UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

In the Matter of	
BAYER CROPSCIENCE, LP and NICHINO AMERICA, INC.,	FIFRA-HQ-2016-0001
Petitioners.	

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

APPEARANCES:

On behalf of Respondent:

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C O N T E N T S

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P R O C E E D I N G S

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

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

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

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

JUDGE BIRO: Okay, welcome everyone. Could you pronounce your last name for me one more time?

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

JUDGE BIRO: Okay. I'm apologizing in advance if I pronounce it incorrectly.

MS. SZMUSZKOVICZ: No apology necessary.

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

JUDGE BIRO: Great. We are here today to hold a hearing on Petitioners' request for a hearing in response to EPA's Notice of Intent to Cancel four conditional pesticide registrations involving the ingredient Flubendiamide under º 6(b) of the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Thank you.

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

First, the terms of EPA's 2008

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

risk of adverse effects.

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

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

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

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

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

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

On the second issue, existing stocks,

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

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

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

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

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

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

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

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

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

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

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

MS. GOERKE: Okay.

Whereupon,

SUSAN LEWIS

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

DIRECT EXAMINATION

BY MS. GOERKE:

Q Good morning.

A Good morning.

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

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

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

SPEAKER: Yes.

MS. GOERKE: Yes. Exhibit 10.

Respondent Exhibit 10.

BY MS. GOERKE:

Q Do you see that?

A I do.

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

A It is.

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

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

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

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

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

A Yes.

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

MS. SZMUSZKOVICZ: No objection, Your Honor.

MS. GOERKE: Additionally I have a --

JUDGE BIRO: Exhibit 10 is admitted into the record.

BY MS. GOERKE:

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

A Yes.

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

A I am.

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

JUDGE BIRO: Is there any objection?

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

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

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

JUDGE BIRO: Do you need time to talk

about that now?

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

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

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

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

CROSS-EXAMINATION

BY MS. SZMUSZKOVICZ:

Q Good morning.

A Good morning.

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

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

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

A Correct.

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

A Yes.

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

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

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

A Okay.

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

A It is.

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

A Correct.

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

A Correct.

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

A Correct.

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

A Yes.

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

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

Q Do you have any degrees in science?
A No.
Q And you have been in no scientific role within EPA?
A Correct.
Q Did you -- were you in any scientific positions -- did you act as a scientist in any of your positions at EPA?
A No.
Q Also, just from a foundational standpoint I'd like to ask you a few questions about the documents that you reviewed. And so first of all there were the 9 Exhibits that you sponsored. And did you review each of those Exhibits?
A Yes.
Q I'd like to ask you to turn to Respondents' Exhibit which contains several 2008 emails between EPA and Bayer.
And there should be a notebook on -- you have the notebook. Did you review any other EPA emails or emails between EPA and the registrants,

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

A From 2008 I --

Q For --

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

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

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

Q And so --

A I believe I was given all of the emails.

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

A No.

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

A Okay.

Q Thank you.

A All right.

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

A Mm-hmm.

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

A I have seen that, yes.

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

A The extension request I have seen.

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

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

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

Q Thank you.

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

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

A Yes.

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

A Yes.

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

A I've seen that.

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

A I read that, yes.

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

A Yes.

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

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

Q Okay.

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

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

A Yes.

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

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

Q Okay. And PBNX 30, EPA's decision memorandum for Flubendiamide cancellation?
A Yes.
Q Okay. And 31, 32 are both EPA documents from 2016.
A Yes.
Q PBNX 33, the des-iodo Spiked Water data evaluation record from 2008?
A That DER, no.
Q Okay. Okay. And the next document is also a DER from 2011.
A No.
Q 35, the EFED review of water monitoring.
A I'm familiar with it, yes.
Q And EPA's EFED review in 2015, that's PBNX 36.
A That I'm uncertain.
Q Okay. And then the next group, 37-51, have been excluded from this proceeding by Judge Biro's Order. So we will skip over those. 52 is the same as RE 9, so we know you reviewed that. And then the PBNX 80 through 115 have been

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

A Yes.

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

A Yes.

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

A Nichino?

Q Yes.

A Yes.

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

A Yes.

Q And did you review either or both of those?

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

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

A Briefly, yes.

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

A Yes.

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

A Yeah.

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

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

Q It ends in 95 in the smaller numbers.

A Okay.

