IN THE ARBITRATION UNDER THE ARBITRATION RULES OF THE UNITED NATIONS COMMISSION ON INTERNATIONAL TRADE LAW
AND
THE NORTH AMERICAN FREE TRADE AGREEMENT

- - - - - - - - - - - - - - - - - - - -x

In the Matter of an Arbitration
Between:

CHEMTURA CORPORATION
(formerly Crompton Corporation),

Claimant/Investor,

and

THE GOVERNMENT OF CANADA,

Respondent/Party.

- - - - - - - - - - - - - - - - - - - -x Volume 4

HEARING ON THE MERITS

Saturday, September 5, 2009

Government Conference Centre
2 Rideau Street
Centennial Conference Room
Ottawa, Ontario

The hearing in the above-entitled matter came on, pursuant to notice, at 9:00 a.m. before:

PROF. GABRIELLE KAUFMANN-KOHLER, Presiding Arbitrator

THE HON. CHARLES N. BROWER, Arbitrator

PROF. JAMES R. CRAWFORD, Arbitrator

Secretary to the Tribunal:

DR. JORGE E. VINUALES

Court Reporter:

MR. DAVID A. KASDAN,
Registered Diplomate Reporter (RDR)
Certified Realtime Reporter (CRR)
Worldwide Reporting, LLP
529 14th Street, S.E.
Washington, D.C. 20003
+1 202 544 1903
worldwide.reporting@verizon.net

APPEARANCES:

On behalf of the Claimant/Investor:

MR. GREGORY O. SOMERS
MR. BENJAMIN P. BEDARD
MS. ALISON FITZGERALD
MS. RENÉE THÉRIAULT
Ogilvy Renault, LLP
45 O'Connor Street, Suite 1600
Ottawa, ON K1P 1A4
(613) 780-8661

APPEARANCES: (Continued)

On behalf of the Respondent:

MR. CHRISTOPHE DOUAIRE de BONDY
MR. STEPHEN KURELEK
MS. YASMIN SHAKER
MS. CHRISTINA BEHARRY
MS. CAROLYN ELLIOTT-MAGWOOD
MS. SYLVIE TABET
MR. MARK LUZ
MS. CELINE M. LEVESQUE
Department of Foreign Affairs
and International Trade, Canada
Trade Law Bureau (JLT)
Lester B. Pearson Building
125 Sussex Drive
Ottawa, Ontario K1A 0G2
Canada
(613) 944-0027

C O N T E N T S

P R O C E E D I N G S

PRESIDENT KAUFMANN-KOHLER: Are we ready to start?

MR. DOUAIRE de BONDY: Good morning, Madam Chair. Yes, we are ready to start.

Before we begin, I just wanted to make one comment. Ms. Sexsmith, who has agreed to appear this morning, is on sick leave right now, and we see that the Claimant has requested four hours for her cross-examination. So, I just wanted to ask for the Tribunal's indulgence that she may request a pause from time to time, and if that's agreeable to the other side...

MR. SOMERS: Of course.

PRESIDENT KAUFMANN-KOHLER: Certainly there should be no problem.

Can we close the door and ask Ms. Sexsmith to come in, or the reverse.

WENDY SEXSMITH, RESPONDENT'S WITNESS, CALLED

PRESIDENT KAUFMANN-KOHLER: Good morning.

We have been told that you're on sick leave and maybe you need once in a while a break. You just--

THE WITNESS: Um-hmm.

PRESIDENT KAUFMANN-KOHLER: You just let us know. I mean, if we think about it, we will ask you, but you know better when is a good time, so you let us know.

THE WITNESS: Um-hmm.

PRESIDENT KAUFMANN-KOHLER: For the record, can you

confirm that you're Wendy Sexsmith.

THE WITNESS: I am Wendy Sexsmith.

PRESIDENT KAUFMANN-KOHLER: Your current position as a Public-Servant-in-Residence at Carleton University here in Ottawa.

THE WITNESS: That's correct.

PRESIDENT KAUFMANN-KOHLER: And previously you had a career with Health Canada, including at the--in different positions at the PMRA during the times we're interested in?

THE WITNESS: That's correct.

PRESIDENT KAUFMANN-KOHLER: Thank you.

You have given two witness affidavits?

THE WITNESS: Um-hmm, yes.

PRESIDENT KAUFMANN-KOHLER: And you know that you're heard as a witness, and that as a witness you are under a duty to tell us the truth.

THE WITNESS: Um-hmm.

PRESIDENT KAUFMANN-KOHLER: Can you please confirm this by reading into the record the Witness Declaration that is in front of you, please.

THE WITNESS: Yes.

I'm aware that in my examination I must tell the truth. I am also aware that any false testimony may produce severe legal consequences for me.

PRESIDENT KAUFMANN-KOHLER: Thank you.

09:04 You know how we will proceed. You will first be asked a few introductory questions by Canada's counsel, and then we will turn to Chemtura's counsel for cross-examination.

THE WITNESS: Sure.

PRESIDENT KAUFMANN-KOHLER: Thank you.

Mr. Douaire de Bondy.

MR. DOUAIRE de BONDY: Thank you, Madam Chair.

DIRECT EXAMINATION

BY MR. DOUAIRE de BONDY:

Q. Good morning, Ms. Sexsmith.

Ms. Sexsmith, I'm just going to have one short area of questions for you, but before then, I understand you have two corrections to make, one to your first and one to your second Affidavit.

A. That's correct.

Q. I understand the first correction is at Paragraph 30 of your first Affidavit. Do you have that before you?

And I understand it's with regard to the third sentence of Paragraph 30. Are you there?

A. Yes, that's correct.

Q. And what was the correction you needed to make?

A. The correction was that in this Affidavit it reads "April 1998," and it really should read September, I believe 4th, 1998.

Q. Okay.

09:05 A. And it was because the--it was numbered, and there was a misunderstanding as to what the month was.

Q. So, that's Exhibit WS-12 at the bottom of the page? The e-mail, it says 9th April 1998. It should actually read the 4th of September.

A. That's correct.

Q. Thank you.

And just for the record, it has been included in the hearing bundle under the 4th of September 1998, at Tab 38.

All right. And then the second correction was in your second Affidavit. I understand the correction is at Paragraph 85 of your second Affidavit.

A. Yeah, that's correct.

Q. Go ahead.

A. Yeah, and it reads--

Q. Which part of the paragraph are you at?

A. Let's see. It's the first bullet under 85, I believe.

Q. Okay.

A. So, it should be--

Q. I think it's the second sentence you were referring to?

A. That's right. It should say fungicide-only products instead of insecticide-only products.

Q. All right. Thank you.

Now, we'll just turn to this one brief area of

09:07 questions.

Ms. Sexsmith, can you confirm that you were at a meeting of November 24th, 1998, with canola industry stakeholders?

A. Yes, I was.

Q. And at that meeting, did you address the issue of potential lindane replacement products; that is, products containing insecticides other than lindane?

A. I did address the issue, but only in a very general way. I would have addressed it in such a way that indicated that PMRA was willing to work with the Canola Council and Registrants to facilitate access to alternatives to Lindane Products, but nothing more detailed than that would have been said at that time.

Q. Did you make any specific commitments as to the timing or number of replacement products that would be considered by PMRA?

A. Not at that time.

Q. Thank you.

When were those--when were any commitments of that nature made?

A. They were made later on after there was sort of general agreement with the VWA, and that would have been in the--I believe it's the February-March time frame, but also it would have been talked about at the June meeting in 1999 what

09:09 the commitments were.

And the time lines were not made--were not committed to. Essentially, the three products that were put forward and agreed to based on a full data package, those were the three products that we committed to do, but we did not say how long we would take to do them.

Q. Thank you.

MR. DOUAIRE de BONDY: Those are my questions.

PRESIDENT KAUFMANN-KOHLER: Thank you.

Mr. Somers?

MR. SOMERS: Thank you, Madam Chair.

CROSS-EXAMINATION

BY MR. SOMERS:

Q. Good morning, Ms. Sexsmith. My name is Greg Somers, and I represent Chemtura--

A. Good morning.

Q. --in these proceedings. I just wanted to ask you questions on the material that you filed, so I will be referring mostly to your two affidavits, the first and the second, and I will reference to some other documents as well that are named in this hearing as part of the Joint Hearing Bundle, primarily in Volume 2 of the Joint Hearing Bundle. Your counsel will be able to help you with that, those documents, when the time comes.

So, I'd like to start by asking you to open your

confidential Affidavit, that's the first one, and turning to Paragraph 20.

A. Yes.

Q. In that paragraph, you state, and I'll just read from it so that the transcript actually will reflect, you know, what we're talking about rather than having us read it silently.

A. Sure.

Q. "Given the announced EPA action, the Canadian canola industry was facing an immediate problem: How to stave off the EPA's announced border closure."

The border closure you're referring to, that's closure in connection with what? Treated seed? Lindane-treated canola seed?

A. Yes. At around about that time, the U.S. had indicated that the movement of lindane-treated seed was not legal, and they were looking at informing FDA to begin inspections of those types of products moving across the border from Canada to the U.S., so that's what I meant.

Q. Did you say the FDA?

A. Yes.

Q. But as far as lindane-treated canola seed being imported into the United States, wouldn't that fall under the purview of the EPA?

A. That's right, but also there was interest in lindane--I mean, canola products other than seed and that they

would--that would fall under FDA's purview, so it was--the threat was while it was focused on the seed, was also--there was also concern around the products of canola, like the oil and the meal, so that's why I mentioned FDA.

Q. Sure. And we'll get to that in a moment.

A. Um-hmm.

Q. So, you continue at paragraph, 22nd sentence, "They decided to respond by ceasing the use of lindane on their crops, seeking to appease the EPA's health and environmental concerns. Due to mounting international concerns about lindane, it is my understanding that the canola industry, in any event, wanted to disassociate canola from lindane, as its use might tarnish the healthy image of their product. Although the Canadian canola industry wanted to stop using lindane immediately, it needed to develop an orderly withdrawal plan.

So, as I take your statement here, it was the desire for withdrawal or ceasing use of lindane on canola seed was driven by the industry's desire to disassociate itself from lindane; is that right?

A. Well, that's in part correct. It was also, as I understood it, their concern about the impact on their industry if, in fact, it was used and the product of the use would not be allowed to cross the border. So, it was the issue of the negative impact of a so called healthy product as well as the economic impact of the movement of treated seed from Canada to

09:14 the U.S. that would not be allowed.

Q. Okay. And your Affidavit has tabs on it. I'm asking you to turn to the tab that's called WS-3, and that's Exhibit WS-3 as well. That's a fax from the Canola Council of Canada to Gustafson, Incorporated.

A. Just a minute. I may need help from counsel here.

Q. It's one of the first tabs. It's the third tab, in fact, in your Affidavit, so--I think you're getting it there.

A. Yes, we have now found it.

Q. All right. This is correspondence from the Canola Council of Canada to Gustafson, Incorporated, a U.S. corporation, and it's commenting on a letter that Gustafson, Incorporated sent to the EPA. Do you recall the issue now?

A. Right.

Q. I'm looking at the fourth paragraph on that fax, in fact, we'll start there, but we'll expand letter, and I'm reading from there. It says, "Your letter appears to have opened a potential trade irritant issue, a potential irritant that we have recognized for some time. And this is Mr. Dale Adolphe writing of the Canola Council.

A. Um-hmm.

Q. "We have been working to avoid a possible trade irritant by working with Canadian Government, the U.S. Government, and industry on both sides of the border on harmonization of pesticide regulations under NAFTA. See our

attached position paper."

"The recognition by both countries of Canada's stringent pesticide residue regulations has today prevented any trade irritant related to pesticides used in Canada but not registered for use in the USA."

And elsewhere, at the last paragraph of the fax on the next page, "If your letter prompts a trade irritant, it will impact a trading relationship that in 1997 represented over 250,000 tonnes of seed," and then he goes on with about the rest of the economic impacts.

But the--never mind not just the focus, but the entire tenor of the letter and all of it ever talks about is the trade aspect of things; isn't that right? Take your time and look through it, if you would like.

A. Yes, I would say you're correct, certainly, in this exhibit, but there are many other exhibits, of course, that talk about the Canola Council's concern about the impact on the image of their crop. But, yes, this really flags the economic issue, as I had indicated earlier, that the Canola Council was concerned about.

Q. And we will get to other documents as well, but thank you.

And jumping ahead in your Affidavit to Paragraph 24, that states in the first sentence, "As these discussions were ongoing within the industry, the CCC approached the PMRA."

09:17 I'll give you a chance to orient yourself. I don't want to take things out of context.

I wondered if you could tell me, though, when the CCC approached the PMRA in the way that you're referring to here.

A. Um-hmm. I recollect that that would have been in the spring and summer of 1998.

Q. Okay. And I see from Paragraph 23 that that's at the same time the discussions between Canadian Canola Associations and lindane Registrants were going on?

A. Um-hmm.

Yes, not um-hmm.

Q. I will ask you to turn to Paragraph 28?

A. Okay.

Q. Where you state, "Moreover, recognizing that only a universally accepted plan would lead to a workable solution, the PMRA emphasized that it would facilitate the voluntary withdrawal only if all four Canadian lindane Registrants participated in the plan and were treated on an equal basis."

Now I'm going to refer to one of those documents in the Joint Hearing Bundle that I referred to later. It's Volume 2 and Tab 51 of the Joint Hearing Bundle.

This is a document that was received by Chemtura from Canada in connection with this arbitration, and it appears to be a PMRA document. The authorship is not attributed.

Have you seen this document before?

09:19 A. I haven't quite finished reading it, so if you'll give me a minute.

Q. Sure, sure.

(Witness reviews document.)

A. Yes, I have seen it before.

Q. It appears to be at odds with your statement, isn't it, in Paragraph 28 of your first Affidavit because at the very bottom it says--it's commenting on a Gustafson piece entitled "Updated the Use of Lindane Insecticide in Canola Seed Protection," dated October 28, '98. See attached. And at the very bottom it says, "Point number 11 is incorrect. PMRA has not made unanimous agreement among all Registrants, a condition to agreeing to the voluntary removal of lindane."

A. Um-hmm. And I did address that in my Affidavit, one of them, and unfortunately I can't take you to that, but essentially I don't know who made these notes. And as you said, they were unattributed.

And I think in my Affidavit what I indicated was that, you know, I have no knowledge of who wrote this, why it was written like that and so, yes, it does conflict with the item that we're talking about, but it's not something that I can acknowledge as far as who wrote it, why it was written like that, and so, I mean, that's all I can say.

Q. Sure. And so, you stand by your statement at Paragraph 28 of your Affidavit?

09:21 A. Absolutely.

And I think the other issue is the point that PMRA has not made unanimous agreement among all Registrants. I mean, that wouldn't be a function, our function. I mean, obviously, the Agreement needed to be there in order for the voluntarily agreement to work, but that really wasn't up to us to do. That was up to the Canola Council.

Q. Well, if it wasn't up to you to do, why would you say the PMRA emphasized that it would facilitate the voluntary withdrawal only if all four Canadian Registrants were treated--

A. Well, we would say that because the Agreement would not work, and we couldn't in good faith broker the Agreement with EPA and get them on board if, in fact, we were essentially lying to them because there would be no agreement.

So, I mean, if there were only three Registrants on board, there would be no phase-out.

Q. There would be no total phase-out?

A. That's right.

Q. That's right.

A. Yeah, yeah. And so, you know, we, in good faith, couldn't broker that agreement, but essentially it was up to the Canola Council to get the Registrants on board, and that's what I'm trying to say.

Q. The need for PMRA to have all four Registrants withdraw was tied to your ability to tell the EPA that lindane

would no longer be used on canola seed in Canada; is that right?

A. Yes.

Q. But my--I guess my question is: It wasn't the obtaining of the withdrawal of each Registrant, but that it be done on identical conditions for each. Was that within the purview of the PMRA? Or was that at the insistence of the PMRA, that the conditions on each would be identical?

A. Well, you know, under normal principles of regulatory fairness, it would have to be the case. I mean, normally, we try to treat Registrants in the same fashion. And under something like that, I don't see how an agreement could work if, in fact, one Registrant was getting one thing and another Registrant was getting another.

Q. Well, taxation authorities, for example, are perfectly happy to take more money away from people who have more than people who have less, and more referring to equality of treatment among equal participants would be appropriate in what you have just stated.

A. Well, certainly the intent under the Voluntary Agreement, for our role at least, was to treat all of the Registrants the same.

Q. I'm going ahead to Paragraph 30 here in your first Affidavit, and in the second sentence--no, I'm sorry, the third sentence, where you state, "As I noted in an internal e-mail,"

09:25 of what we now know is September 4th, 98, "in principle, the EPA was willing to facilitate a phase-out, allowing lindane-treated canola seed to continue to be imported from the Canada to the U.S."--now, this is seed, treated seed--"during a reasonable transition period, rather than immediately closing the U.S. border."

I'm going to want to ask you now to turn to--I'm sorry.

A. No problem.

Q. Keep a mental sort of finger on that remark, I'll move on, and then I'll get to the point in a minute.

A. Okay.

Q. Instead, I'm going to continue on into Paragraph 31, where you say, "The PMRA's main involvement at this point was otherwise to pursue already ongoing discussions with EPA on the broader issue of coordination of pesticide registrations between the two countries. While the CCC sought to reach a deal with Registrants that would resolve the issue with lindane on canola, the PMRA and the EPA sought to address the more systemic issue of registration asymmetries between the U.S. and Canada."

Could you turn now to a tab in your statement, WS-12--

A. Right.

Q. But don't lose your place in the main body of the Affidavit.

09:27 A. No, I have it.

Q. What we're describing--what you're attesting to here is your--the PMRA's main involvement, it wasn't with negotiating a Voluntary Withdrawal Agreement. It was in the larger context of this--

A. Well, you know, I maintain PMRA's involvement was essentially within the Agreement a number of the technical bits that were agreed to that we ended up doing, and outside the Agreement were other activities.

Q. Oh, in addition to?

A. Yeah.

Q. Oh, I'm sorry. All right.

At WS-12, which is the tab I asked you to turn to, in the last line where you say, "I am now going to try to sell this to the EPA with go-ahead from Tony as a way to stop the fuss."

A couple of--just asking you for clarification.

What is "this"? To try to sell "this"?

A. Well, this would have followed on from discussions that the Canola Council had already had with Registrants and with the growers with the concept of the development of the Agreement in mind. I would have received a call from the Canola Council saying, you know, "This is what we're thinking. Can you talk to EPA to see if, in fact, this is something that they would consider as viable regarding stopping the border

09:28 closure for a couple of years if we did this."

And so, that's what was meant by "this." So, essentially, the Canola Council would have informed me of what they were thinking and asked me to contact EPA as regulatory authority to regulatory authority to have a discussion about this so that this would have been the Voluntary Agreement, okay, and the fuss would have been the border closure.

Q. All right. Now I'm going to ask your counsel to put in front of you again the Joint Hearing Bundle Volume 2, Tab 68. The third page under that tab is a draft news release, entitled, "Canadian Canola Growers Lead Industry to Develop New Seed Treatments."

Do you have it in front of you?

A. Yes, I do, thanks.

Q. In addition to trying to sell the VWA to the EPA, you were also assisting. Tony at the top is written, "Tony, comments. Wendy 10/12/98." I assume that's your handwriting to Tony Zatylny?

A. That's correct.

Q. For your comments on his draft news release.

A. That's correct.

Q. So, you were--in addition to selling to the EPA the idea of a Voluntary Withdrawal Agreement, you were also assisting the Canola Council in promoting, if I can say that. I'm asking to you confirm this or you can clarify it for me if

09:30 you like, but promoting the discontinuation of lindane use and the--well, in this news release, the adoption of new alternative products.

A. Um-hmm. Well, I wouldn't categorize it like that at all. I mean, this is a very normal procedure if Governments are working with stakeholders and stakeholders are putting in a document that's going to be for public release, something that refers to a Government activity. And what I was doing was merely providing accurate information that they could include or could not include as they saw fit.

So, it was neither promotion or--it was certainly not promotion. It was really providing accurate information to include in an external document. And this is something that Governments do all the time.

Q. Now I'm turning to Paragraph 33 of your Affidavit, and in that paragraph you discuss harmonizing U.S. and Canadian pesticide registrations.

ARBITRATOR CRAWFORD: I would like to go back to that document. Do we have in the record the release that was actually released following this exchange of comments?

MR. SOMERS: I'm not aware of it.

THE WITNESS: Yes, yes, it is in the documents. I'm not sure--I can't say where it is. Perhaps the legal team can find it, but, yes, it actually was released.

MR. DOUAIRE de BONDY: If I can be of assistance, the

09:32 Press Release is in the record at JB-10, and another copy of it is at TZ-14. The Press Release wasn't ultimately issued until the 15th of February 1999, although there are--

PRESIDENT KAUFMANN-KOHLER: In the Joint Hearing Bundle?

MR. DOUAIRE de BONDY: In the Joint Hearing Bundle--I will look.

ARBITRATOR CRAWFORD: 2-81.

MR. DOUAIRE de BONDY: If I could also point out, there are comments on the original iteration of the Press Release in the bundle, in the document 26th of November 1998, which I believe is R-363.

MR. SOMERS: Just for benefit of the transcript, that's Volume 2, Tab 81.

BY MR. SOMERS:

Q. Ms. Sexsmith, harmonizing U.S. and Canadian pesticide registrations, would that mean--

A. So, we're on 33, are we?

Q. We still are.

A. Okay, just to check. Okay.

Q. That would mean having the same pesticides registered for the same uses in both Canada and the U.S.; is that right? Is that what harmonizing means?

A. Well, one of the goals of the North American initiative, which was essentially the policy document that the

09:34 NAFTA Technical Working Group on pesticides developed that really sets out the overarching goals of harmonization talks about all of the pieces around harmonization, and it really doesn't just mean the same product and same use in each country. It means lots of other things, but it can mean that as well, so instead of going into a very long answer, I just wanted to make sure that people understood that it isn't just about registrations. It's about policies and legal frameworks and data requirements and all sorts of other things.

Q. Well, all right. I'm looking just at the lines just above Paragraph 33, and it's a quote from the U.S. Canola Association Special News Alert. And at the last two sentences of the quote, it says, "USCA is making progress towards achieving equality with Canada on pesticide standards and Regulations governing registration. At the last TWG, the EPA and PMRA agreed to pursue harmonization for Muster, to be followed by other products."

Now, as the U.S. Canola Association understands it, what is harmonization there?

A. Well, I think it reflects exactly what I said. It's more than just products. It's standards, it's regulations, and the end result obviously is or can be the same product in two countries at the same time with the same MRLs and the same use.

Q. And isn't that what it is here? When they say harmonization, they say harmonization for Muster. Isn't Muster

09:36 a product?

A. Yes, it is.

Q. In the case of Muster harmonization meant--

A. Well, it meant in that case that because it was registered in Canada and not in the U.S. on canola, what they are interested in doing is getting it registered on canola in the U.S., so that's what it meant there.

Q. Okay. Thanks.

So, at least in the case of that pesticide, harmonization means the other country agreeing to what's already eligible for use in the first country so that they have the same--

A. Well, we may just be talking semantics here. I'm not really disagreeing with you. I'm just saying harmonization is a lot more than a product registration. That's all.

Q. I appreciate that a lot more would be involved than just okay, let's register?

A. Yes, that's all, really.

Q. I'd like--again, I'm going back to that Joint Hearing Bundle book, it's Volume 2 as well, and this time I'm going to go to Tab 41. I'm going to try to continue the theme of harmonization here. This is a document entitled, "Lindane Seed Treatment Update," October 2, 1998.

A. I have it.

Q. Are you familiar with this document?

09:37 A. Yes, I am.
Q. Do you know who wrote it?
A. It was likely me that wrote it.
Q. Great, okay. I'm going to the source.
And that would have been my guess, too, because the very bottom bullet on the page it says, "Wendy Sexsmith is contact point with Canola Council and EPA, and it's in significant part about what the EPA thinks of the world.
And looking at the second paragraph in particular now where it says, "EPA is concerned about the continuing use of lindane on canola in Canada apparently with a view to seeking cancellation of the use."
That surprised me a little bit because I wondered why EPA would be interfering in a particular use of lindane, which, as you know, is registered for all kinds of other uses in the U.S., so this wasn't a "oh, we don't like lindane" thing. Apparently with a view to seeking cancellation, is that usual for a foreign Agency to be seeking cancellation of a specific pesticide in another country?
A. No, I wouldn't think that would be usual.
Q. How did you come to learn that EPA wanted to cancel lindane on canola in Canada?
A. Well, in looking at this, what I would say it means is that--and I guess one has to appreciate that this is a very, very short Briefing Note or Note to provide some limited

09:39 information on what was going on around the development of the Voluntary Agreement, so there is--because of that very limited information in this document, and it was written just beyond point form in shorthand.

So, from my perspective, what it means is that it really refers to the issue of canola treated seed moving into the U.S. and the issue of EPA considering the border closure, if I could use those words, because of that. So, that's how I would interpret that sentence.

Q. All right. That certainly changes the meaning for me, not cancellation of use, but stop sending treated seeds over here?

A. Yeah, because really that was the issue we were really trying to address there.

Q. To the best of your recollection, who was this update written--for whose consumption was this update written?

A. I believe it was for our senior management.

Q. Senior to you at that time. Would that have been Ms. Franklin?

A. Pardon me?

Q. Would that have been Ms. Franklin?

A. Yes. Dr. Franklin, yes.

Q. Pardon me, I'm sorry.

You go on right after that sentence that we just discussed to say, "PMRA is not in a position to recommend such

09:40 action," cancellation of the use, I assume, "unless there was agreement for concerted action on all lindane products with the U.S. EPA."

So, that sounds to me like you would entertain canceling the lindane use if the EPA would expand the discussion to cover all lindane. Is that fair?

