Whereupon,

9 JEFFREY JOHNSON

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

12 DIRECT EXAMINATION

13 BY MR. EISENBERG:

14 Q Good afternoon, Mr. Johnson.

15 A Good afternoon.

16 Q Please state you full name and title for
17 the record.

18 A Jeffrey R. Johnson, President of Nichino
19 America.

20 Q And for the record, this is the fourth
21 binder, PBNX 118?

22 A Yes.

1 Q Do you recognize this document?

2 A Yes.

3 Q And what is this?

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

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

10 A No.

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

13 A I believe so.

14 MR. EISENBERG: Your Honor, the
15 petitioners offer PBNX 118 into evidence.

16 JUDGE BIRO: Is there any objection?

17 MS. GOERKE: No, Your Honor.

18 JUDGE BIRO: Okay. PBNX 118 is admitted
19 into the record without objection.

20 MR. EISENBERG: We have no further
21 questions at this time.

22 JUDGE BIRO: Okay. Ms. Goerke?

1 MS. GOERKE: My co-counsel will ask the
2 questions this time.

3 JUDGE BIRO: Of course.

4 MR. PERLIS: Thank you, Your Honor.

5 CROSS-EXAMINATION

6 BY MR. PERLIS:

7 Q Mr. Johnson?

8 A Yes.

9 Q As president of Nichino, what is your
10 involvement in the initial registration of
11 Nichino's products?

12 A All products?

13 Q The pesticide products.

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

1 our management team to move it through. So, I'm
2 not intimately involved with all the details on
3 the regulatory side.

4 Q How often do you meet with EPA
5 regulatory official on pesticide matters?

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

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

13 A Yes.

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

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

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

9 Q Did you have any involvement in 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 determination,
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 a
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 in 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 people were --
8 yes.

9 Q Now I take it you know Charlotte Sanson.

10 A Only through these goings on.

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

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

18 JUDGE BIRO: Sustained.

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

21 JUDGE BIRO: Yes.

22 MR. EISENBERG: Yes.

1 MR. PERLIS: Fair enough. Let me
2 rephrase it.

3 BY MR. PERLIS:

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

7 A Yes.

8 Q And did Nichino feel the same way?

9 A Yes.

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

14 A Yes.

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

18 A Yes.

19 Q Okay. And are familiar with Jack
20 Housenger's letter of January 29th, 2016 in which
21 he asked both Bayer and Nichino to cancel the
22 registrations?

1 A Yes. Not every word, but --

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

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

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

11 MR. EISENBERG: I believe he just did.

12 BY MR. PERLIS:

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

20 A I don't believe we did.

21 Q So, to summarize, Nichino's registration
22 was the commitment, you accept that Nichino would

1 not have gotten a registration but for that
2 commitment, and then Nichino failed to live up to
3 the commitment --

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

9 THE WITNESS: Yes.

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

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

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

17 BY MR. PERLIS:

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

22 A I'm aware of the letter.

1 Q Okay. Could I ask you to open -- you
2 should have copies of the respondent's exhibits.

3 A Which?

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

6 A Okay. This one here.

7 Q Could you turn that to Exhibit 7.

8 A Okay.

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

11 A Pages 2 and 3?

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

16 A Okay.

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

22 A Yes.

1 Q Does it say anywhere in there, that the
2 registrants are taking the position that they did
3 not have an opportunity to discuss the science
4 with EPA? Did you notice that at all in your
5 reading?

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

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

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

1 Q All right. Thank you. Now can you tell
2 me why Nichino decided not to keep its commitment
3 to cancel the registrations, when asked to do so
4 by Mr. Housenger?

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

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

1 scientific determination in order to trigger the
2 voluntary cancellation request?

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

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

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

19 JUDGE BIRO: Sustained.

20 BY MR. PERLIS:

21 Q Very well. I believe I've asked you
22 this before, and I'm just trying to make sure that

1 we're on the same page before I move on to another
2 series of questions. You are aware of the EPA, I
3 take it you are aware that the EPA has frequent
4 interactions with pesticide applicants, during the
5 application process?