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

A Correct.
Q And you're relying in part on discussions with staff in the Environmental Fate and Effects Division. Correct?
A Yes.
Q And you're relying in part on discussions with staff in the Biological and Economic Analysis Division.
A Yes.
Q And this list does not include discussions with staff in the Health Effects Division?
A That's correct.
Q And that's the division that looks at human health impacts?
A Yes.
Q Okay. And you were present, were you not, at the internal EPA meeting that took place on December 16, the day after EPA met with the CEOs of the two registrants?
A Is this with Jim Jones?
Q Yes.

A I was there.

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

A Yes.

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

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

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

A Yes.

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

A It is.

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

A July 17, 2008.

Q Thank you. And asking you now to turn

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

A Correct.

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

A Yes.

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

A Can you repeat that again?

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

A That's correct.

Q At some point in the future, at least

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

A Correct.

Q But they'd asked for it up front?

A Yes.

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

A Could you give the number please?

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

A I see, yes.

Q Do you need a minute to read it?

A Yes.

Q Okay. So what I read into the record

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

A Mm-hmm.

Q And you're familiar with that paragraph?

A Yes.

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

A Yes.

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

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

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

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

A Yes.

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

A Sure.

Q -- and see if you can confirm that?

A This is on the top of 29?

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

A Yes.

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

A Okay. I'm trying to keep straight what

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

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

A Yes.

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

A Correct.

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

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

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

not?

A Yes.

Q And he worked there at this time also?

A Yes.

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

A The one week, yes.

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

A I need to look at it.

Q Yeah, take your time.

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

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

A Yes.

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

A Yes.

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

A Okay.

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

A Yes.

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

A Yes.

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

A Yes.

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

A Yes.

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

A Correct.

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

A I need to look at the --
Q Sure, take -- yes, take your time.
A Did you say expiration or --
Q Expiration.
A That's not an expiration.
Q Thank you. Okay, let's turn back to your testimony at Exhibit RE10, and staying with the 2008 time period let's look at your testimony at 200098. And we talked about this a minute ago. You mentioned that you discussed the matter with your staff who were involved and who did that include?
A That included Carmen Rodia. It included Marion Johnson, who was the branch chief at that time. It included Richard Gebken.
Q And would all of those people be at positions that report to your level -- the director of registration?
A Yes, within my position.
Q And did you speak with anyone from that time at your level or above who was at EPA in 2008 at your level or above.

A No.

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

A Their assessment? I did not.

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

A Yes.

Q Did you review that portion of it?

A The risk assessment, no.

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

A Yes.

Q Did you review that HED risk assessment?

A That risk assessment, no.

Q That particular Health Effects Division

risk assessment still stands today, does it not?

A Yes.

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

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

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

A I don't believe they did.

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

A R --

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

A Correct.

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

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

A Yes.
Q Did you draft this memorandum?
A No.
Q Who drafted it?
A It was a combination of our staff, as well as our scientists and portions of legal counsel.
Q And when you mention scientists, are you referring there to the Environmental Fate and Effects Division?
A Correct.
Q And what about BEAD?
A BEAD? We used their report and they reviewed the document and edited it.
Q And what about the Health Effects Division?
A No.
Q Did OPP Management weigh in on it?
A Yes.
Q And what about OCSPP Management?
A Right. I don't know if they saw it.
Q You confirmed earlier that you were at

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

A Correct.

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

A Yes.

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

A I have heard him say that.

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

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

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

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

A Yes.

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

A Correct.

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

A Correct.

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

A Correct. But can I check that real quick?

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

A Which one?

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

A Thank you. Correct.

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

A Correct.

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

A Correct.

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

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

Q So, that would include discussion of any

issue or concern between scientists.

A Yes.

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

A Yes.

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

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

A That's correct.

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

A Correct.

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

A Correct.

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

A Correct.

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

A Correct.

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

A Correct.

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

A No.

Q Or what the environmental impact of that would be?

A Correct.

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

A On the existing stocks? Correct.

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

A That's correct.

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

A That was one.

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

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

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

A Right.

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

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

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

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

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

A No.

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

A I believe so.

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

A Correct.

Q And that was to punish the registrants?

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

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

A Right, it was a registrant bonus.

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

A Correct.

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

A This hearing has been relatively quick, yes.

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

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

Q And published in the Federal Register --

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

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

A Correct.

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

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

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

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

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

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

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

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

A The production line?

Q The production and distribution and contracts and --

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

Q But would it also need to occur before January?

A That I don't know.

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

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

A Yes.

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

A Correct.

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

cancellation proceeding.

A Yes.

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

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

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

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

A Correct.