A. I believe what is meant here is that in the context of North America, if we were going to do something related to lindane; that is, re-evaluation or work together on a North American approach--that we really have to work together on that, and that really relates to the issue of harmonization that we have been talking about here today.

Q. Yes.

A. And the issue of level playing field. And so, it was really us as an organization, even though the language is a bit confusing, I admit. The idea there was that if we're going to move forward in some way on lindane, let's do it together.

And by "moving forward," I mean doing a special review or an evaluation or setting up a NARAP, that we really needed to work together on that.

Q. Okay. And I can see--well, the document shows in the subsequent paragraph various steps that are constituents of a proposal. The next paragraph begins, "The resulting proposal has emerged after follow-up to this issue both with the Canola Council of Canada and EPA staff."

09:42 Would that have been you that had been following up with EPA staff and Canola Council?

A. It would have been me primarily with the Canola Council, and some aspects I would have been following up with EPA, but I may also have been working through PMRA staff with EPA staff, depending on the subject matter.

Q. Sure, sure, okay.

And the third bullet is what I would like to draw your attention to, and it says, "Commitment between EPA and PMRA to work together to phase out all uses of lindane."

That sounds pretty unequivocal?

A. Yes, it does, doesn't it? And I guess I'd like to just reiterate what I said earlier, that this was the barest bones of a note, you know, barely beyond bullet form. And the intent there with that phrase really relates to what I had said earlier, which was if we're going to move forward and work on lindane, let's do it together. I mean, both countries were in the same position of a scientific review needed to be done in order to make any decisions on any type of product unless the product was voluntarily withdrawn by the Registrant for business reasons.

So, that's how I would interpret that station--statement, not as categorical as it sounds because certainly Canada was in no position to say it like that because we can't just phase things out without doing a risk assessment

and having some reason to phase things out.

Q. Right.

A. Unless the company wants to.

Q. I was just going to add that exact proviso.

A. Yeah.

Q. If the industry walks away from it, problem solved?

A. Yeah, that's fine. Absolutely.

Q. And I just want to clarify this because the paragraph above those, "The resulting proposal has emerged," and then "commitment between EPA and PMRA to work together to phase out all uses of lindane."

Does that mean, was there an actual commitment, or was it proposed to have a commitment?

A. By an actual commitment, you mean something in writing, or how do you mean "commitment"?

Q. I will take whatever version it came out.

Was there a verbal commitment?

A. I believe in this case it would have been more verbal than anything, that we were in conversation related to the request that the Canola Council had made for us to contact EPA and see, you know, if the Agreement was something that, you know, they would be able to buy into as appropriate.

And so, out of those conversations, these things would have emerged. For example, while it wasn't part of the Voluntary Agreement, the stakeholder community was very

09:46 interested in more broadly dealing with the movement of treated seed, and we could not agree to developing a policy on the movement of treated seed unless the U.S. agreed, so we'd have to have those kind of discussions.

Q. And that was the fourth bullet, isn't it, at least that's how I read it, commitment by EPA?

A. That's correct. That's correct.

Q. And I will just finish it for the transcript.

A. Sure.

Q. To work together on a harmonized policy for a movement of treated seed. I guess I was trying to focus more on that, phase out all use of lindane part.

A. Sure, yes.

Q. All right. I'm turning now to Paragraph 41 of your first Affidavit, and I'm going to the first sentence of that paragraph. "By agreeing to voluntarily remove canola rapeseed claims from labels by December 31, 1999, and agreeing to a date for last use of July 1, 2001, the pesticide Registrants were effectively given three full years to phase out of production and sale of lindane-based products for canola use."

This was a comparable time frame to phase-outs of other Pest Control Products. As the EPA's November 23, 1998, letter confirmed, the alternative to the VWA would have been an immediate cessation of canola exports to the U.S."

By "canola exports," you mean exports of treated

09:48 seeds, treated canola seeds?

A. That's correct.

Q. Okay. And is there a--by saying the pesticide Registrants were effectively given three full years to phase out, and the alternative to the VWA would have been an immediate cessation, was there a document or a promise or an undertaking from EPA to allow this full three years of phase-out?

A. The best document that I can think of this morning is the record of agreement, where it's documented in the--and I don't have that--I don't have the number in front of me, but perhaps the legal team can come up with it, but the Record of Understanding, I mean, pardon me, that was developed between the U.S. and Canada really related to a large suite of agricultural trade issues. There were 17 broad headings, one of which was pesticides; and of the nine or so pesticide issues under that heading, one of which was the Voluntary Agreement, and--

Q. I'm sorry, I'm just going to interrupt you because it is in your Affidavit. It's under Tab WS-18. That might help you. Yeah, WS-18, Record of Understanding.

A. Yeah, yeah.

So, just offhand, that's the best recording of the U.S. agreement on the Voluntary Agreement.

Q. Right. And I guess my question was--my question was,

09:50 was there any--this was a Record of Understanding between the two. Well, perhaps we can turn to it then. Are you at it?

A. Yes.

Q. Okay. I'm looking at Section 13 of it. The pages aren't paginated, but it's, how many? It's two or three in anyway.

A. Yeah, I have it.

Q. Okay. And the bottom of the page?

A. Yes, I have it.

Q. And we can see the one, two, three, four--the fifth bullet, I think references the VWA.

A. Yes.

And since this was signed by very high-level signatories and agreed to by senior people within Canada and the U.S. in both the pesticide authorities and other areas, this was a public recognition by EPA that they accepted this.

Q. Well, I actually don't see that anywhere in there. I don't see any undertaking or--could you--maybe, I don't know. Am I missing it? There is nothing about the EPA in there. All it says is Canadian canola growers have requested Canadian Registrants to agree voluntarily to remove canola claims from labels of registered canola seed treatments containing lindane by December 31, 1999. All commercial stocks containing lindane for use on canola and lindane-treated canola seed would not be used after July 1, 2001. This is contingent on Registrants

09:51 requesting voluntary removal. EPA, PMRA growers and Registrants will continue to work together to facilitate access to replacement products.

There is nothing there about the EPA averting its gaze.

A. Well, you will note under 13, under Pest Control Products, it says to avoid future disruption and bilateral trade, Canada and the U.S. agree.

Q. Yes.

A. And so Canada and the U.S., and that would be the appropriate authorities of which the pesticide authorities were.

So, there may be other documents, but this is the one I can think of this morning.

ARBITRATOR CRAWFORD: Could I ask you a question. If following the conclusion of this--it's not a treaty, obviously, it's an MOU, but if the EPA closed the border to canola seed, what would your reaction be?

THE WITNESS: Well, we would--under that kind of condition, we would then be working with our Department of Foreign Affairs and our Department of Agriculture to try and resolve the issue.

ARBITRATOR CRAWFORD: Would you have expected such a closure following this agreement?

THE WITNESS: Pardon me?

09:53 ARBITRATOR CRAWFORD: Would you have expected such a closure following this agreement?

THE WITNESS: Not following the Agreement, no. We were--we clearly understood that the EPA supported the Voluntary Agreement. But if this had not happened--

ARBITRATOR CRAWFORD: Including the phase-out?

THE WITNESS: Yes, yes.

If this has not happened, certainly our agricultural trade people and our foreign affairs trade people would be immediately involved. And because we were the technical experts, we would have been involved. I don't know what the resolution would have been, but it would have been a very major issue for our Agriculture and Foreign Affairs Trade people.

PRESIDENT KAUFMANN-KOHLER: Mr. Somers, you can carry on.

MR. SOMERS: Thank you.

BY MR. SOMERS:

Q. In any event, so it's your evidence--I'm looking at the end of Paragraph 41--that absent a VWA, and the language is slippery here, but I'm going to read the last sentence from Paragraph 41. "As the EPA's November 23, 1998 letter confirmed, the alternative to the VWA would have been an immediate cessation of canola exports to the U.S."

And we agreed that we can qualify exports to be exports of treated seed; yes?

09:54 A. Yeah, primarily, although there was the concern about the oil and the meal.

Q. Fair enough.

So, but for--your evidence is that but for the VWA, there would have been an immediate cessation--well, the border would have closed, put it that way, to treated seed?

A. That's certainly my understanding from our interaction with EPA and as evidenced by the Lynn Goldman letter of November 23rd.

Q. All right. Okay. I'm turning now to Paragraph 45 of your first Affidavit.

It states, "In the CCGA,"--Canadian Canola Growers Association--"letter of November 26, 1998, under action time line, the only specific commitment relating to new registrations was as follows: December 31, 1998, any Registrant wishing to gain approval for a lindane-free seed treatment in time for the 1999 canola seeding must make a formal request to the PMRA. This applies only to requests in which lindane is removed from existing formulations of approved seed treatments."

In other words, "The commitment,"--I'm continuing--"did not apply to the registration of new pesticides such as the Claimant's Gaucho. It only applied to existing pest control formulations from which the chemical ingredient lindane had simply been removed."

09:56 With that sort of in mind, I'm going to ask you to turn to one of the tabs in your Affidavit again, WS-17, and that's the action time line that you referred to in Paragraph 45. I think it comes from that document in the second page of WS-17.

Do you have that, too?

A. Yes, I do.

Q. Okay. So, I take it that what you're calling a commitment here in your Affidavit is the statement in Section 5, action time line, Paragraph C, December 31, 1998, "Any Registrant wishing to gain approval for a lindane-free seed treatment in time for the 1999 canola seeding must make a formal request to PMRA. This applies only to requests in which lindane is removed from existing formulations of approved seed treatment."

So, that's what you mean?

A. Um-hum, yes, because that was a very short time line, something like 30 days.

Q. Could I ask you to turn to the previous page of WS-17, which is the first page of that letter to Dr. Franklin, and I'm looking at item three of the letter right there. "The Pest Management Regulatory Agency, PMRA, and the U.S. EPA will continue to work with Registrants to facilitate access to lindane replacement products.

Wouldn't the PMRA have considered that to be a

09:58 commitment as well, "continue to work," "facilitate," "will do so"?

A. Yes, I mean, that is a commitment. That is a very broad general commitment. It doesn't deal with which products or what kind of time line, because as you know, PMRA is not in a position to invent the products. The products come from the Registrants.

So, at that point in time, we had no knowledge of what products were out there, except perhaps the Gaucho one, and which products might be able to be submitted by companies that would, in fact, be able to be lindane replacement. So, we were under no ability really because we didn't know what was out there at that point in time except perhaps the Gaucho product.

Q. You were under no ability to guarantee a time, for example, that a registration would issue. I can appreciate that.

A. Well, yeah, more or less. I mean, we--the commitment was very general. I will admit it's a commitment, but it's a very general commitment. No time lines and no specific products.

Q. Right, facilitate access.

A. Um-hmm.

And that's appropriate for a regulatory agency.

Q. Well, actually--and I was thinking the same thing. And so, when you did the action time line thing, that was kind

09:59 of pushing it, wasn't it?

A. Which action time line?

Q. The one we are talking about, C, because as you stated elsewhere in your material anyway, correct me if I'm wrong, the PMRA can't guarantee a registration?

A. No, we can't guarantee a registration.

Q. So, if somebody puts in a new formulation, even if it's lindane-removed from existing formulation, there is no guarantee, or is there?

A. Well, I think the sense was, and, you know, I'm not the most technical person here, and other people are probably better suited to answer this, but in the removal of a particular ingredient, what it was going to leave was fungicide-only, and that was a fairly simple registration action. So, to be able to do it in a fairly short time frame was well within our ability, and that was a commitment we were able to make.

ARBITRATOR CRAWFORD: Where in the record is your reply to that letter? I'm sorry, it's a question to counsel.

MR. DOUAIRE de BONDY: It's a document of February 9, 1999. It's in the Joint Hearing Bundle at 79, Tab 9, Volume 2.

It's also Exhibit 25 to Wendy Sexsmith's first Affidavit.

BY MR. SOMERS:

Q. You had said at the time that of that letter that you

were aware of Gaucho, I think, as one--

A. I'm just presuming that I would have been at that point of time, so--because it was already registered in the U.S., and so I'm just assuming we would have known that, Gaucho, and that that was likely to come in.

And I think at that point in time it was already in for export only.

Q. All right. I'm going now to Paragraph 49 of your Affidavit, where we explore a little bit the function of the Voluntary Withdrawal Agreement. Again I'll read from there: "By entering into the VWA, canola industry stakeholders hoped to convince the EPA that lindane was indeed being phased out in Canada and would therefore not create an import issue. They hoped that in return the EPA would hold off its announced border action during the phase-out period. This would allow sales to the U.S. of Canadian canola products through at least the 2001 growing season despite the Canadian use of lindane during this phase-out period. Canadian canola farmers were therefore hoping for some sort of sign from U.S. Government that the VWA had been noted, suggesting that the marketing of lindane-treated canola could proceed undisturbed until 2001.

There's a lot of hoping there, but I don't--I still--I understand the request for withdrawal of registrations was embodied in the ROU, but that's all. The ROU, which was in December, I think, of 1998--it was December 2nd--didn't even

10:03 say that there were any Registrants that agreed. It just said they had been asked.

So, was it the case that actually--this was just--this was an offer by Canada, and they were--and by the Canadian canola farmers or canola industry, and that they were just hoping, without any undertaking or assurance or anything else, that action wouldn't be taken against canola?

A. Well, I think the position of the canola industry was in, was at that point a hoping situation, given they put together this agreement, but they had no power to make EPA accept it. And so, hence, the use of the word "hope."

But I think if we recall backwards, EPA, indeed, did not close the border. Indeed, there was no action, so history shows us that, in fact, they did agree.

And not only that, when the leftover treated seed was then allowed to be used in 2002, EPA again did not go forward with any border action, and in my Affidavit I do refer to the Record of Understanding as a vehicle to publicly show that both countries agreed with that proposal.

So, I think it's fair that the Canola Council was hoping because they were not the authorities, so they couldn't make EPA do anything, but EPA, in fact, did agree and did accept the proposal, and did not take any action.

Q. Sorry, was it a verbal agreement? I haven't seen any document where the EPA agreed not to enforce--

10:05 A. Well, what I'm saying is the Record of Understanding was the vehicle to show that EPA had agreed in writing. I mean, it was the EPA and the PMRA that were responsible for working on the pesticide-related activities under the Record of Understanding because while it was driven by both the very senior elements of agriculture in both countries, other departments in Canada that had actions to carry out, like, for example, fisheries might have had an action, the...

Anyway, a number of departments were involved. It wasn't just agriculture.

So, PMRA--EPA was a signatory, essentially, to the ROU.

Q. Yes, I understand that, but the ROU didn't contain any commitments at all from the EPA, did it?

A. Yes, it did. I mean, it said that both Canada and the U.S. agreed to.

Q. No, I mean commitments in relation to enforcing or not pesticide regulations against Canadian treated canola seed.

A. Well, I guess it depends how you read this, but I would read it that if, in fact, Canada and the U.S. agreed to that proposal that the U.S. would stand by, the fact that they wouldn't proceed with border action. It's implicit, if it isn't explicit.

Q. Yeah, I think we understand each other on that. Thanks.

10:07 Can I ask you now to turn to Paragraph 81 of your Affidavit. This is a discussion of the negotiations of the correspondence back and forth between the Chemtura, what is now Chemtura and the PMRA.

A. Yes.

Q. So I'm just going to read again from Paragraph 81. "By making these demands, Mr. Ingulli ignored the fundamental problem created by his own company's subsidiary--that's Gustafson--the EPA, not the PMRA nor any other Canadian Agency was no longer allowing the importation of Canadian Canola Council products treated with lindane into the United States based on the application of U.S. legislation.

And if I go back to your Paragraph 30, we discussed already, here you say Canadian canola products treated with lindane--well, I assume you mean seed again; right? I mean, obviously, nobody treats oil with lindane.

A. No, but there was still a concern about potential levels of lindane--

Q. And we will get to that. But I just mean what you mean here.

MR. DOUAIRE de BONDY: I think she's trying to explain what she means there, and she's saying there is a concern about potential--Ms. Sexsmith, you want to go on?

THE WITNESS: Yes, I just wasn't sure where he was, so maybe you could repeat.

23:00 BY MR. SOMERS:

Q. I'm sorry. The EPA, second line of Paragraph 81, not the PMRA, nor any other Canadian Agency, was no longer allowing the importation of Canadian canola products treated with lindane into the United States based on the application of U.S. legislation."

So, in that sense, we are talking about treated seed; right?

A. No. That would be broader.

Q. So, you mean Canadian canola products oil treated with lindane?

A. Um-hmm, yeah.

Q. All right. Could I ask you to turn to Tab WS-6.

And looking at Page 2 of Exhibit WS-6, and so are you?

A. Yes.

Q. At the second paragraph, "As of June 1, 1998, EPA will ask U.S. customs to regard shipments of canola seeds that have been treated with a non-U.S. registered pesticide as shipments of an unregistered pesticides under FIFRA. FIFRA violations involving sale and distribution of the treated seed for planting within the United States will be handled under existing enforcement response policies after June 1, '98."

So, this is a letter from the EPA to the Commissioner of Agriculture for North Dakota, March 12, 1998.

A. That's right.

10:10 Q. So that's at least part of what you mean in Paragraph 81; right?

A. Um-hmm, yes, and it addresses the concern, which is what I have been talking about, around potential lindane in oil and meal.

Q. Yes, it does.

A. And here they have addressed the issue.

Q. Yes, to say that, well, I will read it, actually.

A. You don't have to. It says that the likelihood of form is exceedingly small, so they address the issue.

I guess what I have been trying to say all along is that, because of the concern raised not only about the seed, but also the other things that created some alarm with the Canola Council.

Q. So the Canola Council--

A. Yeah, so it was beyond just the seed, but here they have addressed that particular issue.

Q. Well, here--yes, they do, and they say they will enforce against treated seed.

A. Um-hmm, but not--

Q. But not against oil and meal?

A. That's right.

Q. Okay. So, I go on in your Paragraph 81, "The VWA had been conceived to stave off this EPA action." Now, that's action being the action as per that letter, closure of the

10:12 border to treated seed; right?

A. Yes.

Q. And there was no guarantee that the EPA would continue to look the other way if Canadian producers failed to abide by the phase-out period agreed to in the VWA. There was no--was there a guarantee that if the Canadian producers abided by the phase-out period in the VWA, the EPA would look the other way? Is that your evidence? I know it's not exactly what it says here, but I'm asking you today.

A. Yes. The EPA had committed to look the other way, if you will, for the period of the phase-out, if the VWA was really in place.

Q. The next document I really want to go to is actually in your second Affidavit.

A. Okay.

Q. It's Exhibit Number and Tab Number WS-99. Let me know when you have it.

A. Yes, I have it. I have it.

Q. Oh, good.

Page 2.

A. Okay.

Q. Okay. Do you have that?

A. Yes, I do.

Q. Okay, good.

It says at the top of the page, "In 1998, treated seed

10:13 was being shipped into the U.S. for planting. Seed treated with lindane has not been sold for planting in the U.S. since 1998."

So, it seems to me, now, this is a letter from--to you from JoAnne Buth, Vice-President of Crop Production it says, of course, of the CCC. Seed treated with lindane has not been sold for planting in the U.S. since 1998. All seed destined to the U.S. is exported bare or treated with a seed treatment that is registered in the U.S. and Canada; e.g., Gaucho, or Helix."

So, the VWA did nothing. It wasn't needed, right, there was no need to have EPA avert its gaze against treated seeds because no treated seeds came into the United States even before the VWA; isn't that right?

A. Well, just to make sure the context of this document is clear.

Q. Please.

A. This document was written by the Canola Council in order to support the use in 2002 of the leftover lindane-treated canola seed, so the Canola Council was required to provide the status of the use of lindane vis-à-vis canola, and some idea of how they could justify the use of lindane-treated seed in 2002.

So, that was the purpose of this document.

Q. Right. Well, thank you for that, but as far as the factual statement in it made by Ms. Buth, there were no

10:15 shipments of lindane-treated canola seeds into the U.S. for the entire period of the VWA, were there, unless she's not accurately--

A. You know, I can't comment on that remark. Obviously, it's from an expert, so I presume it's correct, but I can't comment any further on that. Obviously, it was the Canola Council who wanted the VWA. They wanted it clearly for a reason. It was put in place. EPA agreed to it. There was no border action.

Q. Would it be fair to say that that wanting by the Canola Council of a VWA was very consonant with the desire of the PMRA to phase out all uses of lindane?

A. No. I would say at that point in time they were mutually exclusive. Lindane was an older product. And according to the new re-evaluation policy that was being developed, it would naturally fall into the queue for review. And then with the international activity around concerns for lindane, Canada would be required to do a review, but requiring--being required to do a scientific review is quite different than getting rid of a product because the scientific review has to come first.

So--and the upshot or the result of a scientific review, it could be positive or negative.

So, you know, if you're saying that because the Canola Council wanted to get rid of it that lined up with PMRA's view

10:17 of wanting to get rid of it, I have to say categorically, no, because we don't have personal views of products. We're a regulatory organization. We regulate. We ensure health and environmental safety. And it's the science that tells us whether or not it meets those provisions.

So, for us to make a conclusion before we've done the work is not something that we do as an organization, so I would just have to say no to your statement.

Q. In other words, the PMRA--you're saying no to my statement means that the PMRA had no interest either way in continuing to permit the use of lindane or disallowing it?

A. Yeah, if you're saying PMRA thought this was a foregone conclusion, you know, with or without a scientific review, I mean, I have to say no. Certainly, we could read the tea leaves in that there were--there was a lot of international concern about the product, but that didn't preclude the requirement that we had as an organization under our legislation to carry out a scientific assessment, and that's what we had agreed to through the Aarhus Protocol.

Q. Right.

Just one last observation or question on Exhibit WS-99 that letter from JoAnne Buth. On the first page of it, under Item 1 near the bottom of the page, "In 1998," it says, "we did not know the likelihood of detecting residues in canola seed, oil, and meal."

10:19 And then on the third bullet it says, "Residue testing by lindane manufacturers has shown .0058 parts per million lindane in canola seed, but no detectable residues in refined canola oil or meal."

So, in fact, in hindsight, I guess, because this letter was written November 20, 2001, but before the Special Review resulted in termination of Chemtura's registrations, but obviously long after the VWA had been in place.

In fact, the VWA never really accomplished anything because there were no treated seeds since 1998--we see that--there were no detectable residues. So, had the FDA looked, they wouldn't have found anything in oil and meal. So, there was actually quite a crisis in lending and alarm for nothing.

A. Well, I'm sure you didn't hear that from the Canola Council people, that there was a crisis. There was a real issue for them. They were the ones who created the VWA. Certainly the regulatory authorities did their bits. And I have never heard from them that the VWA accomplished nothing.

Q. I guess I was more asking for your view than theirs.

A. Well, it was their agreement, and my understanding was they were very pleased at the success of the Agreement and stand by it to this day.

(Pause.)

Q. I'm turning to Paragraph 119.

10:23 A. Which Affidavit?
Q. Your first one, I'm sorry. I had to dip into the second for that document, that's all.
A. Okay.
Q. You stated a few times that the VWA was the CCC's arrangement and responsibility, not the PMRA's, but nevertheless the PMRA had a very extensive role in implementing that VWA; isn't that right?
A. Well, we did have a role. There were a number of regulatory actions that we had to be involved in for the VWA to work.
Q. Right.
A. So, I'm not sure I would use the word extensive, but certainly we had very specific roles to play.
Q. All right. And one of those was--is set out in Paragraph 119. The PMRA would have had to issue new labels for the removing canola use from the various products that had originally had a canola use prescribed on the label; right?
A. Yes, we would have had to approve new labels. The labels are actually developed by the companies. They make the changes, and they send them in to us, so it would have been the companies that would have taken lindane off, the uses off, and we would have approved that.
Q. Under the terms of the VWA, which you--I will leave it there.

10:25 In terms of the VWA, manufacture had to cease at the end of 1999 of lindane for canola. The labels also had to have the canola use submitted for removal from at the end of 1999, and that would mean, even though the product would continue to be used until July 2001, it would technically be a breach of the Regulation because it would be being used for a nonlabel use; is that correct?

A. No, it's not correct. It wouldn't be a breach of the Regulation. This is under--carried out under ministerial discretion and is a not uncommon approach to use the phase-out--phase-out approach at the end of a product or use's life in order to deal with disposal of hazardous wastes and other sorts of costly endeavors.

Q. My understanding is that the Regulations restrict usage of the pesticide to labeled uses; is that right?

A. When a product is registered, it's registered for those particular uses, yes, and at those particular rates that are on the label. But what I'm saying is the use of a phase-out period is a common tool implemented under the Minister's discretion for dealing with the end of a use of a product or the end of a product's life.

And this sort of phase-out approach is used certainly in the U.S. very commonly, and often their phase-out periods are much longer, up to six and seven years. And other countries would use the same type of approach. The three-year

10:27 phase-out period is something that's fairly commonly used in Canada.

Q. And in those phase-out periods, the label use is removed at the beginning of the phase-out period and the product is continued to be sold through its phase-out period on an off-label use?

A. Not necessarily. The phase-out could actually take place with the product registration intact.

Q. In place, exactly.

A. Um-hmm.

But what I'm saying is that this is very much within ministerial discretion to carry out this type of approach.

Q. In Paragraph 119, the third sentence, it says, "The PMRA exercised its discretion under the Act not to strictly enforce the new labeling, excluding canola, until January 1, 2001."

A. Okay, that's correct.

Q. And that's where you say that the Act--the Pest Control Products Act, presumably--gives the Minister the discretion to decide not to enforce an off-label use?

A. That's right.

Q. Turning now to the issues around the appointment of the Lindane Board of Review, that's at Paragraph 166.

A. In which Affidavit?

Q. In your first Affidavit.

10:29 There you say, "On May 6, 2002, the Minister of Health notified Chemtura that its requests for a Review Board had been forwarded to the PMRA for appropriate action."

Were you part of the--or would you have been part of the--any of the persons at PMRA who would have taken appropriate action having received a request like that?