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

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

10 A Yes.

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

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

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

20 JUDGE BIRO: Overruled. Go ahead.

21 THE WITNESS: Yes.

22 MR. EISENBERG: Could you at least --

1 can you repeat the question then? Thank you.

2 BY MR. PERLIS:

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

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

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

13 BY MR. PERLIS:

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

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

20 Q Yes. If the EPA cannot rely on the
21 integrity of the pesticide registrants and
22 applicants would that have a negative effect on

1 the licensing program? Let me break that a little
2 more. If we could not rely on the integrity of
3 pesticide registrants and applicants might it
4 negatively affect the ability of Nichino to get
5 the registration?

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

8 Q So the answer to that question is, yes,
9 it would have a negative effect on the licensing
10 program?

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

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

17 JUDGE BIRO: Overruled. Go ahead.

18 BY MR. PERLIS:

19 Q So, your short answer is, yes, you agree
20 that if you cannot rely on the integrity of your
21 registrants and applicants that could have a
22 negative effect on the licensing program? I Am

1 sorry, could you -û I know you're nodding your
2 head but can you use words please?

3 A Yes.

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

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

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

22 A Yes.

1 Q Now, if the condition were not legal
2 that wouldn't have affected your ability to comply
3 with the condition, would it?

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

6 JUDGE BIRO: The question was not legal?

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

9 JUDGE 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 JUDGE 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 JUDGE BIRO: He is not a lawyer, do you
3 want to --

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

6 JUDGE 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 that it was not the appropriate thing to
14 do at the time.

15 JUDGE 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 needed to rely on the commitment
21 that 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 JUDGE BIRO: Sustained.

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

8 JUDGE 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 should operate in a
15 fair 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 We asked for the voluntary cancellation request by
16 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 of 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 permitted any stocks to be used, all the way
3 to stop sales and returns. So, I'm not sure --

4 Q I'm sorry?

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

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

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

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

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

8 A Yes.

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

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

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

1 requested voluntary cancellation when asked to do
2 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 narrow
13 in scope, and we have given Counsel a lot of
14 leeway, and not objecting, but we're far beyond
15 the scope of the witness' testimony.

16 JUDGE BIRO: He is an expert witness.
17 Isn't he?

18 MR. EISENBERG: No. He is not.

19 JUDGE 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 JUDGE 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 for shipment and then sell more product than you
14 likely would have been able to produce and release
15 had 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 JUDGE BIRO: Overruled, and I think it's
2 been asked and answered.

3 MR. PERLIS: Fair enough. Just two more
4 questions.

5 JUDGE 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 or 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 very narrow direct testimony. I
2 don't think he should be asked about his
3 imagination.

4 JUDGE BIRO: Sustained.

5 BY MR. PERLIS:

6 Q So just so we're clear, it's your
7 testimony that EPA, in establishing this existing
8 stocks provision, should ignore the fact that you
9 accepted a condition as part of getting the
10 registration and then failing to comply with the
11 commitment. Is that correct?

12 A No, I don't agree with that.

13 Q Do you think EPA should take into
14 account in its existing stocks provision that,
15 from then on, the failure of Nichino and Bayer in
16 its presumption to request cancellation and ask to
17 do so? So, essentially, asking EPA to ignore that
18 fact when establishing new existing stocks
19 provisions?

20 A I think that while we're going through
21 this hearing process that we should be allowed to
22 sell -- continue to manufacture and sell product.

1 Q Well, during this hearing process you
2 are allowed to sell product, that's a result of
3 requesting a hearing, but you're also asking for
4 an existing stocks provision that would be the
5 same whether you requested voluntary cancellation
6 or not. Isn't that correct? Isn't that what
7 you're asking for in your testimony?