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

management decision, did they not?

A Yes.

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

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

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

A Yes.

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

A I do, correct.

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

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

has to do with the one at hand.

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

JUDGE BIRO: What is in her testimony?

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

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

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

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

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

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

JUDGE BIRO: Sure.

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

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

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

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

JUDGE BIRO: Well, okay.

MS. SZMUSZKOVICZ: May I confer with

counsel for just one moment?

JUDGE BIRO: You may.

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

JUDGE BIRO: Would you like to take a recess?

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

JUDGE BIRO: Okay.

MS. SZMUSZKOVICZ: Thank you.

MR. WRIGHT: All rise.

(Recess)

JUDGE BIRO: Thank you. You may proceed.

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

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

JUDGE BIRO: Okay.

BY MS. SZMUSZKOVICZ:

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

A Okay.

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

A Correct.

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

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

A Yes.

Q Do you recall that?

A I do.

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

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

Q Yes. That was the determination by EPA.

A Okay.

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

BY MS. SZMUSZKOVICZ:

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

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

A Okay.

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

A Okay.

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

A Yes.

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

JUDGE BIRO: Well, we'll see. Overruled. Go ahead.

BY MS. SZMUSZKOVICZ:

Q Would you, would you read it into the

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

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

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

A Yes.

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

A Yes.

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

A Correct.

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

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

Q Okay. From your workgroup?

A From my group, yes.

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

A Correct.

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

A Correct.

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

A Yes.

Q -- characterization?

A Yes, that's fair.

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

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

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

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

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

A I don't recall that.

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

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

A Okay.

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

A March 28, 2016.

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

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

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

A Mr. Housenger is my manager.

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

A Yes.

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

A Correct.

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

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

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

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

A Yes.

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

that statement?

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

Q Thank you.

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

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

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

MS. GOERKE: Okay. Okay.

JUDGE BIRO: And see if I still have questions.

MS. GOERKE: Okay.

REDIRECT EXAMINATION

BY MS. GOERKE:

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

A Okay.

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

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

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

A Yes. "As to your demand that EPA cease

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

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

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

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

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

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

MS. SZMUSZKOVICZ: Objection. We ask

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

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

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

BY MS. GOERKE:

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

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

Q And why do you expect that that would be

the case?

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

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

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

JUDGE BIRO: Overruled. Go ahead.

BY MS. GOERKE:

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

A The issue on human health was not a

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

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

MS. SZMUSZKOVICZ: Objection. Leading.

JUDGE BIRO: Sustained.

BY MS. GOERKE:

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

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

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

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

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

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

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

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

MS. GOERKE: Thank you. No further questions.

JUDGE BIRO: Any re-cross?

MS. SZMUSZKOVICZ: No.

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

THE WITNESS: I do.

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

THE WITNESS: Okay.

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

THE WITNESS: Yes.

JUDGE BIRO: The first one is the

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

THE WITNESS: Yes.

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

THE WITNESS: Yes.

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

THE WITNESS: Yes.

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

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

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

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

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

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

combination product?

THE WITNESS: No.

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

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

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

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

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

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

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

THE WITNESS: I'm not aware of any.

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

THE WITNESS: I don't recall that.

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

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

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

JUDGE BIRO: Okay. So --

THE WITNESS: Does that make sense?

JUDGE BIRO: So, so --

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

JUDGE BIRO: If EPA doesn't affirmatively act.

THE WITNESS: Correct.

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

THE WITNESS: Correct.

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

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

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

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

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

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

JUDGE BIRO: So could the agency have

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

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

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

THE WITNESS: Yes.

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

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

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

THE WITNESS: That's not a term of art

that I'm aware of.

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

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

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

THE WITNESS: Yes.

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

THE WITNESS: Yes. Assistant administrator.

JUDGE BIRO: Okay. And that was Jim

Jones who you referred to?

THE WITNESS: Yes.

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

THE WITNESS: Just Jack Housenger.

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

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

JUDGE BIRO: And what's his background?

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

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

THE WITNESS: Over 20 years.

JUDGE BIRO: In this position?

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

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

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

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

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

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

JUDGE BIRO: Sure.

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

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

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

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

MS. GOERKE: Oh, not 14, sorry.

JUDGE BIRO: Okay, 13, 15 and 16?

MS. GOERKE: Yes.

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

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

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

MS. GOERKE: Yes.

JUDGE BIRO: Okay. Are there any additional questions?

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

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

MS. GOERKE: The respondent has no further witnesses.