A. No, not at that time.

Q. I'm now jumping to Paragraph 168 where the second sentence from the bottom, "Far from commencing proceedings to compel the Government of Canada to perform its statutory duty, Chemtura instead delayed the process by a year only to withdraw its objection."

Do you know who actually appointed the Lindane Board of Review, as it happened? It was the Minister of Health, wasn't it? In the materials attached to your Affidavit, it's--

A. Well, I have to say I wasn't directly involved at that point in time.

Q. I see.

A. So, some of the other witnesses can address this better than I can.

Q. So if I said that the objection of Chemtura that resulted in this delay was to the fact that it was the PMRA initially that was going to appoint the Review Board, and that after this legal process in Federal Court went on, it was the Minister that ended up appointing the Review Board, that

10:31 wouldn't amount to withdrawing its objection. Chemtura wasn't withdrawing its objection; it was achieving the relief that it sought by having the Minister appoint the Board instead of the PMRA.

A. Well, I really have to plead ignorance on that.

Q. Oh, okay.

A. And I think my colleague, Dr. Claire Franklin, who was directly involved, would be better situated to deal with that directly.

Q. Okay. The legal documents and then all of those applications and the letters to lawyers and stuff were all attached to your Affidavit and commented on in it, so that's why I'm taking it up with you, but I appreciate your clarification.

A. Yeah.

Q. I'm now going to your second Affidavit, and I'm beginning at Paragraph 16.

A. Yes, I have it.

Q. Okay. It starts, "The many questions surrounding remaining lindane uses as of the late 1990s, were of obvious concern to the end-users of the product. In Canada, the main end-users were Canadian canola growers. They were facing a combination of negative circumstances relating to their continued lindane use, pressure from environmental groups to withdraw their use of the product, potential negative publicity

10:33 affecting canola's key image as a healthy product, the prospect that current registered uses might not be supported for much longer by the regulator, and the absence of any registered Canadian alternative."

Just kind of as an aside, the prospect that current registered uses might not be supported for much longer by the regulator, you mean the prospect that you might cancel the registrations? And this is the late 1990s.

A. Yeah. Well, at that point in time, there were several issues surrounding lindane from the regulatory perspective, and one would have been the international concern and the requirement for countries who had remaining lindane uses to assess them, and so it certainly was reasonable that a question would remain as to the outcome of the Assessment, whether it was going to be negative or positive, particularly given many countries in the world had by that world had eliminated most, if not all uses of lindane.

And then secondly, as a matter of course, PMRA was in the process of developing a new policy on re-evaluation of older products, and lindane would have been part of that, so, again, it would not be untoward to understand. There might be some question as to the resulting outcome of that re-evaluation when it should take place, so that would be the answer to that.

Q. I'm jumping ahead to Paragraph 19 and picking up there. "In all of these circumstances, Canadian canola farmers

10:35 took the decision that, from a business perspective, their continued use of lindane posed a threat to their industry, and that given all the current questions about lindane, the absence of alternative products left them seriously exposed. In these circumstances, they decided to voluntarily transition away from lindane use and toward other products. This was what the canola industry sought to achieve through the VWA."

And now I'm going to ask you to turn to another document that's attached to this second Affidavit. It's WS-90.

A. Yes, I have it.

Q. Okay. That's an e-mail, and from it's a couple of years later. I can see it's 2001. The part of the e-mail that I'm interested in is January 18, 2001, and it's an e-mail by JoAnne Buth relating a conversation that you had with her. She's says, "Wendy Sexsmith has informed me that the review of lindane had been pushed back, and the Report/decision will not be made until September 2001." She's talking about the Special Review, of course.

A. Yes.

Q. "I suspect that the delay may be due to EPA's workload. We had hoped to have a decision by now. If the decision was positive for both Canada and the U.S., it would give the manufacturers enough time to gear up production for the 2002 season. I know there are varying views on whether or not lindane for seed treatment uses will pass the review, but

10:37 we need to be ready in case the decision is positive."

"A couple of things. Have any of you have had contact with the EPA regarding the time line for the completion of the review? Is there any way to advance the review? I suspect Canada would be able to follow along with EPA if we could get the"--obscured by an exhibit mark--"to commit to an earlier decision time." I assume it said "PMRA" there.

"Two, what amount of lead time do you need to gear up for production for the 2002 season? What is the latest possible date?"

This is from JoAnne Buth to, as we can see from the e-mail above, in fact, to Uniroyal, to Chemtura. It may as well have been sent to other people. It's been obscured. This was the copy that we--obviously you attached to your Affidavit, I don't know, but I'm referring to is in Section one where it says, "Have any of you have had contact with the EPA."

In any event, I guess I'm going to focus on the obvious point of the e-mail, which is that if PMRA had made a positive nontermination, noncancellation of use finding in relation to lindane, they would be right back with it; isn't that right?

A. Well, I would certainly read from this that JoAnne Buth was trying to be prepared as to whichever might happen.

Q. Exactly.

A. And--I mean, I think that's reasonable and logical.

10:39 Q. All right. And, in fact, there was an alternative product already available, wasn't there? The replacements?

A. Yes. There were two, really. There were your Gaucho products and then there was Helix registered in 2000.

Q. So, I guess what I read that to mean is that the industry liked lindane, and if it was available along with Helix and along with Gaucho, they needed to be ready in case the decision is positive, gear up production.

So, is that not the implication you take from this e-mail?

A. Well, I don't think this is news, really, because all through the piece, through the Voluntary Agreement, there was discussion about if the conditions were such that the U.S. maintained the registration or registered canola or the re-evaluation was positive and a tolerance was set, and Canada--the outcome of Canada's Special Review was positive, then lindane could be reinstated.

So, I don't think this is news at all. I think what it shows me is JoAnne Buth is trying to be prepared, as she always is.

Q. I agree. I agree that she's trying to be prepared. All right.

I'm turning now back to your second Affidavit at Paragraph 17.

"As I've reviewed in my first Affidavit as of

10:41 March 1998, following a tip-off by a Chemtura subsidiary," it says, "the U.S. EPA announced that all imports of lindane-treated canola seed would be stopped at the U.S. border as of June 1, 1998. This news did not come in isolation. It was directly related to all of the negative news emerging about lindane as of that time."

I just wanted to ask for your clarification on what that means. How was the tip-off by Gustafson related to negative news emerging about lindane? By "negative," I assume you mean negative environmental news or something, but I'm asking for your clarification.

A. Yes. Well, from my perspective, this news really relates to the announcement that EPA wouldn't allow the import of lindane-treated canola seed, and I mean, that was announced around the same time that there was a lot of concern about lindane internationally, and as well as environmental groups' concerns and so on. So, that's really what is meant there.

Q. All right. I'm going to ask you--I'm again going to go into that Joint Hearing Bundle book. It's Volume 2 again, but I'm now at Tab 42 of it. That is--well, it's Exhibit B-6 in the record, but Tab 42 of Volume 2 of the Joint Hearing Bundle. It's a letter from Lynn Goldman of the EPA to someone called Peter Scher, Special Trade Ambassador to USTR, and in it Ms. Goldman is reviewing the issue of the canola treated seed matter.

10:44 I'm focusing on the first paragraph in the--in that letter. It starts--it's not a great copy, so I apologize, but it says, "There are, however, a set of issues concerning differences in pesticide product availability, use, and pricing."

Do you see that?

A. Yes, I do.

Q. "We are told that these pesticide issues are exacerbating the dispute over trade practices. EPA is prepared to take specific actions which are consistent with our already significant bilateral harmonization efforts and which should reduce friction over pesticide issues."

"One of the most pressing issues for our Northern state growers is the greater availability in Canada than the U.S. of approved pesticides for canola, flax, dried beans, and lentils. While this disparity is real, we believe it exists primarily as a result of private marketing decisions by pesticide producers. U.S. and Canadian registration evaluation practices and standards are quite similar in scope, focus, and effect. But the market for pesticides used on these crops, particularly canola, is substantially greater in Canada than in the U.S."

Have you seen that document before?

A. Yes, I have.

Q. Oh, okay. Good. You're familiar with it.

10:46 As you read that, would you not agree with me that that is in direct reference to the issue that arose following the tip-off by the Chemtura subsidiary?

A. Well, as I read the whole letter, it's, in fact, much broader than that. Essentially as I understand that what Lynn Goldman is doing is reporting to the U.S. trade folks all of the activities that U.S. and Canada are carrying out to try and level the playing field or to try to deal with these nontariff trade barriers that, you know, are obvious, and what she's stating here is that obviously with canola, flax, dried beans, and lentils, there are some specific issues for the Northern state growers.

And interestingly enough, normally, the U.S. has the pesticide registrations before Canada because our market is so small here in Canada--less than 2 percent of the world market--most companies go to the U.S. first to get products registered. Canola is one of the few things that's different in that Canada is the largest grower of canola in the world, and so companies will come to Canada to register a product first. So, you know, I think it's broader than the question than what you mentioned, although it does certainly touch on in a number of areas the movement of treated canola seed, and certainly on Page 2 in the second paragraph it addresses that most directly.

Q. Yeah, and I appreciate that. I guess my point was

10:48 sort of the other way around. It was those parts of the letter that specifically mentioned canola and Canada-U.S. disparity arise because of the tip-off; is that right? I mean, would you agree?

A. Well, I mean, it is very likely that that is the case because they're really addressing the Northern border issue, but I don't know that for a fact. I mean, obviously there appears to be a relationship, but it's much broader. Her--Lynn Goldman's response is certainly not simply zeroing in on the canola seed treatment issue. She's really addressing the suite of potential pesticide trade-related issues.

So, I mean, I can't say yes or no, but obviously there is a link.

Q. Back to your Paragraph 17?

A. Which?

Q. Of your second Affidavit.

A. I'm there, yeah.

Q. I'm back to the last sentence in that paragraph, "This news did not come in isolation. It was directly related to all of the negative news emerging about lindane at that time."

A. Um-hmm.

Q. Just for my understanding, what news, the news that the EPA announced?

A. Yes.

Q. You're suggesting that the EPA announced that imports

10:50 of lindane-treated canola seed would be stopped because of the negative news emerging about lindane?

A. No. This did not come in isolation, that from the Canadian canola growers' perspective, it would be, oh, no, one more nail in lindane's coffin potentially, if I can put it like that.

Q. I appreciate that.

A. You know, that there's the international issues, there's countries getting rid of it. It's a key product for them. They have environmental groups after them to get rid of it. The sense that, you know, it doesn't really play into their healthy image or healthy oil, and then the U.S. is going to stop everything at the border. So, that really is what is meant there, as I indicated previously.

Q. Can I ask you to turn to Paragraph 78 of your second Affidavit.

A. Yes, I have it.

Q. I will just pick it up there. I note that with regard to one of the alleged conditions the Claimant ascribes to the Voluntary Withdrawal Agreement in its original Memorial, the Claimant has significantly changed its position. In its Memorial submission, the Claimant argued that the PMRA's position at that time was that a favorable outcome in the EPA's RED process would ultimately decide whether lindane could be used on canola in Canada."

10:52 With that in mind, could I ask you to turn to--go back to your first Affidavit and go back to Tab WS-28 in there. That's a letter from Dr. Franklin to Mr. Ingulli of Uniroyal.

Let me know when you have it.

A. I have it. I have them both.

Q. Oh, great.

All right. I'm looking at WS-28, first page, last paragraph, three, four lines up from the bottom, and it says--and this is written or signed, I'm sure, I'm sorry, by Dr. Franklin, but in your statement at the beginning of your first Affidavit, you said you wrote all of this correspondence in this regard, so you would have written this; is that right?

A. I may have; I may not have as well because it related to re-registration, so it may have been written by people more involved in that area.

Q. Well, in Paragraph 2 of your first Affidavit, the last sentence says, "I drafted all of the letters sent by Dr. Claire Franklin, then-Executive Director of the PMRA, concerning the voluntary withdrawal of lindane use on canola."

And then I see--

A. Well, I may very well. All I'm saying is there are other people in the organization, and because this deals with lindane, you know, I'm a bit gray on it. I can't exactly remember whether I did it, but it's more dealing with less a Voluntary Agreement and more re-registration, but, you know,

10:54 that's a small issue, to me.

Q. Well, the second sentence of the letter is, "Although the Voluntary Agreement does not promise," blah, blah, but fair enough. If you could help me with it, I would be grateful.

A. Yeah.

Q. The fourth line from the bottom, "The ultimate fate of the current lindane registration is in the U.S. and will be decided in the re-registration review."

Now, that's the basis for the statement in the Claimant's Memorial that you cite at Paragraph 78 of your second Affidavit, and I'm wondering if you can tell me what that meant, if not what Chemtura thought it meant.

A. I will just take a minute to reread this.

Q. Take your time.

(Witness reviews document.)

A. Well, my understanding of this is that that whole paragraph relates to the status of lindane in the U.S., not in Canada, so all of the those sentences in that paragraph deal with the status in the U.S. And I draw your attention to on the next page and Page 2 right at the top, what it's saying is what's going on in Canada, and what is said here is that the PMRA has recently announced a special review of all uses of lindane.

So, that's what that is. It's really documenting the status of lindane in the U.S. and where we are in Canada.

10:56 Q. Well, now, I could understand or arrive to that too. If that sentence said as follows: "The ultimate fate of the current lindane registration in the U.S. will be decided by the re-registration review." Because "Re-registration" is an American word for the "process."

A. Yes.

Q. But that's not what it say. It says the ultimate fate of the current lindane registration is in the U.S. The fate of it is in the U.S., okay?

A. Um-hmm.

Q. So, that's not how I read it.

A. Yeah. Well, I guess it's a bit unfortunate in a number of ways, but certainly it's in the paragraph that really deals with the U.S. status, and talks about lindane is undergoing re-eval through EPA. That current toxic database, that is not our database, that is the U.S. database, and what had EPA done, they required three additional toxic studies. There are some issues under the Food Quality Protection Act, and obviously the--what's going to happen with lindane in the U.S. is the U.S. responsibility and will be decided through the registration review. So, that would be my understanding of what that means.

And then in the following paragraph it talks about the Canadian status, which is fairly simple at that point in time and doesn't really talk about a lot of detail because it's

10:58 fairly early on, because that would have been just announced in March of '99.

So, in fact, we would have just announced it 10 days before this letter, so obviously we didn't have a lot more detail at that point in time on what was going on with the Special Review.

So, my understanding of this that one, two, three, fourth paragraph on that first page was to provide some detail on what's going on in the U.S. and that would have been taken from a U.S. document, so we weren't inventing this. This would have been information provided to us from the U.S.

Q. I'm going back to your second Affidavit, Paragraph 78, and just picking up text where I left off.

A. Right.

Q. Now, it appears that the Claimant is arguing its condition was that the PMRA would reinstate lindane use on canola if the U.S. EPA reached a positive decision prior to the PMRA completing its Special Review, or if the PMRA reached a positive conclusion in the Special Review.

Now, I will ask you to turn--and again I'm going back to your first Affidavit and at Tab WS-40 in it, and that's the letter to Dr. Franklin from Mr. Ingulli, October 27, '99, that we have already seen. In the fourth paragraph, which is Page 2 of WS-40, it says, "In the event that PMRA determines that lindane is safe to be used on canola as a seed treatment or EPA

11:00 should issue a canola tolerance or determine that lindane is exempt from requiring a tolerance in canola, Uniroyal shall request from PMRA the reinstatement. PMRA agrees to grant such reinstatement," and that was the letter. I assume you drafted the Agreement of because it went out over Dr. Franklin's signature the next day.

A. Um-hmm.

Q. So, since she agreed with the provisions--Dr. Franklin, I'm sorry, agreed with the provisions of this letter in writing, didn't that mean that either Agency, a positive outcome from which from either Agency would entitle a re-registration of the Lindane Products?

A. You will have to give me a minute on this one.

Q. Sure.

(Witness review document.)

PRESIDENT KAUFMANN-KOHLER: Ms. Sexsmith, we are waiting for your answer.

THE WITNESS: I know.

PRESIDENT KAUFMANN-KOHLER: You know, good.

THE WITNESS: I just wanted to make sure because there is a series of letters, and I just wanted to be very clear.

PRESIDENT KAUFMANN-KOHLER: That's fine.

THE WITNESS: So, yes, I know it's my turn.

(Witness reviews document.)

THE WITNESS: Okay. Yes, I apologize for the time. I

11:05 just wanted to make sure that I was clear, given the many letters that were drafted and responded to around that period, so...

Now, in my Affidavit, my first Affidavit, the response to your question related to Item Number 4 was essentially that particular request around reinstatement if, in fact, there was a positive finding concerning lindane.

BY MR. SOMERS:

Q. Just to be clear, by "positive" we mean lindane can continue to be used?

A. That's right, yeah, yeah, including the commitment around fast-tracking. You know, we didn't have any objection to that particular statement or set of statements, and it would apply equally not only to Chemtura, but to all of the four Registrants. And it really revolved around the need for the conditions for reinstatement to have been achieved, and that is, you know, the end result of a special review. And I guess we would note that those conditions were never achieved in that the Special Review in Canada was negative, the re-registration decision in the U.S. was negative. There was no tolerance granted in the U.S.

So, sorry for the time it took, but I just wanted to make sure that I was thinking about the right letter.

So, is that clear? Thank you.

ARBITRATOR BROWER: Could I ask you a question,

however.

THE WITNESS: Certainly.

ARBITRATOR BROWER: Because I thought or as I saw it the thrust of the question was that Paragraph 4 seems to say that action by the EPA in issuing a tolerance for determining lindane exempt from requiring a tolerance would alone require you to reinstate the lindane registrations, even though the review was ongoing.

THE WITNESS: Yes.

ARBITRATOR BROWER: For how long would they be reinstated? There is no limitation indicated.

THE WITNESS: It would be until the completion of the review, because in the Special Review we were reviewing the canola uses as if they were still a registered use. And if under our Special Review we hadn't found any negative--any safety concerns, which we did, then in principle we would have had no issue in reinstating if a tolerance had been set in the U.S. But, in fact, through our review, we did have safety concerns, and when that happened, we would not have been able to reinstate because the conditions essentially had changed.

ARBITRATOR BROWER: I understand that, but the point that I thought was being made by or sought to be made by Mr. Somers was that, to the extent the EPA might have acted favorably in respect of lindane seed treatments before your process was concluded, you were willing to basically have your

11:09 action tied to and determined by the EPA. In other words, the EPA action could automatically reinstate in Canada some--

THE WITNESS: Only related to the tolerance--excuse me, sorry.

ARBITRATOR BROWER: I understand. But that's all that was needed in the United States.

THE WITNESS: And only if through our review we hadn't come up with some health or environmental safety concerns which, in fact, we did.

ARBITRATOR BROWER: I understand. But it's an issue of timing involved also.

THE WITNESS: Yeah, yeah.

ARBITRATOR BROWER: Okay. Thank you.

PRESIDENT KAUFMANN-KOHLER: Would this be a good time for a break? This or soon?

MR. SOMERS: No, this would be a good time.

PRESIDENT KAUFMANN-KOHLER: Fine. So, let's take 20 minutes.

And, Ms. Sexsmith, since you are under examination, I would ask not to speak to anyone about your testimony during the break.

THE WITNESS: Sure, that's fine.

PRESIDENT KAUFMANN-KOHLER: Thank you.

(Brief recess.)

PRESIDENT KAUFMANN-KOHLER: So, we are all ready, I

11:33 1 think you start again, Ms. Sexsmith.
2 Mr. Somers, if you are, you may please continue.
3 MR. SOMERS: Thank you, Madam Chair.
4 BY MR. SOMERS:
5 Q. Before the break, earlier this morning, we were
6 discussing about the removal of label uses in December of '99
7 for canola, lindane for canola seed treatment, removal of that
8 use in December '99, but the discretion that the Minister has
9 to not enforce the rule that would normally say pesticides can
10 only be used for label uses.
11 At the conclusion of the Special Review, the
12 Registrant Chemtura, and I assume others, were notified that
13 they would have an option. They could voluntarily withdraw and
14 enjoy a phase-out or, failing which, they would be terminated
15 wouldn't get any phase-out; is that right?
16 A. That's my understanding, yes.
17 Q. The discretion that you testified to that the Minister
18 had to enforce or not could as equally have applied in that
19 situation, could it not? So, even where a Registrant would not
20 voluntarily give up a registration, the Minister could have
21 allowed a phase-out or could have prescribed a phase-out rather
22 than a cold termination and cessation of all sales; isn't that
23 right?
24 A. Well, in fact, the offer on the table was to provide
25 that, and three Registrants took PMRA up on that. It was

11:36 Chemtura that did not.

Q. Right.

But consonant with the approach of PMRA that you described earlier of equal treatment, wouldn't it have been, well, at least possible for the Minister to say, "Well, you're getting terminated and you will get the phase-out, too," rather than have them have to volunteer. Wouldn't that have been within the enforcement discretion of the Minister?

A. Well, I guess when you talk about equal treatment, it would be for equal things. And, you know, as I understand it as a result of the Special Review, three out of the four Registrants agreed with the PMRA proposal, and so got treatment X, whereas Chemtura didn't, and so, under that situation, there was no opportunity for phase-out.

Q. Well, I'm going to suggest a correction to that statement: There was an opportunity for phase-out, but PMRA refused. It was possible to do legally. It was just not done. It was a decision on the exercise of discretion.

A. Well, I would say the offer was on the table equally to all four Registrants, and Chemtura chose not to take the offer of the phase-out.

Q. I was particularly taken by your--just now when you said equal treatment for equal things.

A. Um-hmm.

Q. Because I think it's reasonable to characterize the

11:37 Registrants as being rather in unequal positions in terms of what they were giving up, whether voluntarily or by order of the PMRA, in terms of their relative investment and size and, therefore, corresponding penalty of giving up.

A. Mm-hmm.

Q. The other thing is that, would it not be--would it not pose the greatest disposal problem for the Registrant with the biggest market share and, therefore, the biggest inventory and the biggest amount of lindane in the system to be terminated abruptly and not be allowed to phase its product out? Would it disproportionately impact that Registrant by giving them a huge disposal problem, so not only can they not make the sales, but they have to incur expense with by far larger a volume of material than all of the others put together?

A. Well, then I reiterate the issue that PMRA put on the table resulting from the Special Review which found unacceptable risk that provided for a phase-out period that Chemtura chose not to take.

Q. Yeah. And on the point of, I guess, unacceptable risk, for the PMRA to have allowed the other three Registrants to continue to sell suggests that the risk wasn't as imminent or urgent as what an absolute termination would have suggested or, put another way, if it the risk was imminent or urgent like that, it wouldn't make any sense to allow the voluntary withdraw and accompanying phase-out.

11:39 A. Well, that's quite true. Under situations where there is an urgent risk situation, you know, absolutes will come into play. But typically for older products that have been on the market for a long time, the whole purpose of re-evaluation is to examine those products and make sure they meet current standards, and in this case lindane did not. And so a reasonable course of action is that it can be allowed to be phased out of the marketplace as opposed to, you know, an urgent kind of action with imminent risk. And this is quite a normal process for regulatory programs all over the world.

The issue, I think, on the table is, that Chemtura was offered the phase-out and chose not to take it. So, other action had to be taken.

Q. I understand that. But there were choices. It didn't have to be that particular action, did it? It could have been, yes, you're terminated and phase your stuff out. Because if there was a risk associated with the product causing either termination or soliciting a voluntary withdrawal, creating a disposal problem increased the risk. It didn't reduce it.

A. Mm-hmm.

Q. So, I guess I don't understand how the refusal to exercise a discretion assisted in the management of risk. If anything, it accentuated it by, if I could put it this way, playing hard ball?

A. Mm-hmm.

11:41 Q. Didn't it?

A. Well, I don't see it that way. I think Chemtura had the same options that the other Registrants had. They chose not to take it. PMRA was left with no option, given the unacceptable risk issue. They had to take a stand and take an action, and so that's what was done.

ARBITRATOR BROWER: May I ask a question or two at this point.

THE WITNESS: Sure.

ARBITRATOR BROWER: At the time the registrations were revoked, the Special Review had not been completed; is that correct?

THE WITNESS: No, it had been completed.

ARBITRATOR BROWER: It had been completed?

THE WITNESS: Yes, it had been completed.

ARBITRATOR BROWER: Right. You, PMRA, the Minister, however, would have had discretion, I assume, to permit a phase-out a use of an existing inventory as had been done with the other Registrants.

THE WITNESS: That's correct.

ARBITRATOR BROWER: Okay.

THE WITNESS: And that was the option that was provided to all of the Registrants--

ARBITRATOR BROWER: Right.

THE WITNESS: --at the end of the Special Review,

11:42 given that the risks were unacceptable for that product to continue.

ARBITRATOR BROWER: Right.

THE WITNESS: And so the issue that--the option that was put on the table was that if they came in for a voluntary discontinuation, they would get a phase-out period. The product would be discontinued and then phased out.

ARBITRATOR BROWER: But would it be a fair conclusion that the refusal to exercise discretion to permit Chemtura to sell that plant--it's inventory, let's put it that way--was based solely on its refusal to have cooperated in the Voluntary Withdrawal Agreement?

THE WITNESS: Yes, yeah.

ARBITRATOR BROWER: That's what--

THE WITNESS: Yeah. I mean the option was on the table that this was one approach, and they chose not to take that approach.

ARBITRATOR BROWER: And was--well, then, I think the answer to my next question, in light of what you just said, is probably clear, but I will ask it nonetheless. And this decision not to permit a phase-out because, as you say, Chemtura failed to cooperate with a Voluntary Withdrawal Agreement was done without consideration of the environmental impact of the inventory having to be burned or otherwise disposed of as opposed to being planted? Because we heard a

11:44 number of statements to the effect that the environmentally correct way of disposing of something like this is to plant it and not to burn a big pile of it.

THE WITNESS: Mm-hmm, yeah. And that's often what is done at the end of the life of a product, or even under special circumstances, as was done in 2002 with the leftover lindane-treated seed. But in this particular case, that option was there for Chemtura to take up, and they chose not to take it up. Yeah.