8 A I'm not sure what kind of a stocks
9 provision occurs with a voluntary cancellation.

10 Q But you are asking that everything that
11 Bayer and Nichino has produced prior to the date
12 of cancellation, which would be for existing
13 stocks, you are asking that all of those existing
14 stocks, liquidities of existing stocks that were
15 produced during this hearing, should be allowed to
16 be sold under EPA's existing stocks provision,
17 isn't that correct?

18 MR. EISENBERG: Objection, because it
19 mischaracterizes the direct testimony which states
20 that production has already stopped, and this has
21 come up maybe five times in the questions. It's
22 part of the basis for objection.

1 MR. PERLIS: Excuse me, but the
2 testimony said the registrants believe -- one of
3 the registrants testified that they were
4 continuing to produce.

5 MR. EISENBERG: This is Nichino's
6 president, and he testified their production
7 stopped, so if you're asking about Bayer's
8 production, then you'd have to ask the Bayer
9 witness, I believe.

10 MR. PERLIS: He also testified that he
11 believes the registrants believed it.

12 JUDGE BIRO: Okay, we're not going to
13 argue back and forth between you, because I am the
14 only one you're supposed to be talking to. The
15 question is whether he feels he should be allowed
16 to continue to sell stocks until a final
17 determination on cancellation is made.

18 MR. PERLIS: No, excuse me. I don't
19 believe that's the question because they could
20 clearly continue to sell products registered. The
21 question was whether he believes it appropriate
22 for the -- I'm sorry, he believes it inappropriate

1 for the agency to take into account the failure to
2 comply with the commitment in establishing an
3 existing stocks provision which will kick in at
4 the end of this proceeding.

5 JUDGE BIRO: Do you understand that
6 question?

7 THE WITNESS: I think I do, and I think
8 it's inappropriate, because I think it is more of
9 a punitive action for, again, complying in what
10 we're doing is legal, and that our view of the
11 conditions of this registration obviously differs,
12 that's why we're here, and that if we go through
13 and then resolve our differences one way or the
14 other, then there shouldn't be any kind of a
15 punitive action after the conclusions.

16 MR. PERLIS: Your Honor, I have no
17 further questions for this witness.

18 JUDGE BIRO: Okay. Mr. Eisenberg, do
19 you have any redirect?

20 MR. EISENBERG: Yes.

21 REDIRECT EXAMINATION

22 BY MR. EISENBERG:

1 Q Mr. Johnson, just to call on this last
2 point on existing stocks, were you to sell your
3 existing stocks, who would you sell them to?

4 A My distributors.

5 Q And who would the distributors sell them
6 to?

7 A To the growers.

8 Q So if you're not permitted to exhaust
9 your existing stocks the product would perish?

10 A Our products in particular in a few
11 areas are highly valued, and if that couldn't
12 happen, if it stopped, then we would have to take
13 everything back and we would have to do hazardoud
14 waste disposal, which doesn't help anyone, I don't
15 believe.

16 Q Is Nichino manufacturing flubendiamide
17 at this time?

18 A No.

19 Q When did Nichino stop manufacturing
20 flubendiamide?

21 A The last formulation, it was September
22 28th, and I became aware of the more difficult

1 discussions with EPA on the time limit extension
2 for conditional registration. We originally had a
3 production scheduled in August, but we delayed to
4 try to see what was happening with the conditional
5 registration and the hopeful extension of that
6 registration, and as we got into September, at the
7 end of August, into September, there were a lot of
8 very positive developments, emails back and forth
9 with EPA discussing the 3-year extension, talking
10 about the different studies that were being agreed
11 to get that 3-year extension, and at that point,
12 we felt that it looked like the registration would
13 continue, and so we made the decision to make some
14 product in September. We were out at that point.

15 Q If EPA's existing stocks proposal is
16 adopted as currently proposed, where else if
17 anywhere would you sell off Nichino's existing
18 stocks?

19 A Unfortunately, because our products are
20 a formulation of flubendiamide and buprofezin,
21 there's -- that combination does not have a
22 registration anywhere else in the world, so it's

1 not like we could ship it somewhere else, so it's
2 one of the reasons we're being very conservative
3 with our formulation or production to make sure
4 that we're not creating some economic problem for
5 ourselves if any of this does get cancelled
6 potentially in the future.