JUDGE BIRO: Oh, do you rest?

MS. GOERKE: Yes, Your Honor.

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

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

JUDGE BIRO: Sure.

(Discussion off the record)

MS. SZMUSZKOVICZ: I would like to call

the Registrants' first witness, Ms. Charlotte Sanson.

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

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

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

MS. SZMUSZKOVICZ: Yes. Thank you.

JUDGE BIRO: Are there any objections?

MS. GOERKE: No.

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

record?

MS. SZMUSZKOVICZ: Yes.

JUDGE BIRO: Are there any objection?

MS. GOERKE: No.

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

MS. SZMUSZKOVICZ: Yes, we'll put that on the record.

JUDGE BIRO: Any objection?

MS. GOERKE: No, Your Honor.

JUDGE BIRO: Okay. PBX 128 into the record. Okay. So we are going to swear her.

Whereupon,

CHARLOTTE SANSON

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

DIRECT EXAMINATION

BY MS. SZMUSZKOVICZ:

Q Thank you, Ms. Sanson.

A Okay.

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

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

Q Thank you. And would you turn to Volume 4 of the registrants' exhibits, the petitioners' exhibits. And please turn to Exhibit PBNX 116, if you would? Could you state for the record what that exhibit is?

A This is my verified written statement.

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

A No.

Q Could you take a moment to just confirm that this is a true and correct copy of the statement you prepared?

A Yes.

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

JUDGE BIRO: Any objection?

MS. GOERKE: No.

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

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

CROSS-EXAMINATON

BY MS. GOERKE:

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

A Yes.

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

A That's correct.

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

A Yes.

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

A On a relatively frequent basis.

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

A I typically interact with, depending on the issue at hand, you know, of course, you know, Ms. Lewis, or any of her direct reports, or anybody within the Registration Division, as well as scientists, again, depending on the issue.

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

A I would say so, yes.

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

A Yes.

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

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

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

A It's a conditional registration.

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

A Yes.

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

similarly seen on the Registration Notices?

A Yes.

Q And I notice what also refers to the Preliminary Acceptance Letter, in discussing it earlier today, I have to turn your attention to the Preliminary Acceptance Letter that's integrated into that Registration Notice. And that is available to Respondent Exhibit 2. If you could look at that, Exhibit 2, look at page 200012 the conditions that are listed here. Look at 8, beginning at 8(b), the EPA will complete its review. To your knowledge has the EPA completed all of its review of all the data submitted by Bayer?

A EPA did review everything that was submitted.

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

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

submitted to EPA.

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

A The water monitoring studies that are being conducted presently?

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

A That's correct.

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

A Mm-hmm.

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

A Okay, so the question is?

Q The question is, is that similarly

listed in the PAL as a condition of registration?

A Yes.

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

A Yes.

Q And when did you first learn about this condition?

A When I first learned about this condition --

Q Yes.

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

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

A No.

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

A "EPA scientists and Bayer scientists, as

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

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

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

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

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

the theoretical model that's discussed here.

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

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

Q Made here.

A -- a disagreement on the conclusions.

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

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

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

A It's not there.

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

A Generally.

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

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

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

A Exhibit 4?

Q Yes.

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

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

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

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

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

A It appears that way based on the emails.

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

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

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

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

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

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

A I don't know.

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

A Can you repeat that?

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

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

JUDGE BIRO: Sustained.

BY MS. GOERKE:

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

a term as a voluntary cancellation?

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

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

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

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

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

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

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

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

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

A It would be a non-registration.

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

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

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

A Well, 42 --

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

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

JUDGE BIRO: To your --

MS. GOERKE: -- the existing stocks.

JUDGE BIRO: What again?

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

JUDGE BIRO: Sustained.

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

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

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

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

JUDGE BIRO: Proceed.

REDIRECT EXAMINATION

BY MS. SZMUSZKOVICZ:

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

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

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

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

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

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

A They were required.

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

gave you a complete list.

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

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

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

MS. SZMUSZKOVICZ: Yes.

JUDGE BIRO: Okay.

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

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

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

MS. SZMUSZKOVICZ: All right.

JUDGE BIRO: Do you feel any objections?

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

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

JUDGE BIRO: Okay, so what exhibits are those?

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

JUDGE BIRO: Okay, and we have no objections?

MS. GOERKE: No.

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

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

JUDGE BIRO: Would you look into --

MS. SZMUSZKOVICZ: Yes.

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

MS. GOERKE: No, Your Honor.