ARBITRATOR BROWER: We understand that.

I just had--maybe getting ahead of this, but so this will be the last question for the time being, I think a complaint of Chemtura is that its application to register CS FL was treated rather slowly by comparison to the Helix. Was the failure of Chemtura to have cooperated, as you saw it, in the Voluntary Withdrawal Agreement a factor also in the exercise of PMRA's discretion in relation to how that application for CS FL was handled?

THE WITNESS: No. But I just want to make sure I understand what product you're talking about. Is that Gaucho?

ARBITRATOR BROWER: It's the all-in-one Gaucho.

THE WITNESS: Okay.

MR. DOUAIRE de BONDY: Judge Brower, would you mind if I jumped in?

ARBITRATOR BROWER: As opposed to the two that were--

11:46 THE WITNESS: Oh, the earlier one, the earlier two.
ARBITRATOR BROWER: The two earlier ones, yes, I'm sorry.
THE WITNESS: Yeah, okay.
MR. DOUAIRE de BONDY: If I could just jump in. I think we are speaking at cross-purposes here because the voluntary withdrawal that Ms. Sexsmith is referring to is actually the withdraw that occurred over 2001, 2002, in relation to the determination that the lindane did not meet acceptable use standards. That was in October of 2001.
ARBITRATOR BROWER: Right.
MR. DOUAIRE de BONDY: And so it's the withdrawal with regard to the non-canola products, and so that's what she's talking about, as opposed to the separate Voluntary Withdrawal Agreement relating to lindane use on canola, which had been determined in '98 and happened through to 1991. So I believe that Ms. Sexsmith is actually referring to the withdrawal at Exhibit WS-61 and 62 of her Affidavit with regard to Chemtura's refusal and so on.
ARBITRATOR CRAWFORD: Could I follow up.
THE WITNESS: Yeah. Can I just make sure I've answered this particular question.
ARBITRATOR CRAWFORD: Of course.
THE WITNESS: I mean, if you're saying that because Chemtura was a little reluctant, I guess, at the outset to be

11:47 part of the canola growers Voluntary Agreement, did that impact in any way on our review process, the answer is no. I mean, one of the things about being a regulatory organization is, you know, essentially, we don't have personal views. We're professionals, and we're trying to meet time lines, trying to make sure we get good information so we can do good science, scientific assessments to make sure we are protecting the public, yet providing benefits to Canadians.

And, you know, certainly I stand behind the organization when I was there in that everybody was highly professional and had no personal view that would evoke itself in our registration decisions.

Sorry, so that...

ARBITRATOR CRAWFORD: Am I wrong? My understanding is that the terms of the Voluntary Withdrawal Agreement in terms of the phase-out period for lindane on canola remained in force after the decision of the PMRA.

THE WITNESS: Can you repeat that again? Sorry, I just lost the front of it.

ARBITRATOR CRAWFORD: Certainly. My understanding is that the terms of the Voluntary Withdrawal Agreement which allowed a phase-out until mid 2001 remained in force for Chemtura throughout. That was never revoked.

THE WITNESS: In that the aspects of them asking us to remove the canola use for lindane from their label, the answer

11:49 is yes, yeah; and in that production had to stop in December '99, the answer is yes; and, you know, the use was supposed to stop planting and--product use as of July 1st, 2001, the answer is yes. Yeah.

PRESIDENT KAUFMANN-KOHLER: When you say that there was an offer to phase out for all four Registrants and Chemtura did not take it, this does not refer to the Voluntary Withdrawal Agreement of either '98 or '99, depending on what version you adopt, but it relates to what happened later in 2001 or even 2002 with respect to non-canola uses; is that right? Because I was just confused about your statement.

THE WITNESS: Mm-hmm. Yeah, no, that's absolutely correct, that under the Pest Control Products Act and Regulations at this time, there were certain sections that are used with regard to (a) registration; and, (b) taking products off the market. And in this case, it was, I think, Section 13--anyway, Section 13, I think, and--let's see. Let me just make sure I've got this right.

No, it would be--Section 16 would be used, and if I could read this, it's just the language that is used in the legislation and in the Regulations, and this is Exhibit, as counsel referred to, WS-62 in my first Affidavit, and it talks--this is a letter to Chemtura.

MR. DOUAIRE de BONDY: WS-61, actually.

THE WITNESS: I'm sorry, yeah. WS-61.

11:51 And it's, "Should you choose to voluntarily discontinue sales of your product, as indicated, we request you notify the Minister in accordance with Section 16 of the Pest Control Product Regulation by submitting a letter in accordance with the model letter attached by a time frame."

And so this was essentially after the Special Review was completed, unacceptable risk was found, and Registrants were then--all four of them or more, because there were more Registrants of lindane than Registrants of lindane and canola. So all Registrants who had a lindane product would have been notified that as a result of the Special Review, risks unacceptable, termination of products required, this is a way to do it, and you do it under Section 16.

And it was indicated in that letter that if you don't respond that way, action will be taken under the authority of Section 20. So, this, you know, legal counsel is quite right that this does not refer to the Voluntary Agreement. And sorry for the confusion. It's really the language in the Regulations that used those words.

PRESIDENT KAUFMANN-KOHLER: No, but it is clear now.

THE WITNESS: Okay.

PRESIDENT KAUFMANN-KOHLER: You can continue, then.

MR. SOMERS: Thank you.

ARBITRATOR CRAWFORD: Sorry. Do we have in the record a request by Chemtura for phase-out, notwithstanding the

11:52 withdrawal of the registrations for the non-canola products?

MR. SOMERS: I'm sorry? Was that to us?

ARBITRATOR CRAWFORD: That was directed to you.

Is there in the record a request from Chemtura to the PMRA for a phase-out period for the non-canola products which would be registered as a result of that decision?

MR. SOMERS: I can't name the exhibit number, but there is correspondence from Chemtura in--along with the PMRA's demand to Chemtura to withdraw its non-canola products, was a request for various inventory levels and quantities remaining. The purpose of that--

THE WITNESS: It's WS-62 and 63, if that helps. Where you have made the--you've responded to that by providing the five-year sales figures, but you only say that you don't agree with the Section 16 approach.

ARBITRATOR CRAWFORD: That was my point.

THE WITNESS: Yeah. But no action, no additional information was in the letter about wanting a discontinuation or phase-out.

MR. SOMERS: No, I mean--

THE WITNESS: Yeah.

BY MR. SOMERS:

Q. Well, I don't want to argue with you, this will be for my argument, but why else would a Registrant have put in amounts?

11:54 A. Well, all Registrants were asked to be provided with amounts.

Q. All Registrants were asked to withdraw as well; isn't that right?

A. Yes, they were. Yes.

Q. Okay.

I guess I would like to maybe put a hypothetical on that. I'm still on the non-canola here. We are in post October 2001. PMRA has made a request of all Registrants to withdraw their non-canola products. The benefit, as expressed by PMRA, for doing so will be the ability to phase out their existing product and use it up both environmentally and financially soundly, if I can put it that way. Since Chemtura refused, it was given a cold termination and no opportunity for phase-out. The PMRA had--if you disagree with me, you let me know. The PMRA had the information as to the inventories and quantities that Chemtura would have had to dispose of, whether by, in your discretion, allowing them to sell the material or dispose of through less environmentally sound and more costly disposal procedures, so you knew those quantities as well.

A. Yes, we knew the quantities because you provided them.

Q. Right.

In terms of the promotion of equal treatment, was it not open to the PMRA to tell all four Registrants rather than volunteer and get the carrot, don't volunteer and get the stick

11:55 rather than that just tell them?

A. Well, I'm actually going to have to ask legal counsel for--to provide me with a copy of Section 20 of the PCPR.

Q. Well, excuse me, but before you do that--

A. Yeah, in order to answer your question, I just have to have a quick look because unfortunately it doesn't seem to be in my package.

Q. No, but I'm asking for your knowledge of the situation. In your senior position at PMRA and your knowledge of the Minister's scope of discretion, could he not--and this will not be in the statute, I don't think--could he not--or I'm sorry--she not have allowed directed the termination--just as you did for Chemtura at the end of the day--but directed the termination of all Registrants' registrations for non-canola Lindane Products and allowed to them phase out?

A. Well, as I said before, that was offered to Chemtura as it was offered to all Registrants. And Chemtura, for their own reasons, decided not to take that offer up.

Q. Yes, we understand.

A. So, the option for the Minister at that point was to use Section 20.

Q. One option, one option because they also had the discretion, or PMRA actually, I will say, obviously had the discretion to deviate from that just like they did for nonlabel uses in 1999.

11:57 A. Yeah, just excuse me for a second.
Q. Mm-hmm.
(Document handed to the witness.)
A. So, your question again? Sorry. As I've answered parts of it. I'm just not sure what's left.
Q. Was it not open to the Minister to give all four Registrants the same proposal which is your product shall be terminated and you shall phase out all of your existing inventories? Was that not open to the Minister? Equal treatment.
A. Well, you know, and we have sort of an ongoing disagreement here that the Minister did provide equal treatment to the Registrants. The option was to come in under Section 16, and which would allow for a phase-out, and that was not done. Chemtura refused that option.
Q. Yes, I understand that. What I asked you was something entirely different.
A. Mm-hmm.
Q. My question was: Couldn't the Minister have done it a different way in using her enforcement discretion, have put the same proposal to all four Registrants, which was your lindane registrations as a result of the Special Review will be withdrawn and you all have a phase-out period? Was that not open to--
PRESIDENT KAUFMANN-KOHLER: There are not four

11:59 Registrants for the non-canola uses. There are many others.

THE WITNESS: No, they're many Registrants.

MR. SOMERS: Excuse me, thank you. Thank you for the correction.

THE WITNESS: Yeah.

The only way that could have been done, the Minister would have had to cancel or suspend those registrations.

BY MR. SOMERS:

Q. And certainly the Minister wouldn't above doing that to give it to Chemtura, so could that not have been done for all of them?

A. Yes, it would be possible.

One of the issues, though, around cancel or suspend, that really is code--that is not code. Those are the real legal words for the word "ban." Many Registrants do not like their products to have been banned. Most Registrants like their products to have been withdrawn, taken off the market by themselves, and that's a--really a business reason relating to their good name as Registrants.

So, the first line that PMRA uses in re-evaluation is offering up that possibility to a Registrant. Many Registrants do this on their own because of their own issues. For example, DuPont took benomyl off the market throughout the whole world before any country could use that word "ban," and that was because of several studies relating to babies being born

12:00 without eyes, and it was linked to benomyl. So, DuPont, worldwide, took the product off the market, but nowhere can anybody say that it was banned.

So, the point of Section 16 is to provide that opportunity for Registrants. And for the most part, when an unacceptable risk is found, companies are very interested in following up with taking it off the market as opposed to being canceled or suspended, which is really what the outside world calls "ban."

So, yes, it's possible.

Q. I appreciate that.

A. But the common man approach in regulatory authorities is to use this vehicle where companies come in themselves.

ARBITRATOR CRAWFORD: It would have been possible under Section 20 of the Act for the Minister to de-register the product on terms and conditions, which could have allowed a phase-out.

THE WITNESS: But that's right. This is what I'm saying, but it would have been canceled or suspended.

ARBITRATOR CRAWFORD: Yes.

THE WITNESS: Which is equivalent to the word "ban." And frequently, if not always, companies like to avoid that word because it has negative connotations. If they come in and withdraw it, there is no banning.

ARBITRATOR CRAWFORD: You have explained why you

12:02 offered the Section 16 to the Registrants; I can see that entirely. What you haven't explained is why you didn't consider--

THE WITNESS: Mm-hmm.

ARBITRATOR CRAWFORD: --the Section 20 possibility of a phase-out for the Claimant, and I asked whether the Claimant had asked for that phase-out.

THE WITNESS: And they did not. Nowhere in the correspondence is it in evidence. They said that they disagreed with the reason for termination or that it needed to be terminated, but they didn't provide that.

BY MR. SOMERS:

Q. Could I ask for--I'm shifting gears a little bit here, going on to a different subject. Could I ask for Exhibit 71 to Chemtura's reply to be given to you. I don't think you have it in front of you. It's Exhibit 71 at Tab 71 of the confidential book of exhibits to the Reply of the Claimant, Volume 2 of 2.

ARBITRATOR CRAWFORD: Volume?

MR. SOMERS: Unfortunately it's not in the Joint Hearing Bundle.

Volume 2 of 2, that's right.

BY MR. SOMERS:

Q. The document is a thread of e-mail. The e-mail I'm referring to is the e-mail from Wendy Sexsmith to Lois Rossi of the U.S. EPA of November 13, 2001.

12:04 MR. DOUAIRE de BONDY: I don't believe that the Claimant has provided a copy of this for the witness and therefore--

MR. SOMERS: No, we haven't.

MR. DOUAIRE de BONDY: Do we have it now?

MR. SOMERS: Tab 71.

ARBITRATOR CRAWFORD: It would be good to read it into the record.

MR. SOMERS: Thank you. I will.

BY MR. SOMERS:

Q. Do you have it in front of you now?

A. Yes, I do now. Yes, um-hmm.

Q. Okay. The part I'm asking you about is the e-mail from Wendy Sexsmith to Lois Rossi dated November 13, 2001. It starts, "Hi, Lois"--no, I'm sorry. It's dated November 6 of '01.

A. Mm-hmm.

Q. "Hi, Lois, was nice to meet with you yesterday. I have attached a Lindane Exposure Assessment piece as discussed. Also just as a note, I presume you require for a tolerance petition the submission of a current registered label for uses in the exporting country. With respect to the canola lindane tolerance petition that you have received, there are no currently registered uses for lindane on canola in Canada, and therefore no currently registered label in Canada available for

such a petition."

If I look up the e-mail as well to the one at the top, the e-mail gets forwarded, as we can see, by Lois Rossi, and then presumably to Betty Shackleford who, in turn forwards it to Mark T. Howard of the EPA, so the document travels through the EPA.

A. Mm-hmm.

Q. Marty says: "Betty, I ran a quick compare between the Wendy Sexsmith attachment and the one PMRA had given me earlier. They are the same, so they haven't changed anything between the time I got the Exposure Report from Jeff Parsons and now."

So, presumably, and I will ask you if you can remember and you can confirm for me, the attachment that you sent to Lois Rossi, the Lindane Exposure Assessment piece, had already been forwarded to the EPA previously.

A. Yes. EPA and PMRA had been working closely together on all aspects of lindane re-registration/re-evaluation. And if I recall correctly, Lois Rossi was new, and I had been meeting with her, and there were some follow-up questions that I was providing answers to. And if I recall our discussion, we were just trying to make sure that EPA had the most recent piece of work from PMRA, and it seemed that they did.

Q. They did, okay.

A. Yes.

12:07 Q. And correct me if this is not so, but you say in the second sentence of your--third sentence of your e-mail, also just as a note, I presume you require, meaning Lois Rossi hadn't asked you for anything. You were volunteering this. You were presuming that she needed something and letting her know that you could not give it to her.

A. Yes. You know, I don't remember it very clearly, but that's certainly what that seems to say is that in our discussions it may not have come up, but normally a current label would be required from the other country to the reviewing country in order to establish an import tolerance.

And so all that would mean is they would be looking for an older label, not a current one, as they'd have to find some way of looking at the uses.

Q. Normally, wouldn't that come from the petitioner for the--

A. Normally, yeah.

Q. Why, then, were you advising her of something that would have been a dialogue between the petitioner for the tolerance and the EPA?

A. Well, often Registrants can't seem to find their labels, and so regulatory authorities are asked by Registrants for copies of their own label.

Q. That wasn't the case here, though.

A. No, but it's not uncommon for us to talk about, you

12:09 know, do you have a current label or lot, and we will have a look and see if we have one.

Q. But that wasn't the case here. You didn't talk about because you said I presume--

A. No.

Q. --it would be required.

A. No. No, you know, as a followup, that would be a logical train of thought relating to setting a tolerance in the U.S. for something that would be coming from Canada. Yes.

Q. Could I ask you to turn to your second Affidavit again, please, at Paragraph 81.

Do you have it?

A. Yes, I'm there.

Q. Did I say first? I think I said first. I meant the second Affidavit. I'm sorry.

Where we left off before.

A. Okay.

Q. Paragraph 81 begins: "I would first emphasize what should be obvious: The PMRA never agreed to reach either a positive or indeed a negative conclusion in the Special Review of lindane."

And I'm going to return to the rest of that paragraph in a second, but then jump down to the next paragraph, 82. There you say: "Moreover Chemtura's alleged expectation that the Lindane Special Review would reach a positive conclusion

12:11 was itself deeply unreasonable."

And I'm trying to reconcile those two, and I'm hoping you can help. It was deeply--

A. Well, I guess I would reiterate that as a regulatory organization we don't decide before we do the scientific review as to whether it's going to be positive or negative, that the process has to be undergone and the resulting scientific results really are what drive the decision.

So, you know, it's not something that PMRA was in the habit of doing, which was, you know, we would never agree to actually registering something. We would agree to do the review. So, if we were asked, you know, "As a condition to do X, we need to have a registration by Y," we could never agree to that because the registration means a positive decision, and we could never agree at the beginning of a review of any product, be it old or new, that the decision at the end was actually going to be positive. So, we could never agree to that.

And so with lindane, we wouldn't agree either to a positive or a negative conclusion because we would not have known what the scientific review was going to tell us.

Q. I see. You wouldn't have known that but--

A. No.

Q. --but I guess what I'm trying to understand from you is why it was deeply unreasonable for Chemtura to think that

anything but a negative would come out.

A. Well, certainly the environment at that point in time for lindane was rather negative. It had been considered for the UNECE POPs, and through that, essentially countries agreed to do a reassess--or an assessment of all remaining uses, and that was happening at that particular time. Certainly, a number of European countries had eliminated lindane, and the E.U. itself was looking at lindane as a whole. So, those were some the negative issues.

The other things of course were the environmental groups in Canada were certainly very interested in lindane, so--and I think as I read through some of the Chemtura documents, it was clear in those even that information passing certainly from the Canadian office to the American office indicated that the future was bleakish for lindane. But, you know, you do never know what the outcome is going to be from a scientific assessment.

So, the environment was negative. There just is no question about that. That doesn't mean that PMRA as a regulatory organization would go into a scientific review assured that the outcome would be negative.

Q. But you recall the exhibit we looked at before, WS-90, where JoAnne Buth is asking whether the manufacturers can ramp up quickly and reintroduce lindane in the event of a positive outcome, and she was at the Canola Council.

12:14 A. Mm-hmm.
Q. You wouldn't say that she was being deeply unreasonable, would you?
A. No. I think at that point that's good management, you know, to be aware of what the possibilities were, either way.
Q. But that was even later on.
A. Mm-hmm.
Q. That Wendy (sic) Buth e-mail was in January of '01.
A. Mm-hmm.
Q. You're not saying that the news about lindane internationally was getting better, were you?
A. Huh-uh, no.
Q. So...
A. And I guess the point here is that PMRA was neither firm on the fact that it would be registered or that it wouldn't be registered, but Chemtura was certainly very certain that it would be registered or would remain registered.
And I guess from a regulatory point of view, given the uncertain environment that was surrounding lindane, that didn't really seem reasonable that there should be some doubt, and it wasn't evident except in some of the early correspondence that Chemtura was aware and thought that lindane may be coming to the end of its life worldwide.
Q. I suppose you're saying--that reminds me of the exhibit we looked at earlier in the joint book--of the joint

12:16 hearing book, about the commitment between you and the EPA to phase out all uses of lindane. That would be--that would follow along the same--

A. Yeah, and I think what I did was explain that that was virtually a bulleted form of a note, and the intent of that was really EPA and PMRA needed to work together on lindane, period. And the other language that followed is less important than the issue of working together because of our interest in harmonization and leveling the playing field and removing nontariff trade barriers between the two countries.

Q. I'm now turning to that same joint hearing book, but a different tab: Volume 2, Tab 74.

Do you have it?

A. Yes, I do, yes.

Q. Do you recognize the document?

A. Yes, I do.

Q. And is the handwriting on it yours?

A. No.

Q. Do you know whose it is?

A. No.

Q. Could you turn the page, please, and there's two pages of notes that are attached to that Lindane Agenda.

A. Um-hmm.

Q. Exhibit--it's Exhibit 62 to a Chemtura reply.

Do you recognize that handwriting?

12:18 A. No, I don't. Sorry.

Q. All right. On the first page, Lindane Agenda, it reflects a meeting happening January 19th, 1999, at which you attended.

A. Yes.

Q. And along with the other individuals that I assume are listed and assigned various agenda responsibility on the top there.

A. Yes.

Q. To your recollection, were there any other persons at the meeting?

A. I don't recollect, frankly.

Q. All right. You have no reason to think there was.

A. No, I have no reason to think there was, but quite frankly, I apologize I can't recollect this specific meeting.

Q. On the first page, there's a notation, a handwritten notation, that says "return letter"--that's number one immediately typed to "next steps," "return letter, skip and stick value and efficacy to them."

Does that mean anything to you?

A. No, it actually doesn't. I have no idea what that means.

The--I mean, the one thing I could say is that one of the differences between Canada and the U.S. is that Canada requires efficacy data and also reviews it, and it's very much

12:20 an integral part of our decision-making process. The U.S. does not require efficacy data to be submitted, nor do they review it.

And so one of the issues we had consistently under our approach to harmonization was how were we going to--what role would efficacy play in any joint decision-making? So, this may be just a reference to having a conversation with the U.S. on the efficacy issue, and that's the only thing I can think of, because if we are doing something jointly and the U.S. doesn't review efficacy and we do, what are we going to do with that information in a joint decision? So, that was a perennial issue that we had, and that may be all that that is referring to, was flagging a key difference between the two countries.

Q. Turning to the next page now, and I'm looking at Item Number 4 on that page: Special Review, not re-eval. You can see that.

A. Yes, I can.

Q. So the discussion at this point is turned to the Special Review itself. So this would have been...

A. Yeah, the re-eval. notice came out in March.

Q. Right. So that's sort of in the lead up to the preparations for the public announcement of the Special Review.

A. Yeah. One of many, I would say.

Q. And the third bullet under that states: No Data Call-In.

12:22 So, already in January, it would have been decided that the PMRA wasn't planning to do a Data Call-In for the Special Review. It was going to rely, for example, on EPA data.

A. Well, I think, actually, that this refers to reminding staff that we were looking at a new approach to do re-evaluation, that the policy we were looking to put in place was really to build an approach that allowed us to re-evaluate older chemicals in a much more efficient and effective way.

The background for that is probably over the years leading up to the formation of PMRA, only a handful of chemicals ever did get re-evaluated because the pressure was always on the new products and only in very key issue areas was there re-evaluation. That was a concern to ourselves as an organization responsible for making sure products on the market were acceptable.

And it was also an issue for our people, the people who audited us in Government and our--some of our stakeholders. So, we were looking at a much more efficient way to do this without using up all our resources on old products.

And a key part of that was to gather up all of the information we could from other countries, and what I mean by that is scientific reviews and so on. So, the first step would not be a Data Call-In. And in the old days, as one might say, the first step was always a Data Call-In.

12:24 So, my interpretation of this was that at the meeting it had been reiterated that in the new approach to re-evaluation, the Data Call-In would come later, that our first would be try to find, get as much information from other countries and from within all organizations so that the Data Call-In would be the next step as opposed to the first step, if it was needed.

Q. Was the Data Call-In the next step?

A. You know, and I'm substantially removed from the re-evaluation process so--

Q. Aren't we talking about the Special Review here?

A. Yeah.

Q. Okay.

A. Yeah.

Q. But--

A. But the first step was not a Data Call-In, and that's what that refers to.

Q. But at the top of it, it says "Special Review not re-eval." So, I'm assuming that when you're saying, "I'm removed from the re-evaluation process," so that has no pertinence here because it's a Special Review, not--

A. Oh, yeah, sorry. It's a lingo issue.

Q. Yes.

A. A special review is a type of re-evaluation.

Q. Even though it says not re-eval, it is?

12:25 A. Yes. That the umbrella would be re-evaluation of older products, for example. A special review tends to be a more specific type of re-evaluation, okay.

And as opposed to the old days, the first step would be to gather information from other countries to see what data--

Q. Yes, I understand that.

A. --we would then need through a Data Call-In.

Q. That was your fulsome answer.

A. Yeah.

Q. What I'd asked, was there a subsequent step as a Data Call-In?

A. Well, normally there would be if, in fact, the data was needed in the normal process.

Q. And today we're talking about the Lindane Special Review.

A. Yes.

Q. Was there one there?

A. I believe there was. But as I say, I wasn't involved in the day to day, so you've had other people talk about the process and were much more intimately involved than I.

Q. Okay.

You were not--you're not particularly involved in the Special Review?

A. Only at a very high level from a senior management

12:26 perspective.

Q. On the third page of this exhibit, under item seven, you're mentioned Wendy Canola Council, under item seven, about the fifth bullet down.

A. Right. And that would just refer to the fact that I was designated as the contact for the Canola Council--

Q. Right.

A. --because of the importance of the issue.

Q. And the agenda itself, you're given responsibility for status--I'm looking at the first page, Item 1--status U.S. activity and feedback; item two, status of voluntary removal and documents. And there it's written in handwriting "in-principle agreement," and we are in January 19, 1999.

A. Mm-hmm.

Q. And this is an internal meeting where presumably people are free to let it all hang out, so the volunteer--would that be the Voluntary Withdrawal Agreement since--

A. Yes, it was, yeah.

Q. And it's considered an in-principle agreement there?

A. Yes. Those are words that were used by PMRA and also by some of the Registrants, and it just meant it was an agreement.

Q. But they qualified the Agreement by saying "in principle"; they added words.

A. Mm-hmm.

12:27 Q. There must have been a reason that it was--perhaps that it was an agreement in principle?