7 Q I'd like you to turn back to what's in
8 the respondent's binder, Exhibit 7. And to the
9 second page, please. Counsel, I believe, was
10 asking you on cross about how Dana Sargent's
11 letter described registrants' concerns with EPA's
12 decision, and of course, that questioning asked
13 you if you thought there had been scientific
14 discussions. If you turn to the last paragraph on
15 page 2, where the sentence in the middle starting
16 with "Yet EPA," could you read that to the Court?

17 A This? "Yet EPA, it is now --

18 MR. PERLIS: I'm going to object here.
19 I believe what I asked him was whether there was
20 any discussion that EPA had not had discussions
21 with them, and frankly, I don't think these
22 questions cover that.

1 MR. EISENBERG: The question, and we can
2 go back to the record, I believe the questions
3 were, were there scientific discussions with EPA
4 --

5 JUDGE BIRO: Sustained. I mean,
6 overruled. Go ahead, ask your question.

7 BY MR. EISENBERG:

8 Q So could you please read that into the
9 record?

10 A "Yet EPA is now ignoring that study in
11 favor of a less appropriate study with a different
12 endpoint. Notably, after seven years of
13 flubendiamide use and monitoring, not one of the
14 water monitoring samples that EPA required and
15 that was collected has met or exceeded even this
16 lower endpoint."

17 Q And directing you on to page 3, the
18 paragraph starting "Moreover," would you read that
19 first sentence?

20 A "Moreover, although the unreasonable
21 adverse effects registration standard requires
22 consideration of benefits as well as risks, EPA

1 downplays or ignores the significant benefits
2 flubendiamide provides compared to alternatives,
3 including its excellent safety profile and its
4 targeted control."

5 Q Is that word "ignored" in those places,
6 is that a word you associate with scientific
7 discussion?

8 A No, not necessarily. We're being
9 ignored. You said "ignored," right?

10 Q Yes.

11 A Yeah.

12 Q I just want to point you to the last
13 sentence in the letter. Could you read that into
14 the record again for me?

15 A "We remain available to address the
16 science in a transparent and methodical way,
17 consistent with the FIFRA registration standard
18 and process. If this is done as Congress
19 envisioned, the products should remain
20 registered."

21 MR. EISENBERG: We have no further
22 questions.

1 JUDGE BIRO: Thank you, Mr. Eisenberg.
2 Mr. Perlis?

3 MR. PERLIS: Nothing.

4 JUDGE BIRO: Mr. Johnson, I just have a
5 few questions. Maybe you can clarify some things
6 for me. You indicated that -- I think it's
7 Nichino or some company they're affiliated with
8 created flubendiamide. Is that correct?

9 THE WITNESS: That's correct. They're
10 our parent company, Nihon Nohyaku, from Tokyo,
11 Japan, are the original discoverers of
12 flubendiamide.

13 JUDGE BIRO: Okay. And you said that
14 they spent \$65 million to bring that product to
15 market. Is that correct?

16 THE WITNESS: That's just for the U.S.
17 Probably, on a global basis, it's closer to \$200
18 million.

19 JUDGE BIRO: What goes into that cost
20 that you're talking about, bringing it to market
21 in the U.S.?

22 THE WITNESS: Well, there's the original

1 discovery cost in terms of screening compounds and
2 finding activity and finding safety, and then
3 moving them through efficacy trials and doing all
4 the toxicological trials, environmental -- again,
5 I'm not a scientist, I speak from my experience in
6 managing over top of that area, so there's a
7 considerable amount of work that's done, a lot of
8 man-hours as well that goes into those costs. I
9 think there was recently a survey by Phillips
10 McDougall that shows from discovery to market now
11 it takes roughly 10 years and \$286 million to
12 bring a compound to our marketplace. So when we
13 talk about having choices to get a registration or
14 not get a registration, after spending all that
15 time and money, it's difficult to turn down the
16 conditional registration offers, and, as I said,
17 all of our registrations have been conditional, so
18 there's always unanswered questions, and there has
19 been in the past a very good faith dialogue
20 between our company and EPA to resolve those
21 conditions for all registrations, and this is our
22 first experience with really kind of getting to a

1 point where we kind of hit a brick wall.