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

THE WITNESS: Margaret Cherny.

JUDGE BIRO: -- Cherny, who signed the PAL.

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

JUDGE BIRO: Is that your current position or --

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

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

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

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

JUDGE BIRO: So did Bayer agree that there was an uncertainty as to that issue, or is your impression that, at that time, Bayer thought

that there was no uncertainty?

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

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

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

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

THE WITNESS: Yes.
JUDGE BIRO: And Bayer did the vegetative buffer study.
THE WITNESS: Yes.
JUDGE BIRO: And they submitted their results to EPA.
THE WITNESS: Yes.
JUDGE BIRO: And I understand from looking through the record that, apparently, EPA found some modeling errors, statistical error in the results submitted. Is that also your understanding?
THE WITNESS: I'm afraid I can't adequately answer that question.
JUDGE BIRO: Okay.
THE WITNESS: I understand the buffer strip was effective to some degree, meaning 40 percent, 50 percent, somewhere in that range, but other than that, I don't have knowledge of the statistics that were used.
JUDGE BIRO: But, in any event, it did not resolve the uncertainty regarding the

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

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

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

THE WITNESS: I think so.

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

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

JUDGE BIRO: Okay, but initially, at

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

THE WITNESS: I think so.

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

THE WITNESS: Yes.

JUDGE BIRO: And is it a same ongoing study or a series of studies?

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

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

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

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

or they believe they are still unknown?

THE WITNESS: Well, I believe, based on the results of the data that's been gathered to date, we can see that the actual concentrations of the compound and its metabolite are well below the level of concern the EPA identified, and I think our data shows that it's not increasing over time, as the modeling -- the theoretical computer modeling -- that EPA scientists have done, that shows that they're not looking at real world data, which is, when a company generates real world data, it expects it can be evaluated for what it shows, and it certainly shows there's no increase -- based on 7 years of conducting the studies, and even with the endpoint of 70 times below where it was originally upon which all of our discussions had been based, all our science discussions, and we're still below levels of concern, based on actual use of the product.

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

THE WITNESS: Yes.

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

THE WITNESS: They have, yes.

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

THE WITNESS: Yes.

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

THE WITNESS: We feel it supports an unconditional registration.

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

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

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

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

THE WITNESS: Correct.

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

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

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

MS. SZMUSZKOVICZ: No.

MS. GOERKE: No.

JUDGE BIRO: Okay, thank you very much.

THE WITNESS: Thank you.

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

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

JUDGE BIRO: Okay. All right. So where

are we?

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

JUDGE BIRO: Excluded.

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

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

MS. SZMUSZKOVICZ: Thanks, Your Honor.

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

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

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

MS. SZMUSZKOVICZ: Yes.

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

MR. WRIGHT: All rise.

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

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

(12:35 p.m.)

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

MR. BARKER: Yes.

JUDGE BIRO: Would you like to call your next witness?

MR. BARKER: Yes. I would like to call Lee Hall.

Whereupon,

LEE HALL

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

DIRECT EXAMINATION

BY MR. BARKER:

Q Good afternoon, Mr. Hall.

A Good afternoon.

Q I'm going to ask you to turn to Exhibit 117, which is Volume 4 of the petitioners' exhibits.

A Okay. I'm there.
Q Could you state for the record what that copy is?
A It's a verified witness statement, of Lee Hall, on behalf of Bayer CropScience and Nichino America.
Q And that is your written testimony. Correct?
A That is correct.
Q Do you have any changes, additions or edits to make to your testimony?
A No. I do not.
Q Would you take a moment to confirm and to say, it's a true and correct copy of the testimony you prepared?
A Yes. It appears so.
Q Thank you.
MR. BARKER: Your Honor, I would like to move Mr. Hall's written testimony into the record as evidence?
JUDGE BIRO: Is there any objection?
MS. GOERKE: No.

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

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

JUDGE BIRO: Please proceed.

MS. GOERKE: Thank you, Your Honor.

CROSS-EXAMINATION

BY MS. GOERKE:

Q Good afternoon, Mr. Hall.

A Good afternoon.

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

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

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

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

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

A Could you repeat the question?

Q Sure. So you are seeking here, the same existing stocks treatment, and you did not apply the conditions of registration as a company that has submitted a voluntary cancellation request?

MR. BARKER: Objection; lacking foundation.

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

JUDGE BIRO: Overruled. Go ahead.

BY MS. GOERKE:

A Could you -- could you repeat the question?