A. Well, we used the words because, from our perspective, it was an agreement in principle, but we couldn't implement until the Registrants all came in, and so it was still early days yet. The Agreement had not been implemented. Some of the other Registrants used the same wording, "agreement in principle." Chemtura did not, but a number of the other Registrants just used that series of words, and I don't think it meant anything subversive. It just meant we agree, and, you know, we're waiting to see if it gets implemented which, in fact, it did, ultimately, because this was before the submission of the--from the Registrants to have the canola uses removed.

Q. I guess the way I would understand the word "agreement" would be they would agree to submit at future X date, and then when they finally did submit, that would be implementation of an agreement.

A. Um-hmm.

Q. Prior to that, there would have had to have been an agreement--

A. There was an agreement, and they agreed in principle. You know, I mean I can't say why Zeneca used those words but they did, and some of the other Registrants used those words.

Q. Well, I'm talking about the PMRA people.

12:29 A. Yeah, we used those words, too, but our reason for our using them is we agreed in principle, but the implementation had yet to take place.

Q. I understand that.

A. Yeah.

Q. And finally, you were also indicated on the agenda as assigned with the position/communication on lindane in item seven.

A. Um-hmm. And that just meant that I was the final sign-off before Dr. Franklin. That doesn't mean I did everything.

Q. Do the numbers--I'm looking at the third page now, and if I see that the numbers go to number--up to number seven, do those--one, two, three, four, five--and the handwritten notes correspond with the numbers on the agenda? I'm not sure that they do.

A. It doesn't look like it.

Q. Okay.

A. As there is no eight, and it looks like seven is actually eight.

Q. I see. All right.

A. Or it looks like it's mixed up. I don't--frankly, I don't really know.

And five is talking about categories, and five on the agenda is the international stuff, so I don't think there is

12:30 any--

Q. Obviously not.

A. --coordination at all.

Q. In handwritten item seven on the last page, the last two bullets state, "Communications JoAnne and Wendy," and then "close the door on all."

A. Frankly, I have no idea what that means. The communications, JoAnne was our senior communications advisor and so it would just mean that I'd be the Senior Manager working with her on developing any communication pieces which, in fact, was never done related to the Voluntary Agreement.

Q. I'm turning back to your second Affidavit, Paragraph 82.

A. Okay, I got the wrong one here. Okay, 82, you say?

Q. Yes, Paragraph 82.

At the top of Page 35, which is the end of, you know, the end of that paragraph, the last sentence in it, you say, "in such circumstances"--well, I will step--go back a couple of sentences to get the context in there--the circumstances that you allude to, at the bottom of Page 34. The last sentence on that page is, "indeed, the U.K. PSD's decision to ban lindane on the basis of occupational exposure was announced in June 1999. An E.U. review was known to be underway, and the U.S. EPA had just launched its own review of lindane. In such circumstances, the Claimant's alleged expectation that the

12:32 outcome of the Special Review would be positive strikes me as willful blindness." In other words, Chemtura should have expected a negative outcome.

A. Well, I think as I've said before, I think they should have understood there was some possibility for a negative outcome.

Q. Oh.

A. Which really didn't seem to be apparent except in some of your earlier communications from some staff in Chemtura.

Q. You're aware of the outcome from the 2002 RED at the EPA.

A. Um-hmm, yes.

Q. Where the existing lindane registrations were eligible for re-registration.

A. Um-hmm, but I'm also aware of the 2006 decision where everything was gone.

Q. But I think the expectation we are referring to is contemporary in the sense that I don't think even Chemtura couldn't have predicted what would happen in 2006, but at around the times we are talking about here, which is in the course of the Special Review, so between '99 and 2001.

A. Yeah, but I think people need to understand the process that the U.S. uses. They put out a draft, you know, saying, "This is kind of what we found, give us some more information." And based on that, in 2006, all uses were taken

12:33 off the market in the U.S.

So, what I mean here is really there should have been an expectation of the possibility of a negative outcome.

Q. Can I--I'm turning to Paragraph 85 of that second Affidavit.

A. Okay.

Q. The second sentence is, "the PMRA registered the products"--now, this is in reference to replacement--lindane replacement products related to the voluntary withdrawal.

A. Yes.

Q. "The PMRA registered the products that were put before it by Chemtura as lindane replacement products." To clear up one area of confusion sown by the Claimant, there were two categories of products under consideration as of November '98: "Lindane-free products, i.e., products that had originally contained lindane but that registrants were re-submitting for approval with the lindane simply removed."

A. Yeah, and this is where that change that was made right at the beginning should read fungicide-only products.

Q. Right.

And the second bullet, "lindane replacement products, products that contained an active insecticide other than lindane; for example, imidacloprid and Gaucho, thiamethoxim and Helix."

A. Yes.

12:35 Q. I wanted to--to go into the approval process for Helix a little bit, and in order to do so though, I need to have a letter from Ms. Franklin's statement put in front of you. It's in the Joint Hearing Bundle at Tab 57 of Volume 2. It's also in Ms. Franklin's statement at CF-25.

A. Right.

Yes, I have it.

Q. All right.

Did you write this letter?

A. No.

Q. Oh, all right.

Are you--have you seen it before?

A. Yes.

Q. Oh, okay.

I'm looking at the--this is dated November 18, 1998, so it's, you know, at around the time of certainly discussions about the Voluntary Withdrawal Agreement. And at the fourth paragraph it says, "the Novartis seed dressing Helix, which is an alternative for lindane in canola, and the associated OP replacement opportunities around the new insecticide active ingredient thiamethoxim, which is a component of Helix, represents the next level of advancement. You are probably aware that our respective staffs have been meeting with Novartis U.S. and Canadian representatives over several months. The cooperative outcome has been harmonized submissions in both

12:37 countries covering Helix as a replacement"--I'm sorry--"a lindane replacement for Canola, thiamethoxim as an OP replacement for a wide range of agricultural uses as well as turf nursery applications. There has been a great deal of consultation and planning invested in this initiative. The objective is harmonized registration decisions for Helix and thiamethoxim in a timely fashion, i.e, December 1999-January 2000. Clearly, this is an ambitious objective with tremendous positive potential which merits our full report--support," sorry.

Just, if you could help me understand what OP replacement--

A. Organophosphate and organophosphorus pesticides that comes under scrutiny because of the Food Quality Protection Act that came in the U.S. in 1997, which required all pesticides with a common mode of action to be assessed together. And they're--you know, in Canada we only had maybe 27 OPs, but in U.S. they had substantially more.

And it was a much more complicated Risk Assessment because normally we assess one pesticide at a time, and the resulting Risk Assessment relates to that one but the organophosphorous pesticides were considered to have the same mode of action. Therefore, the Risk Assessment had to add up each individual Risk Assessment so that if you had 40 different OPs, you had to actually add up the Risk Assessment. And in

12:39 order for those to remain registered, they had to come in at an acceptable risk with all of them.

Q. Of course.

A. So, it was a huge concern, and the chances of all 40 or 50 products that were registered in a particular country to actually be able to maintain the registration because you're adding everything up was very unlikely, so the U.S., at that point in time, was really scrambling to look for alternatives to these products that are fairly--very important in agriculture. So that's what an OP is, and that's why it's of importance and of--why it's mentioned.

And it's the same in Canada, we were about a year or two behind, but essentially the new Pest Control Products Act that is now in place also lays out the same approaches as was done in 1997 in the FQPA.

Q. Is it typical of the PMRA and/or EPA to work like this--great deal of consultation, our respective staffs have been meeting with Novartis U.S. and Canadian representatives over several months. Is that typical of the agencies to settle on a producer like that and work intensively with them and accelerate in a timely fashion anyway, and it seems extraordinarily fast to me, even.

A. Well since the North American Free Trade Agreement was put in place in 1995, under that NAFTA banner, the technical work on pesticides was created with the specific mandate, if

12:40 you will, to remove non-tariff trade barriers, but also to work together on health and environmental Risk Assessments, really to try and harmonize our regulatory systems.

And in 1996, we developed a process called a Joint Review, so the first policy paper was out in 1996, that said, "if a Registrant would submit to the U.S. and Canada, at the same time, with the same data, for the same uses a particular pesticide, then those two countries would work together and work towards a registration decision in 12 months. That 12 months was after we had all of the data. So, that had been in place in 1996 for new active ingredients that came in jointly. And as time went on, we learned a lot more about working together, and several other policy papers were written that accommodated different types of Joint Reviews and work-shares and so on.

But I think it's important to recognize that with an organization like PMRA, which was maybe 500 people at the time and EPA at somewhere around a thousand people that making sure that all of the appropriate pieces in each organization, and I mean people, are actually talking to each other, agreeing on what steps they're going to take is a fairly onerous task.

And so, for all of the Joint Review type of work, whether it's work-share or Joint Review, there is huge administrative or management piece, because even in a single organization, to have a team of people working on a pesticide

12:42 Assessment, it takes a lot of coordination, and you can well imagine that between two countries it takes a lot of coordination.

Q. I can understand that.

A. So, this is not uncommon, and products had been worked on before Helix in this manner, and this is new pesticides, but old pesticides also. There was a lot of interaction, I guess 2,4-D would be a good example where the U.S. and Canada work very closely together, and it takes--it takes this kind of interaction, yes. So, presumably that answers your question.

Q. I don't know. I have forgotten it.

(Laughter.)

A. Sorry, I can go on and on, if you like. Do you want more?

Just take it from me that there is a huge management component to not only working within a regulatory organization, but working across regulatory organizations.

Q. The--it would seem to me that all of that immense amount of coordination and cooperation and work adopted by the two agencies in favor of a single company for a replacement product would give it a tremendous advantage in the market, not only accelerating the rival of it but singling it out for this extraordinarily expensive and time-consuming treatment.

A. Yeah, but I think my point is that--

Q. It would be not in consonant with your equal treatment

12:44 policy that you described earlier.

A. Well, I beg to differ. This approach had been in place since 1996 with an ever increasing number of products being submitted by Registrants of. You have to remember that Registrants have to submit these products and have to request a joint approach. And so, it's really up to the Registrant, to the companies.

So, for example, DuPont could come to us and say, "I have a product that I want to submit to the U.S. and Canada," and then we would work with them, and the U.S. would, too. So, it wasn't as if we picked the companies. The companies had to submit to us. This was not something that was specific to lindane. This was something we had been doing since 1996.

With respect to the re-evaluation of lindane, we would have put this same kind of effort that you're reading here into the re-evaluation of lindane. We would have put the same kind of effort into--that you're reading here--into the re-evaluation of 2,4-D, working jointly with the U.S. and Canada.

I mean, what I'm trying to say is that the issue that it happened to be a lindane replacement product, and, you know, Novartis provided it to us. It could have easily have been another company completely outside the Voluntary Agreement that provided this particular--well, a product like it.

So, I guess I just don't agree with your analysis that

somehow EPA and PMRA treated this particular company specially. We didn't. This is what we had been doing since 1996, and certainly they're continuing to this day. And now, in fact, they're doing five country Joint Reviews, which are substantially more complicated than what you see here.

(Pause.)

Q. On the--I'm on the same--on the same issue about the submission of--I'm sorry, about the Novartis seed treatment Helix and the interagency cooperation on expediting its registration. The cooperation that's referred to in that letter, that's in relation to evaluating the submission, or is it in relation to preparing the submission?

A. It's both, because you just can't drop a submission in two countries and expect the countries to work together.

Q. Since the--

A. So, it's both.

Q. Well, no, but--

A. And it would be the case with the re-evaluation of lindane or the evaluation of any new product if you're doing it jointly. You have to do a lot of preparation work.

Q. Do you recall when the Helix submission was submitted?

A. No, I don't. I'm sorry.

Q. This letter is dated November '98, so if the submission went in after that, then the letter would have been discussing not the evaluation of the submission, in fact, but

12:48 the preparation of it.

A. Yeah, and frankly I just don't have that date in my head, so I don't know if it was submitted at that point.

Q. Your counsel can confirm whether or not I'm correct, but it's in the record it's stated as 25th of November, so the submission of the Helix for registration submission post-dated this letter.

A. Okay, well that's useful for me to know, but essentially then that more or less talks about work that leads up to any of these kinds of things.

Q. Thank you very much.

A. Thank you.

MR. SOMERS: Thank you, Madam Chair.

PRESIDENT KAUFMANN-KOHLER: Thank you. Do you have direct questions, and if so, do you have an estimate of how long they would take?

MR. DOUAIRE de BONDY: Madam Chair--

PRESIDENT KAUFMANN-KOHLER: Take them now or after the break? That's the question.

MR. DOUAIRE de BONDY: I think it would be preferable if we take them after the break, also to give Ms. Sexsmith a bit of a rest, but--because I think I might be about--might take about a half of an hour.

PRESIDENT KAUFMANN-KOHLER: Then it is better that we take it after the break, and--

12:50 THE WITNESS: If you're sure, because I'm okay. You know if you're pressed--

PRESIDENT KAUFMANN-KOHLER: We may have questions, too, and then it may be too long.

You still don't--please don't speak about your testimony during the lunch break.

THE WITNESS: Sure.

PRESIDENT KAUFMANN-KOHLER: Fine.

Then we take one hour break, and we will see each other thereafter.

(Whereupon, at 12:50 p.m., the hearing was adjourned until 1:50 p.m., the same day.)

AFTERNOON SESSION

PRESIDENT KAUFMANN-KOHLER: Are we ready to start again? Yes, yes?

Oh, no, it's your turn. Sorry about that.

MR. DOUAIRE de BONDY: Thank you, Madam Chair. Are we ready?

REDIRECT EXAMINATION

BY MR. DOUAIRE de BONDY:

Q. I have about eight points that I'm going to go to, which might seem long, but I think that the first several will be fairly brief.

The first thing I'd like you to do, Ms. Sexsmith, is to turn to Annex R-75. That's Canada's Annexes R-75. It's the Federal Court annexes. This isn't in the Joint Hearing Bundle. We didn't think we'd need to refer to it here.

But if you recall before the break, we were talking about the period in late 2001, early 2002, after Canada had--the PMRA had reached a finding of unacceptable health risk in the Special Review, and Canada had offered a phase-out period to all remaining Registrants. This was for the non-canola Lindane Products, and that the Claimant wrote back in late February and refused, and Professor Crawford's question had been: What was Chemtura's response? Did they send you a letter and whatnot? And you weren't able to think of any letter.

13:52 I just wondered if you would look at this document R-75 in that bundle before you. And as you can see, it's a notice of application in the Federal Court. If you could turn to Page 4 of the document, and look at points (d) and (e) of the document. You can take your time.

So, is it fair--oh, sorry.

A. Yes, I have reviewed it.

Q. All right. So, is it fair to say this was the Claimant's response to the notice that the PMRA sent to you--sent out to them in February of 2002?

A. Yes.

Q. And the date of the document is actually on the last page, Page 6.

A. Yes.

Q. So, that's March 14, 2002.

So, is it fair to say that the PMRA's--the response PMRA heard from Chemtura is that they were pursued in Federal Court with regard to this refusal by Chemtura--with regard to the suspension of their remaining registrations?

A. Can you repeat that?

Q. Is it fair to say, based on this document, that the Chemtura's response to the suspension of the remaining registrations was to begin an action, an application in Federal Court?

A. Yes.

13:54 Q. Thank you. That was all.

My second point on this is--the second point on my list is just a quick question with regard to the default MRL in Canada. As I understand it, the U.S. has a zero tolerance approach if there is no--if there is no residue limit, there is no residue limit, whereas Canada has a different regime. Can you speak to that for a moment.

A. Yes. In Canada, for many years now there has been something that's called a "default MRL."

And just to back up a little bit, when pesticides are used on food, a residue limit of that particular pesticide needs to be established, and so that is done through a scientific review of the data, and normally the tolerance is set. But for many years, any tolerance that might be under point one was not explicitly set but was just set at point one.

And in addition, because there was this default of point one, produce with pesticides used on it from other countries, if in fact they felt or knew that the residues were likely to be under point one, they did not have to apply to Canada for an import tolerance or import maximum residue limit. That's very different than the regime in the U.S., where in any case importing--importers of produce into the U.S. would have to have applied for and received essentially a maximum residue tolerance for that particular product, be it bananas or apples or whatever.

13:56 So, there was a great deal of difference between the two regulatory regimes in that regard.

Q. Thank you. That's fine.

The next point relates to a document which is in Lynn Goldman's Second Report, Volume 2 of 2, Tab 58. It's a chain of e-mails of April 19--around April 1999. It's in the Joint Hearing Bundle at 90.

A. So, where is it?

Q. Lynn Goldman is Tab 58.

A. Okay. I think I have it.

Q. All right. Before the break--before lunch, rather, you were mentioning--Mr. Somers was bringing you to certain statements in your Affidavit where you were talking about the Claimant's expectations about the outcome of the review, and you suggested that there were documents you had seen that were internal to Chemtura that reflected a different expectation than what Chemtura seems to be asserting.

If you look at the bottom of this page, you can see there is a line that says author. Who is the author there? It's just the last little bit on the first page.

A. Rick Turner at Gustafson is the author.

Q. So, I mean the bit below, where it says reply separator author. Just right at the very bottom.

A. Oh, Mr. Ingulli is the author.

Q. And what's the date there?

13:58 A. It's the 19th of April '99.

Q. Right. I just wanted to turn you to the next page, and it's just the last part of this comment from Mr. Ingulli. He's writing here. If you look in the middle of the second paragraph, it starts, "A wild card." "A wild card in all of this is that PMRA has initiated a Lindane Special Review to be completed at the end of 2000. This could spell an end to lindane regardless of what we decide to do."

And it goes on to say, "If I had to guess, lindane probably will be eventually be gone, but I don't think that you should use this argument just yet to resolve your discharge problem."

Was this the comment that you're referring to earlier?

A. Yes, that was certainly one of them.

Q. All right. Thank you.

Okay, the next point is arising in your first Affidavit, so if you could just pick up your first Affidavit.

I just wanted to clarify something. If you could turn to the tab that's at WS-17, or Wendy Sexsmith 17.

A. Yes.

Q. Now, this is the letter of November 26, 1998. And as you can see, it says Registrants of seed treatments containing lindane and other meeting participants agreed to the following," and the second point is, "All commercial stocks of products containing lindane for use on canola and

14:00 lindane-treated canola seed cannot be used after July 1st, 2001."

So, that was your understanding of the date that had been reached at that meeting?

A. That's correct.

Q. Okay. Could we just turn to Paragraph 119 of your Affidavit. This is within your first Affidavit again. Are you there?

A. Yes, I'm there.

Q. Okay, great.

So I'm just looking at it's the second, third sentence, the third sentence in that Paragraph 119, and it says, "The PMRA exercised its discretion under the Act not to strictly enforce new labeling (excluding canola) until," and it says until January 1st, 2001.

Is that accurate? I'm not sure.

A. I don't think so. It should really say June--July.

Q. Just to clarify, did the PMRA begin enforcing, strictly enforcing the new labeling before July 1st, 2001?

A. No, it did not strictly enforce at that point in time.

Q. All right. Thank you.

So, this might have been a correction to add at the beginning that we forgot?

A. Um-hmm.

Q. All right, thank you.

14:01 I'm still in your first Affidavit, and I just wanted to go to Exhibit WS-40. This is something that Mr. Somers turned you to. It's this letter of October 27, 1999, from Mr. Ingulli again.

Just before we turn to the second page, I wanted to turn back to the first page and look at that third condition. "In the event that both Government agencies determine that lindane has adverse toxicological effects and deem it unsafe for use on canola, Uniroyal will not request the reinstatement of lindane use on canola in Canada."

I just wanted to be clear. Does this mean that the PMRA would not permit the reinstatement of the canola use for lindane if the Special Review result came out with a negative result?

A. Yes, that's what it means.

Q. Okay. So, that was one of the conditions.

Now, let's just turn to the next page. This Section 4--

A. Yes, I'm there.

Q. I'm just wondering, if you could--if we go back to October under this October 1999, the Special Review has just started. It started March 15 or at least publicly launched that date. I'm just wondering if you could imagine a situation where the ongoing tolerance application in the United States or a tolerance application in the U.S. could have been granted

14:03 before the end of the Special Review.

Was that at least feasible?

A. You mean on the part of EPA?

Q. Yeah. I mean, there could have been a situation where, for example, PMRA Special Review is ongoing, but the EPA had granted a tolerance, at least--

A. Yeah, that was a feasible scenario. Certainly in the early part of, you know the Special Review that is possible that it could have happened. It did not.

Q. So, could this Paragraph 4 be referring to that situation?

A. That's my understanding, yes.

Q. All right.

A. And none of those events occurred.

Q. All right. But just to be clear, this paragraph isn't saying that the determination of whether canola can be used, lindane can be used on canola is dependent solely on the outcome of an EPA tolerance application?

A. No.

Q. Thank you. All right. We are moving along, halfway down the list.

The other thing I wanted to bring you to was Mr. Somers brought you to Exhibit Wendy Sexsmith 99, which is still in your--no, it's in your second Affidavit, actually.

All right. Again, Mr. Somers was more interested in

14:05 Page 2. I'm interested in Page 1. Now, you mentioned that the concern of the canola growers went beyond the use of lindane on seed as treated seed, but also to lindane residues, and I just wanted to clarify, if you look on the first page, that first paragraph, "Dear Wendy"--this is JoAnne Buth writing to you on November 20, 2001. "Dear Wendy, As you're fully aware, in 1998, use of lindane was identified as a trade irritant of the U.S.--when the Environmental Protection Agency informed us that the importation of lindane-treated seed into the U.S. for planting was illegal. They further stated that since a tolerance was not established for lindane on canola, that the crop grown from lindane-treated seed could not be legally imported into the U.S. This position clearly threatened the export of canola seed, oil, and meal into the U.S." And she mentions the value of that market of approximately 500 million annually.

PRESIDENT KAUFMANN-KOHLER: Mr. Bondy, afterwards, you should check the transcript because part of the quotation is not reproduced. We don't need to do this now. For the question it's clear. It's just the transcript.

MR. DOUAIRE de BONDY: All right.

BY MR. DOUAIRE de BONDY:

Q. And I just wanted to turn to--and so--JoAnne Buth as of number one says, "In 1998, we did not know the likelihood of detecting residue in canola seed oil and meal," and then if we

14:07 turn to the next page at point four, we turn to the second paragraph there. She's talking about, "by having canola grown from lindane-treated seed delivered to the country elevators, exports of oil and meal from canola grown from lindane-treated seed to the U.S. would be minimized."

And so, I'm just wondering if you could clarify that the concern of the canola growers was the canola produced from lindane-treated seed, and the residues in that canola, I think there was some confusion about the fact that the U.S. in 1998 actually did ban the entrance of lindane-treated canola seed, and the issue seemed to be the crop that was grown from that seed; is that correct?

A. Well, I guess as I mentioned previously, certainly the canola growers had concerns both about the seed and the products of canola, and that's the oil and the meal. What JoAnne was doing here was essentially providing the PMRA with information that would show us that if the treated seed was going to be used in 2002--and this is the leftover treated seed after the Agreement date, which was July 1, 2001, that if, in fact, the seed was used, that there would be no product of lindane-treated seed moving into the U.S. So, that was the point of what she was saying, and so I think by that certainly it indicates the continuing concern about oil and meal related to potential residues from lindane.

Q. All right. Thank you.

14:09 The--I think it's about the third last point I wanted to go to concerned the ROU. This is listed at WS-18 of your first Affidavit. And if we go to page--I think it's about five pages in, the bottom of the page under Pest Control Products, that section we were looking at which begins EPA and PMRA will investigate--no, sorry, "Canadian canola growers have requested Canadian Registrants to agree voluntarily to remove canola/rapeseed," and so on. So, that's the passage.

A. Yes, I have it.

Q. Okay. Now, we talked about this as a sign that EPA was willing to refrain from enforcing its legislation during a three-year period. This was after the EPA's attention had been directly drawn to the presence of lindane on Canadian canola.

As a regulator, would you expect the EPA to expressly state that they would not enforce their legislation during that period?

A. No, that's a very difficult thing for a regulator to explicitly talk about, so this was a different way of publicly stating the issue and the Agreement with the issue.

Q. Okay. And we've emphasized what EPA was undertaking in this--in relation to this comment in the ROU. What would have happened if one of the members of the Voluntary Withdrawal Agreement pulled out after December? Did either Agency have any way to enforce the reference to a Voluntary Agreement here?

A. No.

14:11 Q. And did either Agency have any vested interest in the voluntary--in this agreement as set out here?

A. No.

Q. So, at whose request was this reference included in the ROU?

A. It was done in consultation with the canola growers, so, in fact, we would have asked the canola growers if they thought this was a useful opportunity to put--to put this in, and so it would have worked that way because clearly it was a grower-driven initiative, not ours, but agreement by the two Governments was also important.

Q. And that was agreement in the sense of refraining from strictly imposing the terms of the legislation in light of this phase-out?

A. That's right, plus the technical aspects of removing things from labels.

Q. And that was what the PMRA was doing?

A. Yes.

Q. Okay. Thank you.

So, I'm on my last two points. The second last one is this document that you have been brought to which is in the Joint Hearing Bundle. It's at document 41. And again I wanted to draw your attention--Mr. Somers brought you this. I wanted to bring your attention to a part that we hadn't actually discussed just earlier. He brought your attention to this

14:13 line, commitment between EPA and PMRA to work together to phase out uses of lindane, and you commented on your understanding of the meaning.

I also wondered if you could comment on that in relation to the two sentences in Paragraph 2 of the same document where it says, "PMRA is not in a position to recommend such action, unless there was agreement for concerted action on all lindane products with the U.S. EPA. The consideration of lindane as a candidate for a North American Regional Action Plan under the CEC was identified as one mechanism for this cooperative action."

What are they talking about with that last sentence?