2 JUDGE BIRO: When EPA offers you a
3 conditional registration, it's not really a take
4 it or leave it approach, is it? You can turn it
5 down and then file suit, isn't that correct?

6 THE WITNESS: That may be technically
7 correct. I'm not totally aware of all that, how
8 all those laws work. I'd say practically, given
9 the time, the money that you're, as a business
10 person, you're in a situation where you take what
11 you can get and try to address all the questions
12 that are being asked in good faith, again, and
13 that's really been a fairly normal process for our
14 industry.

15 JUDGE BIRO: Besides Bayer, have you
16 licensed flubendiamide to anybody else?

17 THE WITNESS: No.

18 JUDGE BIRO: So they're the only other
19 company selling the product or selling some
20 combination of the product?

21 THE WITNESS: In the U.S.

22 JUDGE BIRO: How about elsewhere?

1 THE WITNESS: Elsewhere, it's mainly
2 Bayer and there's a couple other smaller companies
3 I'm not quite aware of the names in some other
4 countries, some smaller countries, but it's
5 primarily Bayer and Nihon Nohyaku that market the
6 products.

7 JUDGE BIRO: And give me a ballpark
8 number how much has your company made each year
9 from licensing or selling your product with
10 flubendiamide?

11 MR. EISENBERG: Your Honor, just
12 respectfully, I want -- this may touch on some CBI
13 here.

14 JUDGE BIRO: That's why I'm asking for a
15 general ballpark figure. Is that CBI? Do you
16 consider that confidential business information?

17 MS. SZMUSZKOVICZ: One moment.

18 JUDGE BIRO: Okay.

19 (Discussion off the record)

20 MR. EISENBERG: This is not publicly
21 available information in the general course.

22 JUDGE BIRO: I was just interested in

1 knowing. Since you're telling me the cost of
2 making it, I'd like to know the cost of the return
3 on the investment, but it's okay. I'll accept him
4 withholding the information. Where do you
5 manufacture flubendiamide?

6 THE WITNESS: Flubendiamide is
7 manufactured in Japan; we import the active
8 ingredient.

9 JUDGE BIRO: And your product that you
10 sell?

11 THE WITNESS: We import the active
12 ingredient here and have it formulated --

13 JUDGE BIRO: Here in the United States.

14 THE WITNESS: Yes.

15 JUDGE BIRO: You import it from 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 third-party
19 contract formulator.

20 JUDGE BIRO: You indicated that your
21 unique product that's a mixture of ingredients is
22 only registered here in the United States. Is

1 there anything that would stop you from applying
2 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 JUDGE 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 JUDGE BIRO: You talked a lot about why
14 you didn't feel that voluntary cancellation clause
15 was triggered, and I just want to go over that
16 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 JUDGE BIRO: Well, an aspect that was
3 not -- you would agree that EPA notified you that
4 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 JUDGE BIRO: Yes.

10 THE WITNESS: In their letter, yes, they
11 did.

12 JUDGE BIRO: Okay. And they did have
13 meetings with Bayer scientists. EPA scientists
14 did have meetings with Bayer scientists discussing
15 the science regarding whether it created an undue
16 -- unreasonable adverse effect on the environment.
17 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 JUDGE BIRO: Right, so that's the real
15 nub of the issue. EPA went on its modeling, you
16 went on what you consider real world data, which
17 is actual data with points taken from the ponds
18 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 JUDGE BIRO: Is that not correct?

1 THE WITNESS: That could be a little
2 oversimplification.

3 JUDGE 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 JUDGE BIRO: Oh, so that's a different
9 issue from either relying on modeling or real
10 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 the end use label which
15 would actually fit into EPA's models, and we even
16 got down to a very, very truncated label that we
17 believed would pass the model, and then they
18 changed the model.