Q Sure. Sure. So, what you are seeking

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

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

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

JUDGE BIRO: Asked and answered. Move on.

BY MS. GOERKE:

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

A I'm not sure that I'm understanding

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

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

A Yes.

MS. GOERKE: No further questions, Your Honor.

JUDGE BIRO: Any redirect?

MR. BARKER: No, Your Honor.

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

THE WITNESS: Okay.

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

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

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

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

JUDGE BIRO: Two hundred and fifty?

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

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

THE WITNESS: The name of the product is Synapse.

JUDGE BIRO: Synapse, right.

THE WITNESS: Yes.

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

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

a voluntary cancellation to remove that product from the market.

JUDGE BIRO: Have you had other products that have been involuntarily cancelled?

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

JUDGE BIRO: So when you are talking about your standard experience, is that with just pesticide registrations where you voluntarily cancel?

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

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

MR. BARKER: No, Your Honor.

JUDGE BIRO: Okay. Ms. Goerke?

MS. GOERKE: No, Your Honor.

JUDGE BIRO: Thank you so much, Mr. Hall.

THE WITNESS: Okay.

JUDGE BIRO: Hello, Mr. Eisenberg?

MR. EISENBERG: Hello. Good afternoon. I would like to call Jeffrey Johnson.

Whereupon,

JEFFREY JOHNSON

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

DIRECT EXAMINATION

BY MR. EISENBERG:

Q Good afternoon, Mr. Johnson.

A Good afternoon.

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

A Jeffrey R. Johnson, President of Nichino America.

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

A Yes.

Q Do you recognize this document?
A Yes.
Q And what is this?
A It's a verified written statement of Jeffrey Johnson, on behalf of Bayer CropScience LP and Nichino America.
Q And take a moment and look through it. And Mr. Johnson, is anything you have in your testimony that you wish to change?
A No.
Q Is this a true and accurate copy of your written testimony?
A I believe so.
MR. EISENBERG: Your Honor, the petitioners offer PBNX 118 into evidence.
JUDGE BIRO: Is there any objection?
MS. GOERKE: No, Your Honor.
JUDGE BIRO: Okay. PBNX 118 is admitted into the record without objection.
MR. EISENBERG: We have no further questions at this time.
JUDGE BIRO: Okay. Ms. Goerke?

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

JUDGE BIRO: Of course.

MR. PERLIS: Thank you, Your Honor.

CROSS-EXAMINATION

BY MR. PERLIS:

Q Mr. Johnson?

A Yes.

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

A All products?

Q The pesticide products.

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

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

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

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

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

A Yes.

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

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

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

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

A In 2008?

Q Yes.

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

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

registration of flubendiamide again in 2008?

A No.

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

A A fair characterization of?

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

A It sounds like it is.

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

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

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

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

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

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

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

A I believe the regulatory people were -- yes.

Q Now I take it you know Charlotte Sanson.

A Only through these goings on.

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

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

JUDGE BIRO: Sustained.

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

JUDGE BIRO: Yes.

MR. EISENBERG: Yes.

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

BY MR. PERLIS:

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

A Yes.

Q And did Nichino feel the same way?

A Yes.

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

A Yes.

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

A Yes.

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

A Yes. Not every word, but --

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

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

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

MR. EISENBERG: I believe he just did.

BY MR. PERLIS:

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

A I don't believe we did.

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

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

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

THE WITNESS: Yes.

MR. EISENBERG: Or is it the entire condition?

MR. PERLIS: It's a voluntary cancellation.

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

BY MR. PERLIS:

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

A I'm aware of the letter.

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

A Which?

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

A Okay. This one here.

Q Could you turn that to Exhibit 7.

A Okay.

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

A Pages 2 and 3?

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

A Okay.

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

A Yes.

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

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

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

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

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

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

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

scientific determination in order to trigger the voluntary cancellation request?

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

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

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

JUDGE BIRO: Sustained.

BY MR. PERLIS:

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

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

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

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

A Yes.

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

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

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

JUDGE BIRO: Overruled. Go ahead.

THE WITNESS: Yes.

MR. EISENBERG: Could you at least --

can you repeat the question then? Thank you.

BY MR. PERLIS:

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

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

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

BY MR. PERLIS:

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

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

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

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

A I think integrity is important all the way around.

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

MR. EISENBERG: Objection; mischaracterizes his testimony.

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

JUDGE BIRO: Overruled. Go ahead.

BY MR. PERLIS:

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

sorry, could you -û I know youÆre nodding your head but can you use words please?