A. The--when NAFTA--when the North American Free Trade Agreement was put in place in 1995, there was a side agreement developed under the banner of the Commission for Environmental Cooperation; and under that Commission, there were a number of processes developed to work on issues of concern. One of those processes was called the North American Regional Action Plan, the NARAPs, and essentially that process was really in place so that all three countries could work together on an issue and through consultation and so on, develop an approach to deal with that particular issue.

So, the sentence there relates to one approach to working together on lindane could be under the Commission for Environmental Cooperation, the side agreement to NAFTA, using

14:15 one of these processes, and in this case it was the NARAP. So, it was really just--what we are talking about here is if we are going to work on lindane, let's work on it together because it impacts, you know, our growers and under our commitment to harmonize and reduce regulatory barriers as appropriate. We are really interested in moving forward together whatever direction it was, and the suggestion here was that one possible process would be the North American Regional Action Plan, but that would include Mexico, of course.

Q. Right.

And when something is proposed for a NARAP, does that necessarily mean that some kind of summary or quick suspension of the product in question will result?

A. No. A NARAP process is a very long process because it requires in this case three countries to gather up all their information, to carry out detailed consultations within each of the countries, and they're typically five to six to seven years long because of the logistics, but also the process.

Q. Okay, thank you.

Just another bit in this document, I see under the part that was interesting to Mr. Somers a commitment between EPA. There is another commitment, a commitment between EPA and PMRA to work together on a harmonized policy for movement of treated seeds, and here they have a date of December 1999.

So, you had talked earlier about harmonization. Is

14:17 that--what's being--what sort of action is being referenced here?

A. Well, the issue there really, while it resulted from the lindane issue in part, it also relates to the ongoing issue of countries not being exactly clear about what's required with regards to moving treated seeds from one country to another, and in this particular instance, the EPA had already issued a draft notice on the movement of treated seed, and certainly Canadian stakeholders were very concerned that if a final notice on the movement of treated seed was completed in the U.S., that would certainly foreclose in all likelihood any ability to have a harmonized policy.

So what ultimately was agreed to is talked about here, and stakeholders on both sides of the border were very interested in this, and that was to work together to develop a policy that would work for both countries on the movement of treated seed, and that would essentially be to clarify what the data requirements are, but also what the compliance practices would be. Certainly in both countries, you know, the tendency was to be a little vague on seed treatments.

So, this was a substantial--this was a very positive thing to get EPA to agree to work with Canada on the development of this policy.

Q. Okay. Thank you for that.

And I see that the document is titled "Lindane Seed

14:19 Treatment/Update," and it talks about a variety of potential agreements between PMRA and EPA in relation to the Voluntary Withdrawal Agreement, which is mentioned here.

Did the U.S. EPA and PMRA see this as a lindane-specific agreement? In the sense that, you know, were they merely focused on lindane in this agreement or potential agreement?

A. Well, it was broader than that in that. I mean, it was focused on lindane, but it was also broader than that because it talked about the PMRA notice for treated seeds and the Agreement to develop a draft or a harmonized policy on treated seed.

If I can have a look here, you know, but I think it's fair to say the focus was predominantly on lindane with the exception of the linked activity around the Regulation of the movement of treated seeds.

Q. And with regard to harmonization, was the harmonization about lindane or was the harmonization a broader issue?

A. It was a broader issue.

Q. So that would--because if there is lindane on a treated--on a seed, there might be many other products on seeds as well?

A. Yes.

Q. And there might be products that don't have

registrations or tolerances on both sides of the border?

A. That's right.

Q. So, is it--would it be in the interest of U.S. EPA and PMRA to work on a more general policy?

A. Yes.

Q. And so, was that something that U.S. EPA and PMRA were interested in at the time?

A. Yes, very much so.

Q. All right. And that's reflected in this document?

A. That's right.

Q. All right.

The last thing I would like to bring you to is a document which is actually in Claire Franklin's second Affidavit. It's CF-22.

You mentioned NAFTA on several occasions now, and I think you mentioned a Technical Working Group on Pesticides. Are you familiar with this document, which is Exhibit CF-22? It looks like it's dated September 2001.

A. Yes, I'm very familiar with it.

Q. Okay. Can you describe what this document is.

A. Yes. I think I mentioned in earlier testimony that the Technical Working Group on Pesticides was set up under NAFTA in 1995 when NAFTA was put in place, and really the purpose of the Technical Working Group, as I stated earlier, was to work on harmonizing the regulatory approaches in both

14:22 countries, really to level the playing field for the growers, remove inappropriate regulatory barriers. And for Canada particularly, we were very interested in seeing new products come to Canada sooner than they would have originally, and by that I mean because Canada has such a small market share in the world related to pesticides, as many other things, we are only 2 percent of the world market.

So, in most cases, companies would come to Canada five to six years after the products had been registered in the U.S., and it was certainly obvious to growers in Canada that this presented huge difficulties. And, in fact, when--PMRA is a relatively new organization. It also was set up in 1995, and leading up to that there was a substantial consultation across Canada. And so, when PMRA was set up, one aspect of its mandate was in fact to harmonize regulatory approaches between the U.S. and Canada.

So, anyway, in order to do that, the Technical Working Group was set up, and this report talks about the accomplishments over the last several years, and it allowed the public at large and our stakeholders to really understand what had been done and to help provide input into what directions we should be taking in the future.

Q. All right. Why don't we turn to page--thank you for that--the first page of this document--sorry, not the first page physically, but Page 1. It's starting, "Introduction:

14:24 Looking Beyond Borders." There is a reference at the second paragraph to CUSTA, the U.S. Canadian Government Center to do free trade agreement in 1998, realized the differences in their regulatory structures and requirements could inhibit trade. For example, differing tolerances, maximum pesticide residue limits on food products could prevent farmers growing the same crops in the same geographic region from using the same pesticides. And this says it's led to the establishment of a pesticide working group whose task it was to find ways of alleviating trade barriers posed by such regulatory differences without compromising public health and environmental standards, and they talked about this being pursued under the NAFTA.

So, was it unusual for the PMRA to be involved in trade-related issues relating to pesticides at this level of harmonization--

A. I--I'm sorry.

Q. Go ahead.

A. Okay. No, it really wasn't unusual. I've been involved in sort of pesticide regulation for most, if not all of my career, and I certainly haven't been involved in any decision, regulatory decision, in isolation of its context.

And what I mean by that is while trade issues are not explicitly or economic issues aren't explicitly under our legislation part of the decision-making process, there is no way that any decision is made without the knowledge of that

14:26 context.

And, for example, apples are grown in Canada. Apples are grown in the U.S. If a pesticide company comes to the U.S. six years before it comes to Canada, then our apple growers feel that they are severely restricted in the types of products that they can use, and, you know, it's certainly not uncommon for them to raise those kinds of issues because if they can't move their apples from Canada to the U.S. because some of the factories in the U.S. say that they're only going to allow the use of this type of product registered in the U.S. to be used on the apples they are going to buy from Canada, then that becomes a trade issue, and certainly the apple growers will raise it.

So, while our mandate is to protect health and the environment really for the benefit of Canadians, any decision making needs to understand the context in which those pesticides are being used, and that can and does include trade issues.

And, in fact, when pesticides are used on food, as I said before, a maximum residue limit has to be established. And before those--before those limits are formally established, Canada or we, in fact, have to alert all of our trading partners to this level and give them a chance to comment on this level before it is formally set in law.

So, everything practically that we do touches on

trade, particularly with agriculture and forestry products, even.

Q. Now, Ms. Sexsmith, does this mean that in the context of reviewing any particular pesticide for a re-evaluation, for example, that the outcome of that review is going to be dictated by, for example, getting rid of a trade irritant?

A. No. It would be dictated by the results of the scientific review. But it was certainly in our best interest to work closely with other organizations so that we could benefit from their knowledge and their reviews with the proviso always that countries are sovereign and are going to make their own decisions.

Q. And that's what happened in the case of U.S. EPA versus the PMRA, at least initially with regard to lindane?

A. Yes. While we made every effort to work together, and in the early days of the--leading up to the Agreement, Voluntary Agreement and so on, it looked like we could stay on--on target together, but--

Q. This is in the context of your scientific review?

A. That's right, yeah, in the context of the re-evaluation/re-registration of lindane.

But as time went on, other pressures came about in the U.S., and their priorities shifted because of those pressures, and so we felt that in Canada we still needed to move forward with our review of lindane, and so that's really what caused

14:30 the separation there, but we still maintained a close link as far as sharing information.

Q. So, despite the efforts at harmonization in the sense of working together in a workshare in the context of the lindane review, at the end of the day both agencies are going to apply their own scientific standards and policies?

A. Yes, and that's the same with whether it's a new product or an old product. One of the intents, though, of the North American initiative and the NAFTA Pesticide Working Group was to try and get to a point where our standards and our approaches were more and more similar.

So, I mean, one of the issues is if a pesticide is submitted to one country one day, and then six years later that very same pesticide is submitted to a different country, it's very possible that the information and knowledge that the world has about that particular chemical has changed has changed, so there is a huge benefit and if it's a new product to submit at the same time with the same data, so you're really doing the review under the same circumstance. And--but every country, even if you're doing it jointly, reserves the right to make their own decision. It's just the more we work together, the more likely it is that our decisions are going to be more and more similar.

Q. Thank you.

MR. DOUAIRE de BONDY: Those are my redirect.

14:32 PRESIDENT KAUFMANN-KOHLER: Thank you.

Does the Tribunal have questions?

We're going to ask questions. If you have something on recross, we will see afterwards.

Judge Brower.

QUESTIONS FROM THE TRIBUNAL

ARBITRATOR BROWER: Yes, thank you.

I think we all understand that what we are dealing with here is an inherent tension, which is at least hypothetical and to some extent real between the interests of free trade, meaning uniformity throughout the affected area on the one hand, and the respective national mandate to follow the science with respect to certain issues; namely, those dealt with by the PMRA and, to that extent, by the EPA. That leads me to ask the first of my questions.

There has been a cooperative mechanism involving the United States and Canada and later Mexico since about 1988; is that right?

THE WITNESS: Yeah, it would be U.S. and Canada since about '88, and then Mexico would have been included after NAFTA in the 1995 period.

ARBITRATOR BROWER: And I realize for the reasons that you've cited, there may be temporal differences between action, let's say, by your Agency and action by the EPA on a particular substance.

14:34 THE WITNESS: Um-hmm.

ARBITRATOR BROWER: The question I want to ask I think is best phrased as, are there or have there ever been persistent unresolved differences between EPA and PMRA on specific substances that just went on for years or some period and have never been resolved.

THE WITNESS: Well, I would just comment, first of all, generally about an unresolved issue, and I mentioned it earlier, and that really related to the fact that PRMA and Canada required efficacy data to be generated and submitted and reviewed. The U.S. did not require the data to be submitted and reviewed.

And so, certainly in my time that was still an issue that was unresolved as relates to the development of MRL levels because it relates to that, and also--

ARBITRATOR BROWER: MRL meaning?

THE WITNESS: Oh, sorry, maximum residue limits in food, and to rates. So because if you have efficacy data that you review, you can see what is the lowest but best rate. If you don't review efficacy data, you may not, in fact, see what the lowest but best rate is. So, that was one issue that we certainly had with the U.S. in my day because if we worked jointly together, we may in fact come out with different rates that we would like to see on the label, and so we had to work through that. So, that was one--that's one sort of specific

14:35 issue that broadly affected working together. It wasn't unresolvable, but it was something we had to deal with.

ARBITRATOR BROWER: Yes. Go ahead, please.

THE WITNESS: On the Risk Assessment side--I mean, I think it's important to understand that while we'd had a working group in place since 1988, I would say that it was much more active starting in the early nineties; and starting in the early nineties, essentially most countries in the world started to work together. The first big OECD meeting was held in the U.S. in 1992, and before that countries actually didn't work together very much, not on substantive things. So, I think it's important to put into perspective how long we've actually been working together.

So, if we really started looking at the nuts and bolts in '92 up to '95 and so on, there were lots of things that were different, and that could be the way we put our submission or had our submission put together. It could be the assumptions we made related to Risk Assessment. It could be cancer risk and how we looked at that.

So, without sort of avoiding your question but trying to set context, it was really through the NAFTA initiative that we started to peel away the differences and to bring both organizations closer and closer together, not only on the sort of administrative things, you know, like how or what a submission looks like, but also on these very scientifically

14:37 related issues.

So, I can't think of a specific issue, really, without revealing confidence, but what I can say is often in the Risk Assessment area there were differences, and particularly like a cancer risk or how a scientist read a particular study. But in the context of NAFTA, we did try to work through those and come up with a solution that both countries could live with.

ARBITRATOR BROWER: My question addressed itself to results and not to procedures, and I well understand the process by which various countries' authorities could through consultation come to more uniform procedures which make things, in a sense, a little fairer to the multinational Applicants and also to the collaboration of the agencies.

Parenthetically, does the EPA still not consider efficacy, and if so, is that because of a statutory restriction?

THE WITNESS: As far as I know, they don't consider efficacy, and it's not because of a statutory restriction. It's because, as I understand it, quite a number of years ago they decided that they wouldn't review efficacy. They would require the Registrants to generate it, and that it had to be there if EPA wanted it, but they would not routinely review it. So, it meets the statutory requirements, but it isn't something that they used their resources to review, and it was just a policy decision that they made.

14:39 ARBITRATOR BROWER: Right. Let me go back to my original question or what I think was my original question.

Has it ever happened that there have been different results, notwithstanding collaboration, between the EPA and the PMRA as regards either the registration of a specific pesticide or a chemical used in the pesticide and a difference that endured was never, despite all your cooperation, unable to be resolved to the same result in both countries? It may have taken a period of time, but...

THE WITNESS: Yeah. I mean, that's a rather big question, and I'm going to answer it sort of using two points, and one I will say that with our experience with Joint Reviews, we found that if the pesticide was submitted to both countries at the same time with the same data, and the two countries worked together, the decisions were the same or similar without barriers, so that's one because you really have to have that kind of--certainly in the early days, that back and forth, and everything has to be very much the same.

The sort of second part to my question will be absolutely, yes, there would be instances where there has been no resolution but not under the joint review or workshare type of process because that's where we are working together. But if a product had been submitted to the U.S. six years previous and then comes to Canada--and I'm just using that time frame six years loosely--it is very possible that it's registered in

14:42 the U.S. and then does not, for some scientific reason, get registered in Canada, you know. So, it's very possible.

ARBITRATOR BROWER: I understand. Let's go to the Joint Review process. Those substances which have been submitted to the Joint Review process which has been since--

THE WITNESS: '96, 1996.

ARBITRATOR BROWER: 1996, in other words under the--right, okay, 1996.

THE WITNESS: Right.

ARBITRATOR BROWER: In every case, the EPA and PMRA have arrived at the same--substantially the same result either to register or to reject.

THE WITNESS: Yes, for specific Joint Reviews, and that I mean by that is products that have been submitted at the same time with all the same data for the same uses because we also do a different type of collaboration called workshares, and that may be that the submissions come in at the same time with some uses in common, but other uses not in common. So, we work together nonetheless because there is a core piece that we can still work together on, but the decision--outcoming decisions may be different because what went in was slightly different.

ARBITRATOR BROWER: I understand that a submission made simultaneously with the same documentation to both may be different in the applications.

14:43 THE WITNESS: The uses might be different.
ARBITRATOR BROWER: Or use which they, so...
THE WITNESS: Yeah. Sorry, go ahead.
ARBITRATOR BROWER: But in those cases all Joint Reviews have resulted either in all requested uses being approved, or all being rejected?
THE WITNESS: You know, this is going back a long way for me, but I mean, it's entirely possible that both countries agree that out of the 10 uses submitted, only these six can be approved, so it's quite possible that that happened in the very strict Joint Review context where we would agree completely. In the less strict Joint Review context, it's very possible that some uses both countries agree with, and then other uses one country says yes to and the other country says no to, and some of that can relate to certainly at that time what our risk cup looked like and how we used drinking water in our Risk Assessment and so on.
So, even though we worked very closely together, we still had some specific Risk Assessment approaches to work out and make more and more similar.
So, it's quite possible that we could work together and still have somewhat different outcomes.
ARBITRATOR BROWER: Do you happen to recall any such cases?
THE WITNESS: Yes.

14:45 ARBITRATOR BROWER: And they are...

THE WITNESS: Well, Helix, which is one you know about because it's been on the table, is one where both countries agreed to the canola use, but a number of other uses were not supported in Canada while they were supported in the U.S. at that point in time. Canada needed some additional data because of the way we did the risk cup in order for us to consider some additional uses.

ARBITRATOR BROWER: All right. But the risk cup, I take it, relates to particular conditions or aspects of use or of the makeup of the receiving environment let's say in Canada--

THE WITNESS: In part, that's right.

ARBITRATOR BROWER: --as opposed to the United States.

THE WITNESS: Yeah.

ARBITRATOR BROWER: It's not due to differences in the science.

THE WITNESS: Not necessarily, but it could be differences in some aspects of science related to how we gather drinking water data, for example.

ARBITRATOR BROWER: But under the workshare, that would not be, as an example, assigned to either the EPA or the PMRA to work up?

THE WITNESS: Yes, it could be, but they would still have to use the Canadian piece of the data.

14:47 ARBITRATOR BROWER: Separate.

THE WITNESS: Yeah, so it's still very possible. I mean, I'm a bit away from it now, and I presume things have evolved, but you know environmental conditions are different from one country to another, and so, you know, even with identical tools and approaches and data, it still is very possible that our Risk Assessment could be different.

ARBITRATOR BROWER: No, I understand that. That's because that's--

THE WITNESS: Environmental conditions.

ARBITRATOR BROWER: That's because of conditions extraneous to the substance itself.

THE WITNESS: Yeah, that's right.

ARBITRATOR BROWER: When you say the science never differs in these cases between the two agencies, I mean the basic Assessment, let's say, of toxicologist.

THE WITNESS: That's right. It may not differ, but if, in fact, where the product is going to be used in Canada is very sandy soil and the product is a leacher whereas in the U.S. it's not going to be used in sandy soil, then you can see how the Risk Assessment related to water might be different.

ARBITRATOR BROWER: Again, that's Risk Assessment based on surrounding conditions and not differences in the scientific analysis.

THE WITNESS: Absolutely.

14:48 Yeah, but I think what I'm saying is it's possible for both to exist because--and it may be very different now. I mean, we are in 2008, and so that's really 10 years on, but if countries only started to work together in 1992, and really with sort of a very planned approach as of about 1995, in 1998 or 1999, we weren't very far down that list of things that we had to sort out, if I can say that.

So, I don't think--I'm not disputing you. I'm just trying to say that it could happen because of different conditions or because some of the Risk Assessment approaches still differ.

ARBITRATOR BROWER: Right.

Now, counsel will correct me if I still haven't understood the point about the complaint or a complaint of the Claimant is with respect to the long period of time that was taken to deal with CS FL also known as a form of Gaucho also known as the all-in-one pesticide and fungicide; have I got that right? Okay.

Was that application submitted jointly to the EPA and the PMRA?

THE WITNESS: Not to my knowledge.

ARBITRATOR BROWER: Okay.

THE WITNESS: As I understood it, it was already registered in the U.S. some years previously.

And the submissions we got in Canada, the first one

was for export only and was not an all-in-one, and then the second one for Canada was not an all-in-one.

So, it was the third or so on submission that we would have gotten that was the all-in-one.

ARBITRATOR BROWER: Right. But the fact it was already registered in the United States and presumably there was data available at the EPA wouldn't affect how you approached the application.

THE WITNESS: It could have affected how we approached the application.

Typically, what we ask the Registrants to do is provide any reviews that the U.S. has done in their application. And if they haven't done that, then we as an organization have to find those pieces of information.

And I'm sufficiently removed I can't talk in specifics to this particular application, but some of the things that we face in any application is there is a list of data requirements that have to be met. And if a submission comes in and doesn't meet those data requirements, then it goes back to the Registrant, and it's up to the Registrant to fill those data requirements.

So, it's very hard for us to review a submission that is incomplete. So as an organization, when we were set up in 1995, that was part of our efficiency measures, is that we would only review submissions that were complete. So, in this

14:51 case I don't know exactly what would have happened, but certainly one of the issues is an incomplete data package.

ARBITRATOR BROWER: Okay. Maybe I don't know whether you or counsel or both of you can clear this up. Was Claimant precluded from making a joint submission of CS FL because the registration in the United States predated the adoption of the joint submission procedure?

THE WITNESS: I wouldn't have thought that was the case. I would have thought that because it was already registered in the U.S., it doesn't meet the criteria for a joint submission.

ARBITRATOR BROWER: That's what I mean.

THE WITNESS: Yeah.

ARBITRATOR BROWER: It was not possible to make a joint submission--

THE WITNESS: I'm sorry, I couldn't tell if you were asking me a question or giving me an answer.

ARBITRATOR BROWER: It was not possible for them to make a joint submission in conformity with the joint submission setup that PMRA and the EPA arranged because they were already registered in the United States.

THE WITNESS: Exactly, yes, but that didn't preclude us working together in some way. Yeah.

ARBITRATOR BROWER: That, I understand.

THE WITNESS: Well, yeah, okay.

14:52 ARBITRATOR BROWER: But not in the same way that you do on a joint submission that meets the criteria.

THE WITNESS: That's correct.

ARBITRATOR BROWER: When you receive joint submissions, are they processed in the order in which received?

THE WITNESS: Yes.

ARBITRATOR BROWER: Okay. And you accept all requests for processing of joint submissions?

THE WITNESS: Well, certainly we did in those days.

You know, I think it's important to note that as a regulatory Agency or as regulatory agencies, we were beating the bushes, so to speak, to get joint submissions in. You have to remember that this was an unknown concept in those days in 1996, and Registrants were for probably lots of good reasons reluctant to do this because they thought, you know, if it's really slow with one organization, how slow can it possibly be with two, and I think those are fair observations.

So, as we as regulatory organizations had to work with the Registrants to show them that, in fact, it was a good thing, and so we didn't have--what I'm trying to say is we didn't have buckets and buckets of Joint Reviews coming in the door. We had, you know, enough. Between then and my time leaving the organization, I can count them on one hand--or two hands, I mean.

ARBITRATOR BROWER: You have in front of you the

14:54 volume containing your first Affidavit and certain exhibits you were shown previously, the one at Tab 18, which is the ROU, an action plan.

THE WITNESS: Yes.

ARBITRATOR BROWER: May I ask you to turn to the page which has item 13 towards the bottom.

THE WITNESS: Yes, I have it.

ARBITRATOR BROWER: And in the very bottom bullet on that page it states as follows, "EPA and PMRA will request U.S. and Canadian canola associations to prioritize pesticide registration needs from a list of pesticides now available in either country which are pending approval in the other country. That would apply to CS FL, I presume, which was registered in the United States and not in Canada.

THE WITNESS: It could have done if the growers put it on a list.

ARBITRATOR BROWER: Okay. The associations--I continue, "The associations in consultation with pesticide Registrants would also be asked to identify alternatives to pesticides such as organophosphates, and I take it we are dealing with organophosphates; is that right?

THE WITNESS: How do you mean?

ARBITRATOR BROWER: No, lindane--

THE WITNESS: It was an organochlorine.

ARBITRATOR BROWER: Sorry. Shows I didn't get past

high school chemistry.

Or other risk concerned. The resulting list will then be a basis for a longer term strategy to assure adequate reduced risk pest control tools for canola growers and will fit with current NAFTA efforts to promote a coordinated approach to integrated pest management for canola.

Now, that suggests that the CCC or the CCGA would be given an opportunity to say to the PMRA which of potential Registrants it would like to see registered before others.

THE WITNESS: Yeah. The concept there was because each state and each Province potentially would have a different list of needs.

ARBITRATOR BROWER: Right.

THE WITNESS: And so, what we were asking here was that U.S. and Canada work together on the canola grower side and come up with a already sorted list of some kind because, you know, regulatory organizations can't do everything all at once, and so the idea was give us a sort from your perspective because it wouldn't all be new pesticides. It might be older registered pesticides that are in one country or another, and then how are we going to deal with those.

So--and it was really--what we were asking for, and we do this with other grower groups, is work with the Registrants, work with the companies, find out what's coming, and give us some sense of, you know, where your interests lie.

14:57 ARBITRATOR BROWER: Right.

Did at any time the CCC or the CCGA urge PMRA to get on with Helix and get it registered, give it a push, as it were?

THE WITNESS: Well, there was a letter from the Canola Council, and maybe counsel can find it for me, from Tony Zatylny, in fact, that it didn't specify the types of products or the products, but it did talk about the importance of alternatives and so on. So, there is a letter from the Canola Council, and somebody I'm sure will find it, but it didn't specify which product or which products. It just talked about the importance and so on. And they urged us to move forward.

ARBITRATOR BROWER: Right.

MR. DOUAIRE de BONDY: Counsel has found it. It's at Exhibit WS-24.

ARBITRATOR BROWER: I think we have seen it before, actually.

THE WITNESS: It's in the second Affidavit, is it?

MR. DOUAIRE de BONDY: Yeah, your first Affidavit.

THE WITNESS: Of course.

Yes. And there it is.

So, in no place does it specify specific products.

ARBITRATOR BROWER: So the answer to my question is no?

THE WITNESS: That's right.

14:59 ARBITRATOR BROWER: Thank you.

Last question, I think, back to your Tab 18 to your first Affidavit, and over to item 13 again, and if you turn over the page to where 14 appears, you will see the penultimate bullet above that reads as follows, "The U.S. Department of Agriculture (USDA) and Agriculture and Agrifood Canada in conjunction with EPA and PMRA will convene preferably by March 1999 a high-level meeting with Chief Executive Officers of North American pesticide companies to encourage companies to take advantage of the pesticide Joint Review process, which obviously was no longer available to this Claimant with respect to CS FL"--I understand that--"and to encourage industry's role in harmonization goals."

Was that meeting ever held, and if so, when?