19 JUDGE 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 JUDGE BIRO: Everybody keeps using this
3 term "political issue." What do you mean by that?

4 THE WITNESS: Well, I think that when I
5 came into the meeting on December 15th at the EPA,
6 and the assistant administrator came in and sat
7 down and said he personally didn't believe that
8 this compound should have ever been registered,
9 that that was not a good sign in terms of any
10 further discussion. And he never really
11 elucidated why other than he believed it was
12 persistent, and I don't believe that it's
13 necessarily been totally concluded that it's
14 persistent, and if it were concluded that it were
15 persistent, is it toxic, does it have risk versus
16 all benefits. So it's a tremendous compound, all
17 categories, they're focusing on a very narrow area
18 of concern, and we were addressing those concerns
19 as best we can. And so the science is developing
20 and looking at the water monitoring, so from our
21 standpoint, and particularly in Bayer's case,
22 who's been really doing all this work, we're

1 working in good faith to provide those answers
2 around this concern that, as we are here now,
3 don't believe it's an imminent situation, there's
4 not imminent harm occurring, that we have time to
5 clarify what happens with this compound, and if we
6 find, as was stated earlier, that it looks like
7 there is an issue, then I think the registrants
8 would then move with the voluntary cancellation.
9 But that's why we don't believe we're at that
10 point, and we have a great tool for growers. It's
11 environmentally very good, human tox, avian,
12 aquatic tox, except for this one benthic organism
13 -- not that they're not important -- but that is
14 still a big question as far as how toxic it can
15 be, and it doesn't appear that it's building up
16 based on water monitoring and the USGS monitoring,
17 so we feel if we get a fair, clear opportunity in
18 a unbiased situation to provide that scientific
19 dialogue, that it would not be viewed as this
20 unreasonable risk. And so that's why we're here.

21 JUDGE BIRO: Okay. I don't want to cut
22 you off, but I would like to get back to my

1 question, which what makes you think it's a
2 political determination? What do you mean by
3 that?

4 THE WITNESS: Well, it just seemed that
5 there was a lot of good faith back and forth
6 dialogue, as we've experienced with our
7 registrations, conditional registrations, in the
8 past, and then suddenly in October, the
9 communications seemed to stop, and almost like a
10 light switch, and then --

11 JUDGE BIRO: So by political, you mean
12 that the agency decided to go in a different
13 direction in terms of its scientific
14 determination?

15 THE WITNESS: I'm not sure if it was
16 scientific or it was more try to make an example
17 out of the compound, try to use it as a way to
18 make policy, because it seemed that no matter what
19 we tried to do to address the scientific concerns,
20 they would move the goalpost. So the impression
21 is from -- my personal impression is that there
22 was someone that reached a conclusion inside the

1 agency and that everything was being backed into
2 that, as much as we tried to address it.

3 JUDGE BIRO: And the conclusion was to
4 terminate this pesticide, no matter what? What is
5 the end goal of the political consideration you
6 think is in play here?

7 THE WITNESS: Possibly to deem this as a
8 persistent pesticide and have to take it off the
9 market.

10 JUDGE BIRO: To what end?

11 THE WITNESS: To help drive a potential
12 new persistence policy within EPA. And in the
13 December 15th meeting, the assistant administrator
14 also talked about heavily halogenated compounds,
15 was very concerned about those, and that
16 persistence in and of itself should be a reason to
17 not allow the product on the market, regardless of
18 whether there's risk or not. And that's very much
19 against the risk approach that EPA takes.

20 JUDGE BIRO: Okay.

21 THE WITNESS: Or has taken.

22 JUDGE BIRO: Thank you, Mr. Johnson.

1 Mr. Eisenberg, do you have any follow-up
2 questions?

3 MR. EISENBERG: May we have a moment?

4 JUDGE BIRO: Of course.

5 (Recess)

6 MR. EISENBERG: We'd like to try and
7 address the question posed that we thought touched
8 on CBI in a way that protects the company's
9 interest so we'll try and phrase it more
10 generally.