A Yes.

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

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

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

A Yes.

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

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

JUDGE BIRO: The question was not legal?

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

JUDGE BIRO: That's all right.

BY MR. PERLIS:

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

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

JUDGE BIRO: Go on.

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

as well.

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

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

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

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

JUDGE BIRO: Okay. Move on.

BY MR. PERLIS:

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

likely to bring that registration than yours in 2008?

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

JUDGE BIRO: Sustained.

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

JUDGE BIRO: You are asking him to suppose on EPA's behalf, on what EPA would have done?

MR. PERLIS: Fair enough.

BY MR. PERLIS:

Q Would you agree, generally, that EPA's pesticide licensing program should operate in a fair and sensible manner?

A Yes.

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

A Yes.

Q Would you agree that cancellation would

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

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

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

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

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

A Correct.

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

A Yes.

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

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

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

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

A Could have occurred --

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

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

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

with that?

A Yes.

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

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

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

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

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

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

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

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

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

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

A Yes.

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

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

with existing products that have been cancelled and permitted any stocks to be used, all the way to stop sales and returns. So, I'm not sure --

Q I'm sorry?

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

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

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

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

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

A Yes.

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

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

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

requested voluntary cancellation when asked to do so?

A It's my understanding --

MR. EISENBERG: Sorry. Objection, another hypothetical.

MR. PERLIS: I don't think it's a hypothetical at all. What I'm asking is, and I think I'm entitled to ask a hypothetical question, and I already identified the paramaters to the hypothetical.

MR. EISENBERG: I think if you look at Mr. Johnson's direct testimony, it is very narrow in scope, and we have given Counsel a lot of leeway, and not objecting, but we're far beyond the scope of the witness' testimony.

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

MR. EISENBERG: No. He is not.

JUDGE BIRO: Okay. Sustained. Go ahead.

MR. PERLIS: Your Honor, this witness testified on this stocks provision and I'm trying

to restore what he doesn't --

JUDGE BIRO: Any questions about personal knowledge that he has, and no more.

BY MR. PERLIS:

Q Okay. Is it fair to say that you, in your testimony, suggested that it would be appropriate for Bayer and Nichino to be able to sell and distribute all product that they produce before the effective date of the cancellation?

A Yes.

Q So under your proposal Bayer and Nichino would be able to sell -- would be able to release for shipment and then sell more product than you likely would have been able to produce and release had they complied with the commitment, isn't that true?

MR. EISENBERG: Objection. Again, calls for speculation.

MR. PERLIS: Your Honor, I don't think that calls for speculation. We've had testimony in this proceeding that cancellations could have been processed --

JUDGE BIRO: Overruled, and I think it's been asked and answered.

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

JUDGE BIRO: All right.

BY MR. PERLIS:

Q Do you think it's fair and sensible for government to treat companies that don't honor commitments better than companies that do keep their promises?

A I think that if you're trying to characterize this situation in that light, it's a misdirected characterization of these discussions and the reason for this hearing.

Q I'm not sure that was an answer to the question, but let me try it another way. So imagine if Bayer or Nichino had honored this commitment and the other did not. Would you think it fair for government to treat the company that spurns it better than the company that honored it?

MR. EISENBERG: Objection. I mean, the question started with "imagine," given the fact

that this is very narrow direct testimony. I don't think he should be asked about his imagination.

JUDGE BIRO: Sustained.

BY MR. PERLIS:

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

A No, I don't agree with that.

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

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

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

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

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

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

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

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

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

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

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

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

JUDGE BIRO: Do you understand that question?

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

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

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

MR. EISENBERG: Yes.

REDIRECT EXAMINATION

BY MR. EISENBERG:

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

A My distributors.

Q And who would the distributors sell them to?

A To the growers.

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

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

Q Is Nichino manufacturing flubendiamide at this time?

A No.

Q When did Nichino stop manufacturing flubendiamide?

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

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

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

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

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

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

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

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

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

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

BY MR. EISENBERG:

Q So could you please read that into the record?

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

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

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

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

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

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

Q Yes.

A Yeah.

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

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

MR. EISENBERG: We have no further questions.

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

MR. PERLIS: Nothing.

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

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

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

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

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

THE WITNESS: Well, there's the original

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

point where we kind of hit a brick wall.

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

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

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

THE WITNESS: No.

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

THE WITNESS: In the U.S.

JUDGE BIRO: How about elsewhere?

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

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

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

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

MS. SZMUSZKOVICZ: One moment.