THE WITNESS: Yes, it was held, and it was held by March 1999. The first one was held in Canada, and we had some 110 participants, and then the second one about six months later was held in the U.S., again with high-level participation.

ARBITRATOR BROWER: And Chemtura participated in that meeting?

THE WITNESS: I, unfortunately, have no recollection of that, and I don't have the documents in front of me as to whether they did or didn't.

ARBITRATOR BROWER: Right.

15:00 THE WITNESS: But certainly they would have been given the opportunity in both cases.

ARBITRATOR BROWER: Thank you very much. Those are my questions.

PRESIDENT KAUFMANN-KOHLER: Thank you.

Professor Crawford.

ARBITRATOR CRAWFORD: I just want to take you back to the PMRA letter of 18 November 1998, which counsel took you to. It's Volume 2 in the Joint Hearing Bundle, Tab 57. I'm sorry, I don't know how that translates into--I'm using a Joint Bundle. It's a letter in which you're writing to the EPA about harmonization.

THE WITNESS: Yes. Yes, I have it.

ARBITRATOR CRAWFORD: It discusses at some detail.

Beginning at the top of Page 2, you have got a description of the work you're doing on Helix. This was, I understand, just shortly before the Helix, the first Helix submission went in. Obviously there was a great deal of work put into this joint submission.

THE WITNESS: Um-hmm.

ARBITRATOR CRAWFORD: Why didn't you do the same thing for Gaucho CS FL?

THE WITNESS: Well, I can only presume the same thing was done for Gaucho CS FL. I think I stated earlier, and I'll talk about it again, that this process that is described here

would be the needed process for any Joint Review, not just Helix. So, the Joint Review we did in '96. The ones we would have done between '96 and this period of time, because of the complications regarding working together with two countries with a somewhat dissimilar regulatory regime at that point, it took a lot of front end management.

Plus, it was new to us. It was a very new concept to the companies. It was very innovative, and so it took a lot of front end planning in order to make it work.

So, I really can't emphasize enough that this was not done just for Helix. It was done for every Joint Review or workshare. And as it turned out, Helix became a workshare because it ended up being two different as far as the submissions were, but this would have been a common approach in the sort of Joint Review or workshare processes for new products, and it would have been a common approach for the re-evaluation products where we worked together, at lindane would be an example of that, and other well-known products like 2,4-D we worked very closely together. And these kinds of efforts as far as figuring out how to work together would be very, very, very similar.

And I can't imagine that similar work wouldn't have been done for Gaucho. I don't know the details of that particular submission, but if part of it was lack of data requirements, we certainly would have worked with the company

15:04 to let them know what those were.

ARBITRATOR CRAWFORD: Thank you.

PRESIDENT KAUFMANN-KOHLER: Now I am confused. Did you not say before that Gaucho was--CS FL was already registered in the U.S., and therefore because it was already registered, the Joint Review was not available?

THE WITNESS: No, that's quite correct, but that doesn't preclude us as an organization communicating with the company to say that, you know--I mean, I'm only speculating because I don't know the details of the submission, but telling the company that you have some data requirements missing and, working with them as closely as we possibly could to get that information in, or working with the U.S. to get whatever data we could to help us with that review.

PRESIDENT KAUFMANN-KOHLER: And while we are on this document--that is, the letter of November 18, '98, that is Tab 57.

THE WITNESS: Of course, I have it.

PRESIDENT KAUFMANN-KOHLER: If I understand it correctly, the Helix submission was dated a week thereafter November 25th.

So, if I read here the second page refers to meetings between the respective staffs and Novartis, that means there is a lot of advance work prior to the submission being done with the company and the agencies?

15:05 THE WITNESS: Yes, that's correct. That's very common with respect to new active ingredients, which is what this is, as different than the Gaucho submission, not to say that we wouldn't work closely, but Gaucho was not a new active. It was already registered as an active ingredient. Imidacloprid was already registered in Canada. And typically, with a new active, there's a lot of unknowns, and so Registrants worked very closely with the regulatory authority to make sure they've understood the data requirements. If there are any particular issues related to the Active, are there additional data requirements that might be useful to clarify things.

So, for new active submissions, this is very normal to do a lot of upfront work. You know, for example, there are a number of two- and three-year toxicology related studies and exposure studies. Well, A company isn't going to just do those without any contact with the regulatory organization. They're going to come in. If the submission came in in November of 1998 or whatever we are talking about now--

PRESIDENT KAUFMANN-KOHLER: '98.

THE WITNESS: '98--they would have been in contact with PMRA and EPA three or four years earlier, saying, you know, we've got this one, it looks pretty good. There's a little issue here. We're going to propose to do an additional exposure study, what do you think?

So, that is very common, and particularly for new

15:07 active ingredients, but, you know, I would have to say that regulatory organizations try to be as open as possible to companies' needs without allowing--I mean--yeah, without allowing frivolous meetings, I guess if I can put it that way. So, you know, it would not have been any different, I don't think, with the third Gaucho submission. I just don't know the specifics of that, but it wouldn't have been a new active ingredient for one, and then I don't know the rest of it, but that doesn't mean we wouldn't have made all efforts to communicate with the company what the issues were.

PRESIDENT KAUFMANN-KOHLER: And a Joint Review was possible even though the application did not involve a new active ingredient?

THE WITNESS: For Gaucho?

PRESIDENT KAUFMANN-KOHLER: No, generally.

THE WITNESS: Well, in the early days, it was only for a new active ingredient.

PRESIDENT KAUFMANN-KOHLER: That's what I had understood, but now you speak of a possibility of a Joint Review for Gaucho.

THE WITNESS: If you understood that, I misspoke.

PRESIDENT KAUFMANN-KOHLER: Or I misunderstood.

THE WITNESS: Yeah, but I mean I am sort of building on something.

When we first started, we tried to keep it simple:

15:08 One active ingredient, a few uses because it was a complex process. But as we learned more, we opened the process up more, so probably now there's opportunity for Joint Reviews for secondary products like Gaucho. But even so, the U.S. already had that registered, so it wouldn't have even fit in the newer category.

ARBITRATOR CRAWFORD: So if I can summarize, I'm suffering from some of the same confusion. There were two reasons distinguishing Gaucho CS FL from Helix. One was that Gaucho CS FL was already registered in the U.S., and the other is that it didn't involve a new active ingredient. Can I have yes or no to that.

THE WITNESS: Well, I'm going to equivocate because it's not a simple yes-or-no answer. I mean, yes, those are absolute differences.

MR. SOMERS: I'm sorry, I hesitate to interrupt, but the water is just getting murkier. Gaucho CS FL was not registered in the U.S. until long after its submission to Canada. It's something like July 2003, it was registered in the United States.

ARBITRATOR CRAWFORD: It wasn't the subject of a joint submission.

(Comment off microphone.

MR. DOUAIRE de BONDY: I think the confusion is simply Ms. Sexsmith is referring to a registration of a Gaucho product

15:10 in the U.S. which is based on imidacloprid, and I think my understanding as well is that wasn't an all-in-one or it was a Gaucho product, but it may not have been CS FL. That's all.

ARBITRATOR CRAWFORD: I mean, if we are not talking to the right person, let's not talk further about it because I think it's a question of who is the right witness to discuss this issue with.

THE WITNESS: Well, if I can just say, the bottom line is, imidacloprid was registered in the U.S. and in Canada already.

ARBITRATOR CRAWFORD: Yes.

THE WITNESS: And that at that point in time that it precluded the Joint Review concept, okay? So, I guess to try to get out of the murk a little bit.

ARBITRATOR CRAWFORD: Thank you very much.

ARBITRATOR BROWER: It was not a new substance, not before treated.

THE WITNESS: Um-hmm.

And the reason for that, the way the Joint Reviews were originally created was to really try and encourage new active ingredients to get registered in Canada, so that was the Canadian perspective at least. And so that's why we focused on new active ingredients, new products in the Joint Review process. That has subsequently changed.

ARBITRATOR BROWER: From all you've said, one could

15:11 have the impression that dealing with CS FL in Canada should have been a lot easier than dealing with a joint submission, as was in the case of Helix, because you didn't have to go through all this bureaucratic coordination of workshare and so forth, and you could just presumably tap into whatever EPA had, and you had something that was already registered.

THE WITNESS: Well, within the PMRA, we had categorized all different types of registrations, and Category A was typically a new active ingredient or a completely--an active ingredient in new use site, and with a specific time line. And frankly, I don't know where this one particularly fell. All I can say is every effort would have been made to work with the Registrant as we would do with any of our submissions, and it may very well have been simpler if, in fact, we had received all of the necessary data.

So--and I don't really know what the circumstances are, but that is certainly a deal--well, not just a roadblock. If we get a submission that does not have all the data, and we send that back to the Registrant and we don't get any more data, it makes it very difficult for us to move forward whether it's easy or not. And I'm not saying that's the case. I'm just citing a possibility.

PRESIDENT KAUFMANN-KOHLER: Any further questions? No? Fine.

Then that, Mrs. Sexsmith, completes your examination.

15:13 Thank you very much.

THE WITNESS: Thank you.

(Witness steps down.)

PRESIDENT KAUFMANN-KOHLER: So, I would suggest we take just a 10-minute break, if that is fine with you, and then we go over to the next witness? Good.

(Brief recess.)

PRESIDENT KAUFMANN-KOHLER: Good afternoon.

SUZANNE CHALIFOUR, RESPONDENT'S WITNESS, CALLED.

THE WITNESS: Good afternoon.

PRESIDENT KAUFMANN-KOHLER: You're Suzanne Chalifour?

THE WITNESS: I'm Suzanne Chalifour.

PRESIDENT KAUFMANN-KOHLER: Thank you.

You are Acting Director in the Review and Science Integration Division of the Registration Directorate of the PMRA.

THE WITNESS: That's right.

PRESIDENT KAUFMANN-KOHLER: You have given two Witness Statements.

THE WITNESS: Yes, I have two affidavits here.

PRESIDENT KAUFMANN-KOHLER: And you're heard here as a witness. You're under a duty to tell us the truth. I would like to ask you to confirm this by reading into the record the Witness Declaration that is in front of you, please.

THE WITNESS: I'm aware that, in my examination, I

15:29 must tell the truth. I'm also aware that any false testimony may produce severe legal consequences for me.

PRESIDENT KAUFMANN-KOHLER: Thank you.

Now we will first turn to Canada's counsel for some introductory questions, and then to Chemtura's counsel for cross-examination.

You have the floor.

MS. ELLIOTT-MAGWOOD: Thank you.

DIRECT EXAMINATION

BY MS. ELLIOTT-MAGWOOD:

Q. Ms. Chalifour, I understand that on reviewing your affidavits, there's a few small things to clarify from your first affidavit, so we will just walk through them in the order that they appear in your Affidavit.

The first one, I believe, is at Paragraph 56.

A. The point that I'm making here is this submission to register Gaucho CS, all the necessary information was provided in February 2001 when, in fact, the submission went on hold again and was not--all the information was not submitted until May 2001, when it went for a full review.

Q. Thank you.

And in Paragraph 62?

A. Okay. In this paragraph, I'm referring to three products that were given priority review under the Agreement. And in fact the product that was given priority review was

15:31 Gaucho 75 seed treatment, and not Gaucho 480, although that also was registered as a priority review.

And I think earlier on I indicate that Gaucho was one of the three products given priority review.

Q. Okay. And your final clarification, I believe, is at Paragraph 66 of the same Affidavit.

A. In fact, the original submissions to register Helix and Thiamethoxim Technical were withdrawn in 2000--withdrawn and rejected in 2000 respectively, and the second submissions followed in early 2000 as well.

Q. Rather--

A. 1999. Thank you.

Thank you. Those are all my questions.

PRESIDENT KAUFMANN-KOHLER: Thank you.

Mr. Bedard?

MR. BEDARD: Thank you, Madam President.

CROSS-EXAMINATION

BY MR. BEDARD:

Q. Ms. Chalifour, my name is Ben Bedard. I'm here on behalf of Chemtura.

A few clarification questions first for you. You've given some evidence on the Withdrawal Agreement and what was contained in that.

Were you involved in the Withdrawal Agreement process?

A. No, I wasn't at all. Dr. Claire Franklin and Wendy

15:33 Sexsmith were more closely involved in that.

Q. Okay. And were you in the Lindane Special Review?

A. No, I wasn't.

Q. Or the recent/ongoing REN re-evaluation process on lindane?

A. Not at all.

Q. Okay.

I will be asking you questions on your first and second affidavits. If you could start with your first Affidavit, Paragraph 11.

This is where you mentioned--but first under management and submissions policy, and you make the statement there in the second sentence: This policy has not been issued as a finalized Directive.

Are you saying there that the MOSP is not binding on the PMRA? Is that what you're saying by that second sentence?

A. Well, first of all, it is a policy, and it provides guidelines and time lines for submission and review of various types of submission.

It is a proposal and was never finalized, so it's policy.

Q. Not binding, but this is the document that's out there to guide the process.

A. That's right.

Q. And if it had been a finalized Directive, are

15:34 directives binding on PMRA?

A. It depends.

Q. Not necessarily.

A. Not necessarily, yeah.

Q. Okay.

Paragraph 14 of your first Affidavit is where you start getting into the different categories and it gets a little bit confusing because we have Category A's and Level A's, and Category B's and Level B's?

A. That's true. That was a mistake.

Q. Am I correct that Helix was a Category A submission and the Gaucho CS FL was a Category B.2.6?

A. Yes. Helix was a Category A submission for registration of a new end-use product, and its sister submission for registration of tactical was also a category submission.

Helix CS was registration of a new formulation of a registered active ingredient, and was a Category B submission.

Q. Just to clarify the record. You said Helix CS. I believe you meant Gaucho CS FL.

A. I did mean Gaucho CS.

Q. And are you--you say it's a Category B submission. Are you reluctant to agree that it's a B.2.6? Are you disagreeing with that?

A. No, I'm not disagreeing. There are a number of

15:35 different Category B submissions. I think the point that's important here is that it was to register a new formulation.

Q. Okay. And so getting to that, Gaucho CS was really the old Vitavax Dynaseal with the lindane replaced by imidacloprid; is that correct?

A. It was a new formulation of imidacloprid, the end-use product insecticide, end-use product, combined with two fungicide active ingredients. So, it was a new formulation and new combination of technical active ingredients into a new end-use product.

Q. The two fungicides were thiram and carbathiin?

A. Yes. They were already registered.

Q. And they were already registered for use on canola.

A. That's right.

Q. As was imidacloprid?

A. In the form of Gaucho 75ST and--

Q. And 48 FL. Yes.

A. Gaucho 480 Flowable--I'm trying to remember.

Q. Okay. Gaucho 75 was--

A. --when it was registered.

Gaucho 75 was certainly because that was first registered in '96.

Q. And Helix at the time it was submitted was comprised of an insecticide and three fungicides. The insecticide had never been registered in Canada for any use; is that correct?

15:37 A. That's right. It was a new active ingredient.
Q. And two of the fungicides had never been registered for use on canola in Canada; is that correct?
A. I believe so, although I was working in the Insecticide Section, and I'm not certain what the use pattern for the fungicides were. I believe you're right.
Q. Just generally speaking, Category A compared to Category B and specifically looking at Category A for a new insecticide never registered for anything on Canada. Category A versus a Category B, the Category A submission would be significantly more extensive than Category B.
A. Because it was for a new active ingredient that hadn't been registered in Canada, it would require more supporting data, yes.
Q. Right. Lots of different studies that are applicable to a new active ingredient, that would not be applicable to a new formulation.
A. That is right.
Q. Yes? Okay.
So, I think we've got Category A and Category B, and now if we can talk briefly about Level A and Level B.
A. All right.
Q. I'll try to summarize it, and you tell me if I'm incorrect.
The Level A stage--so these are stages of the

15:38 submission process; is that right?

A. That's right.

Q. And I'm in your Paragraph 17 here--

A. That's right.

Q. --if you want to review it.

Level A is sort of a very basic paperwork check: Have they given us the right forms, have they given us a check. It's that kind of basic pro forma minimal paperwork review to see if everything is in the package; correct?

A. That's right.

Q. And then Level B is the screening stage, and that's more of a checklist process to see if all of the required elements are there?

A. That's right.

Q. And then Level C is a preliminary review of the data, and Level D is a more detailed review of the data. Are those also correct?

A. That's right.

Q. Okay.

We'll get later to a few of your exhibits, but I want to understand as well in the processing of submissions we see the phrases "in queue" versus "started." Can you tell me the difference between those two?

A. "In queue," for example, "Level B in queue" means that the submission has completed the Level A verification review,

and is now waiting for an evaluator or screener to pick the submission up.

Q. Okay.

"And started?"

A. "Started" means that it has been picked up by the evaluator or the screener, and they are going through the process at whatever stage they are in.

Q. Okay. And so at a Level C or Level D stage, there are different teams, if that's the right word, different groups of evaluators looking at the package?

A. At a level...

Q. At a Level C or Level D, at the review stage.

A. In the review stage, the Level C review, which is the preliminary review, the science team is assigned, and they are looking at the data that have been submitted and determining whether or not the data are adequate for a full review. And usually, although it can happen, usually the evaluator that does the Level C review will continue if--will continue to do the Level D review, unless, of course, the submission goes on hold and their workload may be managed differently and it be assigned to another evaluator. So, it's not guaranteed that it is the same evaluator.

Q. Okay. In a level--so let's talk about a Level D review. If it's "in queue" Level D, that means it's past Level C.

15:41 A. That's right.

Q. "Started" for Level D means that all of the evaluation groups are looking at it now?

A. No. Actually, we have a division status table in our database which indicates all the evaluators that have been assigned to do a Level D review, and they all, as they pick up the submission, will flip it to "started" when they begin their review. So, it's quite possible that you have an evaluator in one review stream who has picked it up where the submission is still "in queue" waiting for another evaluator to pick it up.

Q. Okay.

So, when we look at some of your exhibits for Helix, if it says "Level D started," that means all of the evaluators have picked it up, and if it's still "in queue," it means not all of the evaluators--

A. The overall status of the submission is Level D started, and that should indicate that all the evaluators have picked it up.

Q. Once we get to "started"?

You have to say yes for the--

A. Yes. Once we get to "started," all the evaluation team should have picked up and begun their review.

Q. Okay.

The screening stage--I don't think we need to turn to the MOSP, but do you recall that screening for Category B, the

15:42 standard is 45 days; is that right?

A. The screening stage Level B is 45 days--

Q. 45 days.

A. --for the PMRA to screen the submission.

Q. Right, okay.

If we flip ahead to Paragraph 36 of your Affidavit, the last sentence of that paragraph says: "On October 13, 1999, the PMRA provided information regarding data requirements for a Category B.2.6 submission and provided a list of required supporting data."

And then you footnote that to Exhibit SC-33. And if we flip ahead to that, to SC-33, we have an e-mail here to Bob Chyc at Gustafson. And if we flip to the second page, this is the checklist for a B.2.6; correct? We see it on the second, third, fourth, and fifth pages.

A. This is what we call a "DACO table," and that simply means the data requirement for this type of a submission.

Q. Right.

These are the elements you're looking for in the screening process.

A. Yes.

Q. Okay.

This is the standard data screen for a B.2.6?

A. That's right.

Q. It was at this time.

15:44 And when you're at the screening stage and you've just received the submission, you're not--you, PMRA--are not reading every page. You're comparing what's come in against this data screen, this checklist, to see do we have something for 1.A, do we have something for 1.B. That's the exercise.

A. It's that detailed, that's right. The screener is looking to make sure that all the data requirements have been addressed.

Q. Right.

They're not reviewing the data substantively.

A. No, the screener is not.

Q. Right, okay.

And if the submission addresses all of the elements, then it's passed and it moves to the next stage.

A. That's right.

Q. And to satisfy an element--correct me if I'm wrong--you can either submit data, you can either refer back to previously submitted data, or you can request a waiver based on a scientific rationale; is that right?

A. That's right.

Q. So, you don't need data for every element necessarily.

A. That's right. But the caveat is there that if a waiver request or rationale is submitted, that that will be assessed at Level C.

Q. At Level C. Right, okay.

15:45 And the Gaucho CS FL application that was submitted in March 2000, it had--it addressed each of those elements; is that correct? It either had data or a waiver?

A. No, that can't be correct because the submission went beyond hold, so there were elements that were missing or not fully addressed, and the letter was returned to the Applicant, asking for further elements.

Q. Okay. So, I believe the letter you're referring to is Exhibit SC-29. And this is July 27th, 2000.

And we can see this letter has a copy of that data screen, that checklist, with comments for each of the elements.

A. It does have that, and it also has Attachment 3, which defines the deficiencies that were found at the screen.

Attachment 2?

Q. Yes.

A. Sorry.

Q. No, that's fine.

So, first of all, just as a question, the submission was filed March 27, 2000, and this first response is July 27, 2000. So, it's been, if you'll take my word for it--and I'm ignoring a few days for the Level A--it's been about 118 days since the submission was filed. The standard, you agreed with me, was 45 days for a screen. So, the Level B process if someone that looks at this checklist, compares it to the package, sees if there is something missing.

15:47 Can you explain why it would have taken 118 days for someone to go through this five-page checklist to see whether the package had or did not have these elements?

A. I do know that there was quite a lot of correspondence between the Applicant and the PMRA between the time that the submission was made in March and this letter went out. There was a lot of correspondence back and forth. In fact, when the submission came in, there was a request for an expedited review, and that had to be addressed, and there was other correspondence as well regarding it.

Q. That correspondence didn't go to the substance of the application, if I'm correct. It only addressed that issue that you just mentioned of whether or not it should have an expedited review; is that right?

A. I have to read that letter to determine what it referred to. I just recall that there was correspondence between...

So, I believe it's part of my--but also to answer your question--to answer your question, the deficiencies that were required or were that--that were found at Level B are outlined here. So, to the extent that the screener was satisfied that these were missing, they looked at the information that was provided and determined that these were deficiencies.

It's true, it took longer than the 45 days, if that is your question.

15:50 Q. This deficiency list arises from a review of the submission against the checklist, against the data screen.

A. That's right.

Q. Regardless of whether or not you find deficiencies, that process is not a particularly involved process; correct?

A. Well, it's fairly involved and it takes 45 days and at the same time the submission--the screening section is reviewing a number of other submissions.

Q. Ideally it takes 45 days.

Can you go through--have you seen the Gaucho CS FL submission? Did you actually look at the submission in preparation for your testimony in this proceeding?

A. Yes, I did.

Q. And would you have been able to tell what the initial submission was as opposed to what came in afterwards? In other words, what was filed on March 27th, 2000, as opposed to studies that came in subsequently, is my question.

A. Well, when you say did I see the submission, I saw the submission file, which has correspondence regarding the submission. I didn't see all the data, actually handle all the data that were submitted.

Q. Okay. You did not review the data. Not review--"review" is a technical word here. I apologize for that.

You saw the submission that was filed on March 27th.

15:51 A. I saw the submission file. It would have been accompanied by boxes and boxes of data which would have gone to the review divisions for their Level C review.

Q. Did you see those boxes and boxes of data? I'm not trying to be facetious. A B.2.6 submission, especially in this case where it's a fairly simple submission in the sense that imidacloprid is replacing lindane, it did not involve environmental fate studies. It did not have plant and animal metabolism studies; is that right? It wouldn't have had those studies. Environmental fate.

A. But if you go back to the DACO list, it may have required environmental fate studies. In fact, there is some toxicity, environmental toxicity data, that are conditionally required and could be requested.

Q. Right. They may or may not be required, and that will unfold during the review of the submission--

A. During the Level C review, that will be established.

Q. The deficiency list that you referred to--I understand it, and we will get to it--does it say that any of the required elements were not addressed, either by the provision of data or a waiver? Waiver request, I'm sorry.

A. Well, it lists what are required, what deficiencies are in Attachment 2.

Q. Okay. It's probably worthwhile to look into those deficiencies a bit.

15:53 Did you see the Helix submission? Have you reviewed the Helix submission?

A. I read--I reviewed the submission file.

Q. Okay. Not the boxes and boxes of data?

A. No.

Q. Okay.

If we flip back, and I think we're around Paragraph 34 of your first submission, what I think you've said in your Affidavit is that there are four--and I'm summarizing your evidence here--there are four nontrivial issues that you raise that caused the Gaucho CS FL submission to take so long. And I'm summarizing here, but correct me if you disagree with these: The absence of product chemistry and toxicity studies in the initial submission, the new pest claims, the mustard issue, which you call a new use site which relates to disease claims for mustard, and the tank mix issue. As you recall, your evidence, are those sort of the major issues that would have caused the delay?

A. You're referring to Paragraph 34?

Q. Well, I believe it starts--sorry, 35 is where you mentioned the pests, and further down in 35 is where you say a new use site mustard was also proposed. You mention product toxicity, product chemistry and toxicity studies in 37, and you mention the tank mix issue in 39.

You don't have to agree with me. I'm asking you what,

15:55 in your recollection, were the major issues that caused the application to take so long. Do you recall those four issues that I mentioned?

A. Well, what caused this submission to take so long was the fact that it went through Level B twice. And you're right, the review time is 45 days for the PMRA, so it went through twice. We had to wait for the Applicant to respond to those Level B Deficiency Letters and further requirements that were specified. It then went through Level C, and there were deficiencies identified there, and those were addressed after a period of time by the Applicant--came back in, went through a third Level B to make sure that everything that was asked for was provided.

Q. Okay. You've given us quite a helpful timeline in your second Affidavit, which I think--well, which we will get to, but maybe we can address these four issues because certainly in your first Affidavit, these were some the reasons specifically why you say the application took so long.

So, you recall saying that there were no product chemistry or acute toxicity studies submitted with the original application. Do you recall that?

A. I believe that's the case. I believe a waiver request was submitted for the acute tox data, even though it is required data and not conditionally required data. And see-

Q. Sorry, just on that point, required versus

15:57 conditionally required, you can meant a required element by requesting a waiver, a data waiver. Whether PMRA accepts it or not, a different Level C issue, but people, Applicants file a waiver request for required elements; correct?