11 JUDGE BIRO: Okay.

12 BY MR. EISENBERG:

13 Q Mr. Johnson, you were asked earlier by
14 the Judge whether the company - what the profits
15 were for flubendiamide for your company. I want
16 to ask that a different way. If you still have a
17 concern let us know, but please try to answer in
18 general terms. Looking at the \$65 million that
19 you said - or larger \$200+ figure, would you say
20 the company has recovered its costs through sales
21 of flubendiamide?

22 A That's a difficult question to answer,

1 the reason being the way this business was
2 established is that the revenues don't all run
3 through Nichino America. So Bayer's business is
4 separate from our business, and our business if it
5 were based just on Nichino America business, no.
6 It would not have paid us back by yet. I'm not
7 sure about the Bayer business and its separate
8 licensing arrangements with the parent company and
9 so all I would do is guesstimate.

10 Q Thank you.

11 MR. EISENBERG: We have no further
12 questions.

13 JUDGE BIRO: Mr. Perlis?

14 MR. PERLIS: Just one.

15 RECROSS EXAMINATION

16 BY MR. PERLIS:

17 Q Has anyone at EPA ever suggested to you
18 that the cancellation here is being based on
19 persistence without regard to any toxicity issues?

20 A No.

21 Q Thank you.

22 MR. PERLIS: I have nothing further,

1 Your Honor.

2 JUDGE BIRO: Thank you, Mr. Johnson, you
3 may step down.

4 Okay. Who's standing up next?

5 MS. SZMUSZKOVICZ: We have no further
6 witnesses and there are no further exhibits. So
7 we would rest.

8 JUDGE BIRO: Let's go over the exhibits
9 we have now before we close so we're all on the
10 same page. For the Agency, the Respondent, I have
11 exhibits No. 1-10.

12 MS. GOERKE: That is correct, Your
13 Honor.

14 JUDGE BIRO: For the petitioner, Bayer,
15 I have Exhibits 7-21, 26, 33, 52, 116-118, 123,
16 127, 128, and then 22-25, 27 through 32, and 34
17 through 36. I'm sorry, they weren't in sequential
18 order, but -- are we all in agreement?

19 MS. SZMUSZKOVICZ: Yes, that's right,
20 and we'll double check.

21 JUDGE BIRO: Okay.

22 MS. GOERKE: I believe that's correct as

1 well.

2 JUDGE BIRO: Okay, and then you can
3 submit a statement of any other documents and
4 testimony you want to submit as part of your offer
5 of proof with your post-hearing brief. I'd be
6 happy to let you do closing statements if you
7 wish, but you certainly don't need to, because I'm
8 going to give you an opportunity to file
9 post-hearing briefs.

10 MS. GOERKE: No.

11 MS. SZMUSZKOVICZ: No.

12 JUDGE BIRO: We're going to wait? Okay,
13 great. So we're anticipating actually not getting
14 a transcript tonight, but we should have a final
15 transcript by Thursday. We would like any motion
16 to conform the transcript to the testimony to be
17 filed by May 16, and it would be lovely if you
18 could get together before you file that and see if
19 you can agree on the changes so we could not wait
20 for any replies and we could rule on that as
21 quickly as possible because of the tight deadline.
22 We'd like post-hearing briefs by May 18, and we

1 weren't going to set time for doing reply briefs
2 because of the deadline. If you really feel a
3 need for reply briefs, we'll take them. You can
4 move, tell me some issue that you haven't had a
5 chance to fully brief. Is there any other issue
6 we should discuss before we close for today?

7 MS. SZMUSZKOVICZ: I don't have any
8 issues.

9 MS. GOERKE: None.

10 JUDGE BIRO: All right, thank you very
11 much for your cooperation. I really appreciate
12 it. Have a good evening.

13 (Whereupon, at 2:00 p.m., the
14 HEARING 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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