JUDGE BIRO: Okay.

(Discussion off the record)

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

JUDGE BIRO: I was just interested in

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

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

JUDGE BIRO: And your product that you sell?

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

JUDGE BIRO: Here in the United States.

THE WITNESS: Yes.

JUDGE BIRO: You import it from Japan.

THE WITNESS: We import the active ingredient from Japan and then have it formulated into the end use products at a third-party contract formulator.

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

there anything that would stop you from applying for registration elsewhere?

THE WITNESS: No, we could technically apply for that registration elsewhere. It would take -- depending on the country, it could take many years, but it is possible.

JUDGE BIRO: Is EPA's cancellation definitive as to whether any other country will give you a registration?

THE WITNESS: Not directly. I believe other regulatory agencies around the world look to the EPA, but it's not directly related.

JUDGE BIRO: You talked a lot about why you didn't feel that voluntary cancellation clause was triggered, and I just want to go over that little bit with you. You feel that it wasn't triggered because EPA was making its determination based on an endpoint for toxicity to aquatic invertebrates, different from the endpoint that Bayer scientists thought was appropriate. Is that correct?

THE WITNESS: That's one aspect of it,

as I understand it.

JUDGE BIRO: Well, an aspect that was not -- you would agree that EPA notified you that they had concluded that they found that the product created an unreasonable adverse effect on the environment. Isn't that correct?

THE WITNESS: I would agree that they notified us?

JUDGE BIRO: Yes.

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

JUDGE BIRO: Okay. And they did have meetings with Bayer scientists. EPA scientists did have meetings with Bayer scientists discussing the science regarding whether it created an undue -- unreasonable adverse effect on the environment. Isn't that correct?

THE WITNESS: There were discussions over time, yes. I'm not sure that they were always fruitful discussions. There was not necessarily agreement around the science, the use of the studies, and it's really, I think, the crux

of the issue why we're here that we believed that that discussion got abruptly stopped in late September, early October, because when we were really coming to a point where we were going to extend the registration, redo the water studies, to elucidate and clarify the questions about the data, and the real world water monitoring studies are really the basis for that, and the longer you can run those studies, the more information you can get a clearer picture and you can derive from that rather than just using the model, say. That's a lot of the discussion that kind of broke down.

JUDGE BIRO: Right, so that's the real nub of the issue. EPA went on its modeling, you went on what you consider real world data, which is actual data with points taken from the ponds that you were monitoring, and you came to different points in terms of the toxicity levels based on those two sets of data.

THE WITNESS: Well, I don't --

JUDGE BIRO: Is that not correct?

THE WITNESS: That could be a little oversimplification.

JUDGE BIRO: Oh, I'm sure it is.

THE WITNESS: So the endpoint is a whole other argument in itself, and it got changed late in the game. It was not a transparent discussion at all.

JUDGE BIRO: Oh, so that's a different issue from either relying on modeling or real world data?

THE WITNESS: No, it feeds into the modeling, but we were in discussions about litigation and taking uses off the label and trying to do things for the end use label which would actually fit into EPA's models, and we even got down to a very, very truncated label that we believed would pass the model, and then they changed the model.

JUDGE BIRO: What do you mean --

THE WITNESS: So the goalpost got moved and, at that time, it was apparent to us that it was starting to be more of a political issue and

not a science issue.

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

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

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

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

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

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

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

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

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

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

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

JUDGE BIRO: To what end?

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

JUDGE BIRO: Okay.

THE WITNESS: Or has taken.

JUDGE BIRO: Thank you, Mr. Johnson.

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

MR. EISENBERG: May we have a moment?

JUDGE BIRO: Of course.

(Recess)

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

JUDGE BIRO: Okay.

BY MR. EISENBERG:

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

A That's a difficult question to answer,

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

Q Thank you.

MR. EISENBERG: We have no further questions.

JUDGE BIRO: Mr. Perlis?

MR. PERLIS: Just one.

RECROSS EXAMINATION

BY MR. PERLIS:

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

A No.

Q Thank you.

MR. PERLIS: I have nothing further,

Your Honor.

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

Okay. Who's standing up next?

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

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

MS. GOERKE: That is correct, Your Honor.

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

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

JUDGE BIRO: Okay.

MS. GOERKE: I believe that's correct as

well.

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

MS. GOERKE: No.

MS. SZMUSZKOVICZ: No.

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

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

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

MS. GOERKE: None.

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

(Whereupon, at 2:00 p.m., the 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