A. Usually that data is required. It's not--and, in fact, we did accept the submission with a waiver request for those required elements. But at Level C at the preliminary review, those data were required. So that was the Applicant's--the Applicant's prerogative to submit a waiver request.

Q. Right.

The element is met for Level B purposes. At Level C, PMRA may say, I don't buy that waiver, give us the data.

Is that a fair summary?

A. And when you look at the Deficiency Letter, that is not cited as a deficiency at Level B.

Q. Right. I agree.

PMRA said in Level C, we want those studies, as I think you just said, and the studies were provided on October 26, 2000. Does that sound right to you?

A. Yes, it does.

Q. It does?

A. Yes, it does, sorry.

Q. So, the product chemistry and acute toxicity studies, their absence from the initial submission, that issue was off

15:58 the table as of October 26, 2000, in the sense that PMRA's issue with it was addressed.

A. No, actually, no. When they were submitted on October 26th, we had not conducted a preliminary review, so they weren't off the table. It was addressed. We had the data, and then they had to undergo a preliminary review to determine that they were adequate.

Q. The absence of the studies as an issue was addressed as of that point. They still had to be reviewed just like everything had to be reviewed on Level--

A. The Applicant submitted the studies, yes.

Q. Okay.

Their absence as a factor in slowing things down was gone as of October 26. Everything had to be reviewed as it always does in Level C, but their absence as a factor slowing down the process was no longer an issue as of October 26, 2000.

A. They were submitted; that's right.

Q. Are you familiar with the Vitavax RS Fungicide product?

A. Only that it was a registered product.

Q. Are you aware that the Vitavax RS Fungicide submission was reviewed and approved in the absence of any product chemistry or acute toxicity studies?

A. No, I'm not.

Q. Okay, fair enough.

16:00 Mustard, Paragraph 35. This is on Page 12 of your first Affidavit.

A. Page 12, Paragraph?

Q. 35. So, it's at the top of Page 35 there.

A. Starting on Page 11 and continuing? Yes?

Q. Correct.

So, I'm on Page 12, and you've got a comment here near the end, "A new use site, mustard, was also proposed."

A. Right.

Q. And I think what you're saying there is if we go back to the Deficiency Appendix 2--Attachment 2 that you were pointing out to me--

A. So that's--

Q. This is SC-29.

A. Thank you.

Q. And it's Page 9 in the numbering. So I'm in Attachment 2, Page 9. Are you on that page?

A. Yes, I'm there.

Q. Okay.

So, Section 5, part one, Labels, the second paragraph says: "Several pesticides or pests and sites have been proposed on the draft label with no currently registered precedence to support them."

And then part two: "Mustard is not an approved crop for the control of seed rot, damping-off, seedling blight and

16:01 early season root rot."

A. Right.

Q. Is that a new use site issue or a disease claim issue?

A. It's a new use site. No use claims were on the--or in the use pattern for the fungicide components of this proposed product. Nowhere had we reviewed that use site for those use claims or--for those use claims.

Q. You're saying what this sentence says is that--well, let's go to Gustafson's response because I think that will be helpful. So, if we go to SC-30 on September 7, 2000, Gustafson is responding. So SC-30, this is a letter to Sean Muir of the PMRA.

If we go to the second page near the bottom--this is their response to this deficiency list. So Section 5, the last paragraph on this page, the first sentence is: Instructions for use of this product on mustard seed have not been removed from the label. There are several registered products with combinations of carbathiin and thiram for control of seed rot damping-off, seedling blight, and early season root rot on mustard.

Do you see that?

A. Yeah, I do see that.

Q. Okay.

Their position was that PMRA made a mistake in that deficiency list, that, in fact, all those Vitavax products had

carbathiin and thiram approved for these diseases.

Do you have any further information to clarify whether PMRA made a mistake in that deficiency list?

A. No, I don't. But I think that when it came in at Level C, the fungicide evaluator would have looked at that Claim and verified it.

Q. Okay. You don't have any information that this issue continued on through the review process. You don't have any knowledge--information to confirm whether this was a live issue throughout the process or whether, in fact, at Level C the evaluator said, "Oh, you're right, it is on several Vitavax Product Labels." You don't--

A. No, I don't.

Q. Okay.

And also in Paragraph 35, but let's move back to Page 11, part way through 35, it says: "The submission covered a number of new pests, either a no-registered products with these use claims as precedence for the active ingredient imidacloprid, including aphids, lygus bug, and cabbage seedpod weevil."

You described this as a new pest Claim that complicated the submission and required more time; correct?

A. Right, and the fact those new use claims were not supported by efficacy data--

Q. Right.

16:05 A. --is a complication as well. We couldn't evaluate whether or not the product was effective without the data.

Q. Okay.

And Gustafson's response--and if we go back to SC-30, this is that letter we were just looking at--again it's still in that same section, so it's the second page, Page 5, part one, Labels is the heading: Instructions for aphids, lygus bug, and cabbage seedpod weevil have been removed from the label as requested.

So, you came back to them and said, there is no data to support this. They came back and said, okay, forget about it.

Is that right?

A. Yes.

Q. So as of September 7, 2000, the new pest issue was no longer an issue. They withdrew the Claim.

A. We no longer required the data.

Q. Right.

A. We--they didn't have to support that use Claim.

Q. It could not have impacted the timing of the review because it was no longer part of the submission.

A. Well, it had already impacted the timing because it was a deficiency. We had to write and request the data because the Applicant addressed that deficiency by removing the use Claim. That still didn't--it still took time to go through the

16:06 deficiency process.

Q. Sorry. I was asking as of September 7, 2000, going forward from there, it was no longer an issue.

(Pause.)

I'm sorry, can you say yes.

A. Yes, yes.

Q. If yes is your answer.

A. Yes.

Q. The tank mix issue, Paragraph 39, in the middle of this paragraph, you say, "The Applicant also made requests for changes to the formulation and for the addition of new combination (tank mix) claims to the proposed label."

Do you see the sentence I'm referring to?

A. Yes, I do.

Q. And if I understand it correctly, a tank mix Claim would allow a seed treater to combine two registered products into a tank and apply them simultaneously, as though they were one product; is that right?

A. Yes.

Q. Okay.

And in the case of Gaucho CS FL, the tank mix Claim that was proposed was that Gaucho CS and Gaucho 480 would be combined and that would give you a higher rate of insecticide; is that your understanding?

A. Yes.

16:07 Q. Okay. For--

A. Without getting a higher rate of fungicide.

Q. Exactly, okay.

And your evidence was that this tank mix issue was one of the elements that caused the submission to take longer to review and approve.

A. Well, it was a new request, a new Claim. Potentially, there were data that needed to be reviewed--submitted and reviewed to support that Claim.

Q. Okay.

If we go to SC-57, this is--and it's not a great copy, so I apologize for that. This is in October--do you have the SC-57? I'm sorry.

A. I was actually going to Paragraph 57.

Q. Oh, I'm sorry. It's Exhibit C-SC-57.

So, this is an October 26, 2000, letter, from Gustafson to PMRA.

Do you see the letter?

A. Yes, yes.

Q. It's not clear.

A. No, it isn't.

Q. But at the very bottom of this, so Gustafson is describing the tank mix issue, and then at the very bottom they say: However, we do not wish for this tank mix submission to hinder the progress of Submission Number 2000-0706 for

16:09 registration of Gaucho CS Flowable.

And as we flip over: Formulation in any way.

So, Gustafson was saying, we'd would like a tank mix approval, but do not let this hinder the application of the Gaucho CS submission.

I have a question, but I'll take you first to another exhibit, and that's SC-49.

Now we are at February 21, 2001. This is Gustafson writing to the PMRA. And if we flip to the second page, and I'm in the first paragraph: If for some reason it is not possible--towards the ends of that paragraph--

A. Which page again?

Q. I'm sorry. It's Page 2 of SC-49.

A. Right.

Q. So, up at the top, the paragraph starts: The submission that included.

A. Um-hmm. Yes, I see that.

Q. And I'm actually in the last sentence of that paragraph.

A. All right.

Q. "If for some reason it is not possible to process the two submissions side by side, Gustafson would like to proceed with the low rate only of Gaucho CS FL, although we prefer to proceed with the tank mix label."

So when they talk about two submissions here, one is

16:10 for Gaucho CS and the other is for the tank mix option, if I can shorthand it that way.

Do you agree that that's what this paragraph is talking about?

A. Just a second. I will read it.

Q. Sure.

(Witness reviews document.)

A. Yes, I agree that's what's going on there.

Q. And you'd agree with my summary, I think, that these two letters are saying it would be great if we could get the tank mix option, but please do not allow the tank mix option to hold up the main Gaucho CS submission.

Is that what these letters are saying?

A. It appears so, yes.

Q. Okay.

A. Yes.

Q. So, I guess there is one of two consequences: Either the tank mix option did not slow down the approval of Gaucho CS or the PMRA ignored those requests. It has to be one or the other. Is that fair?

A. Well, considering the tank mix solution addressed the problem that originally the submission came in with two rates of Gaucho CS to increase the rate of insecticide, and this was a solution so that when the rate of insecticide was raised; the rate of fungicide was not raised, there already had been some

16:12 discussion, a lot of discussion back and forth looking for the solution, so that took time.

Q. Okay.

So, if we go--I appreciate that clarification.

If we go to SC-48. This is a letter from PMRA dated February 15, 2001, to Gustafson. And on the second page of that--sorry. The third page, the top of which is Attachment 1, Deficiency Review Notes, there is section part one label, and there is a section in the center there "required data": If the petitioner wants to register the higher application rates, thiram and carbathiin, supporting residue and environmental data would be required.

A. Where are you again?

Q. Sorry. Required data. It's in sort of the middle of the page under part one, Label.

A. Okay. Yes, sorry. Thank you.

Q. If we go--and so this was a Deficiency Letter from February 15th, 2001, to Gustafson, and then if you flip to SC-85. This is an attachment to your second Affidavit, but it's actually the response to this letter.

A. SC-85.

Q. Yes.

This is an e-mail dated February 21, 2001, from Gustafson to Sean Muir.

Do you have the e-mail? It's SC-85.

16:14 A. Right. It's to Chantelle Fortier.
Q. Yes.
A. And copy Sean Muir.
Q. Right, yes.
And halfway through that paragraph--so he's--this letter is in response to PMRA's February 15th letter--there is a paragraph, second paragraph: We do not want the rate issue to interfere with the registration of this product. Most of the use of this product will be at the low end of the rate of 1400-milliliters per 100kg, and if necessary, the label can be revised to only include the low rate.
So, he's addressing there, I believe, the rate issue that you mentioned; is that right?
A. He is addressing the rate of insecticide issue here, yes.
Q. His letter is in response to the February 15th letter from PMRA, and that's where we were just looking at, SC-48, and that required data section in the middle of the page, that was talking about fungicides; correct?
A. Yes, it is talking about fungicides.
Q. Okay. In this e-mail you're saying he's not talking about fungicides?
A. In this e-mail he's talking about--oh, okay.
Q. He concludes this--sorry to interrupt--"My response to your letter does not give any new data. I believe that the

16:16 issues raised in the Deficiency Letter have been addressed."

A. Okay. And your question is?

Q. You made the comment that the initial submission had differing rates of fungicides. Was that the statement you had made?

A. No. I think the proposal was for two rates of the combined product when the higher rate was applied, and I think the goal of applying the higher rate was to have a higher rate of insecticide because it was a product formulated with the fungicide active ingredients. Inadvertently, the rate of fungicide was raised, where that had not been reviewed and was not actually proposed or needed or--it wasn't--it had not been reviewed. So that would have been a rate of fungicide higher than the rate that was currently in the use pattern.

So, two rates of Gaucho which is a product formulated with fungicide and insecticide. The aim of the higher rate was to control the insecticide pests that were claimed on the label, that also because it's a product formulated with fungicides increased the rate of fungicide.

Q. And when they introduced the tank mix option, that was so that they could achieve a higher rate insecticide if they needed it while keeping the lower rate fungicide.

A. While not raising the rate of fungicide.

Q. While not raising the rate of the fungicide. Okay.

Let's take a break from dates and go back to para 22

16:19 of your Affidavit.

Here you're talking about the Voluntary Withdrawal Agreement.

The purpose--to oversimplify, the purpose of the Voluntary Withdrawal Agreement was to address the lack of harmonization between Canada and the U.S. It was driven by this trade irritant issue that lindane-treated canola seed was being sent to the U.S., and lindane didn't have a tolerance--wasn't registered in the U.S. for canola and didn't have a tolerance for canola. Is that a fair summary of the genesis of the withdrawal, as you understand it?

A. Well, I wasn't really involved in the negotiation of this Voluntary Withdrawal Agreement, and the purpose--I think you'd be far better discussing that with Dr. Claire Franklin, who was involved in that process.

Q. At the end of Paragraph 22, you say--well, maybe let's start partway through, maybe at the beginning. "The first category lindane-free products consisted of currently registered products which were co-formulations of lindane along with fungicide active ingredients."

And then if we go to the end, "the Claimant's product of this nature, Vitavax Fungicide, was granted--amended registration on May 3rd, 1999."

You agreed earlier, I think, that the fungicides and Vitavax Fungicide were thiram and carbathiin?

16:20 A. All right, but I would need to look at the specifications of that product.

Q. So, you--fair enough.

You have this paragraph in your evidence, but you weren't really involved in this activity, either the voluntary withdrawal or the registration of Vitavax Fungicide; is that right? Were you involved in the registration of Vitavax RS Fungicide?

A. No, I wasn't.

Q. No, okay. In Paragraph 23, you start that paragraph, "the second category replacement products"--this is still talking about the Withdrawal Agreement--"the second category replacement products were replacement products in which a different insecticide active ingredient was registered as an alternative to lindane."

Were there any lindane only products on the market for canola--insecticide only lindane product on the market for canola? Do you know?

A. No, I don't know.

Q. Okay. Paragraph 32, you--at the time were Section Head of the Insecticide Section, "I oversaw the work carried out by my colleague Jeff Parsons."

Was Jeff Parsons making all the major scientific decisions on Gaucho CS? Was he the scientific lead on Gaucho CS?

16:22 A. No, he was evaluating the insecticide efficacy and value data, so he was looking at the data package supporting the insecticide use claims that were on that label, and assessing whether or not the product performed as claimed--as proposed.

Q. For Gaucho CS?

A. That's right.

Q. Okay. And was he performing a similar function for Helix? Do you know? The Helix submission.

A. I believe so.

Q. You believe so.

A. Um-hmm.

Q. Was he involved in the Lindane Special Review?

A. I don't know.

Q. You don't know, okay.

He was--was he within your group? It didn't sound as though he was reporting to you.

A. He was. He was either my colleague, and I was peer-reviewing his assessment of the efficacy and value data, or I was his Section Head and I was again peer-reviewing and approving his assessment.

Q. If we go to Paragraph 54, you say here, "Gaucho 75 was first registered in the U.S. on November 18, 1994, and the Claimant therefore had several years to develop an all-in-one version of this product."

16:24 Gaucho, the insecticide, was registered in the U.S. Is it fair to assume that the fungicide needs of canola in the U.S. might be different than the fungicide needs of canola grown in Canada?

A. I have no idea.

Q. Fungicides are not you not your thing. You're an insecticide person?

A. That's right.

Q. Okay. We're going to start to get into the Helix submission a bit. I would like you to turn to SC-22.

A. Paragraph 22 or Attachment?

Q. Exhibit SC-22.

This is a letter from Claire Franklin to Mr. Ingulli of Crompton June 21, 2000. This is part of that correspondence that you were talking about earlier, and Crompton/Gustafson had asked for priority review.

She says, "given your"--if we go to the second page, "given your request of April 20, 2000, another request that we received, we did investigate the possibility of opening the door again to Registrants with respect to lindane replacements outside the Joint Review program. Given our current workload and the request to accommodate a variety of similar requests, it was determined that no additional special consideration could be given."

I would like you now to have open nearby your second

16:26 Affidavit, and let's start with Exhibit SC-74.

That page is the submission status history for the original Helix submission; is that right?

A. I believe so, although it could be for the thiamethoxim--yes, it was for the original CS-submission. There was a sister submission for Thiamethoxim Technical.

Q. And that'll be SC-75?

A. Um-hmm.

Q. This submission status history shows that the original Helix submission was rejected March 27, 2000; is that right?

A. That's right.

Q. There were issues, and maybe we will talk about them in a bit more detail, but as of March 27, 2000, the original Helix submission has been rejected. And if I could ask you to flip to Exhibit SC-78, this is the submission status history for the subsequent Helix submission that came in later that year with a new occupational exposure study; is that right? The second Helix submission.

A. Yes.

Q. Okay, and it looks like the process started--it was filed September 8, 2000; is that right?

A. Yes.

Q. Okay. If we go back to SC-22, the exhibit, not the paragraph, when Dr. Franklin is writing to Mr. Ingulli on June 21, 2000, "Helix has been rejected, and the Gaucho CS FL

16:27 submission is the only lindane replacement submission that the PMRA has in its hands;" is that right? There is no other lindane replacement product being considered by the PMRA for canola?

A. I'm trying to remember what the registration dates were for Gaucho 75ST and for Gaucho 480.

Q. Okay. I will give you a different question so you are more comfortable with the answer. This was the only all-in-one insecticide-fungicide application--submission for canola that the PMRA was considering at this time. If--you're wondering when 480FL had been completed? Is that your...

A. That's right.

Q. Okay. Well, 480FL was insecticide only.

A. That's right.

Q. So, if we are looking at combination insecticide-fungicides, this was the only insecticide-fungicide lindane replacement that PMRA had in its hands in June 2000.

A. Well, actually I can't say that with certainty. I don't know what other submissions there were.

Q. You don't know whether there were other possible lindane replacements being considered by PMRA at this time?

A. I think the Premiere Z submission was still open at that time.

Q. In June 2000?

A. I believe so.

16:29 Q. The PMRA--

A. That was withdrawn--I will have to check the date, but the Premiere Z submission was withdrawn after this point, I believe.

Q. After June 2000?

A. I believe so.

Q. If we look at Paragraph 20 of your second Affidavit, you make the statement, the second sentence, third line, "the Gaucho CS FL application was submitted to the PMRA over a year after the Helix application was and close to two years before--close to two years passed before the PMRA received a complete data package."

The first Helix got rejected, as we just saw; correct? That SC-74 that we looked at--the first Helix submission was rejected by PMRA in March 2000?

A. That's right, after a complete review, the submission was rejected.

Q. And the second one, as we saw, was submitted September 2000. I thought that was it.

A. That's right.

Q. Exhibit SC-78.

Let's--exhibit--paragraph 57 of your first Affidavit.

Actually, let me ask the question: Helix, partway through, became two products: a low rate and high rate version. You're aware of that?

16:32 A. Yes.
Q. Were product chemistry and acute toxicity studies for the lower rate Helix included in the initial submission?
A. Product chemistry and acute toxicity--
Q. Toxicity.
A. Likely.
Q. Even though the product only became two products halfway through this period. In November '98, there was just the high rate version; am I correct? The full rate--what became Helix Xtra; is that right?
A. I believe it was what became Helix Xtra, yes. I'm not sure at this point what the guarantee of the initial insecticide component for the initial Helix submission was. There is a name change there.
I'm not sure what your question is, to tell you the truth.
Q. My question was, "what was submitted in November '98 with the Helix submission." Helix ultimately became a high rate version and a low rate version.
A. That's right. It was sort of to address the same issue that was addressed with the tank mix of Gaucho CS and Gaucho 480. A higher rate of insecticide is required, and in the case of Gaucho it was addressed by tank mixing with an insecticide alone product. In the case of Helix, that issue was addressed by two formulations with the same amount of

16:34 fungicide in both the Helix formulation and twice the insecticide in Helix Xtra.

Q. And when you're approving a second formulation, presumably you need certain types of data to support the two different formulations?

A. Uh-huh, yes, that's your question, yes, yes.

Q. And you don't know whether the data submitted November 1998 supported the two different rates, I believe was your answer. You weren't sure whether they--

A. Well no, actually, I wasn't sure what your question was. So, you're asking me if in 1998 the data submitted supported both the low and high application rate of insecticide.

Q. Correct.

A. The efficacy data?

Q. All of the data. Whatever data would be required to support formulation one and formulation two.

A. It depends what was proposed on the label. If the two rates were proposed, then yes, the data was submitted.

Q. Or it should have been submitted?

A. Should have been submitted.

Q. Okay, and you don't know what was proposed on that original label in November '98? No?

A. No, I don't.

Q. Okay. Fair enough.

16:35 Back at Paragraph 17, we described the stages or levels, and on Page 6--

A. Back--where are we now?

Q. I'm sorry, Paragraph 17 of Affidavit number one. And I'm on Page 6, it's the Level E description.

A. Right.

Q. "Level E is decision making prior to enactment of the new PCPA in June 2006. The PMRA issued a Proposed Regulatory Decision Document, PRDD, for all new active ingredients, at that time a consultation period of up to 45 days ensued from the date of publication of the PRDD."

A. You're reading this in Paragraph 17?

Q. Yes, your first--it's Level E.

A. Oh, Level E, I'm sorry.

Q. It's on Page 6.

A. Okay, yes, all right.

Q. So, just in a nutshell, it says, "the PMRA issued a Proposed Regulatory Decision Document PRDD for all new active ingredients. At that time a consultation period of up to 45 days ensued from the date of publication of the PRDD."

Do you see that passage?

A. Right.

Q. Was a PRDD issued for Helix?

A. No, because the decision was made to grant temporary registration and a Regulatory Note was registered--was

published instead.

Q. And is the temporary registration valid for a certain period of time? Was it a one-year period, or is it longer than one-year period, or it depends?

A. Temporary registration under the then PCPA was for a period of one year, but on application could be renewed.

Q. Okay. Are you aware whether it was--so this was--it received the temporary registration in November 2000. Are you aware whether it received one year renewals for 2001, 2002, 2003, 2004, 2005?

A. Yes, an application to extend the temporary registration would have been made by the Applicant, considered by the PMRA, and the registration would continue for another 12 months.

Q. Okay. In Paragraphs 79 to 80 of your first Affidavit, and before we get here, those one year extensions we just talked about for those five years, I think it was, did you file those on the record?

A. Pardon me?

Q. The temporary--the extensions, the one year annual renewals of the Helix temporary registration, the ones for 2001, 2002, et cetera, were those filed on the record?

A. Have I referred to them in my Affidavit? Is that what you're asking me?

Q. I'm asking you if you filed the renewals.

16:39 A. Do I have them here as an exhibit?
Q. I don't believe so.
A. No, I don't think I did.
Q. In Paragraphs 79 and 80 you're talking about the new regime, so Helix was transitioned in 2006 to the new--
A. A new PCPA act was enacted in 2006.
Q. Right. And I believe your evidence is that with these temporary registrations as they're transitioned, and it's here at the end of Paragraph 79, "the conditions of registration were made public by publication of a document known as a Section 12 Notice in the public registry on the PMRA Web site."
A. That's right. Those are--under the new PCPA, we grant conditional registration for a period of time, not limited to one year, as it was under our previous Act, and we publish the conditions of registration in our public registry as a Section 12 Notice.
Was that your question?
Q. I'm not sure.
But my next question was going to be whether you filed the Section 12 Notice for Helix?
A. A Section 12 Notice would have been filed for Helix.
Q. Sorry, would have been filed with the public, but you didn't file it as part of your evidence. Would you agree with me? That's okay.
A. I don't believe I did.

16:40 Q. Okay, fair enough. Let's look at Paragraph 82. I'm still in your first Affidavit.

A. Paragraph what?

Q. Eighty-two.

A. All right.

Q. And here you've said, "the PMRA may choose to consult publicly but the final regulatory decisions will not be subject to reconsideration."

Actually, let's flip to SC--Exhibit SC-45, and this is the Regulatory Note that you spoke about for Helix. And if you just flip, so you've got the cover page for SC-45, and then there's the forward on the next page, at the end there, the last paragraph, it says, "Syngenta crop protection will be carrying out additional toxicology and value studies as well as a stewardship program as a condition of this temporary registration. Following the review of this information, the PMRA will public a Proposed Registration Decision Document and request comments from interested Parties before proceeding with the final regulatory decision."

You would agree with me that the publication, as I think you have already agreed, that was never done. The PRDD was never issued for Helix, because it stayed a temporary registration until 2006?

A. And then it was transitioned to a conditional registration, and the Section 12 Notice would have been put in

16:42 our public registry, indicating what the conditions of conditional registration are.

Q. Did Syngenta file all of that additional data? Do you know? That first sentence, "will be carrying out additional toxicology and value studies as well as the stewardship program."

A. I believe the submission to convert from conditional to full registration is with the PMRA, and that would mean that this data has been submitted.

Q. You're not certain. That's your belief. You haven't reviewed that data, you haven't seen that data?

A. I haven't reviewed that data, no.

Q. Still in your first Affidavit, Paragraph 88, "the value assessment of the fungicide performance stated that the data supported label claims of control of seed-borne blackleg and the seedling disease complex." And then you list the diseases caused by the plant pathogens, et cetera, et cetera, "but that there were not sufficient data or evidence to consistently determine that the half-rate of fungicide was the lowest effective rate necessary or was the lowest rate needed to provide consistent control under various conditions. This lack of evidence justified the approval of the full rate of fungicide."

What's the purpose of requiring the lowest effective rate?

16:44 A. The purpose is to determine the rate that is required of a pesticide to control the pests, but the lowest rate that would be effective to do that. And there would be no value to having a higher rate of insecticide than was needed, and you would be introducing higher rates than were necessary into the environment.

So, at the time, the value data were to determine whether or not the rate that was proposed was the lowest rate.

Q. And so the standard--there is the rate in the submission, and then the reference to the half-rate is an evaluation to see whether it's effective at the half-rate?

A. Right.

Q. And if the half-rate is sufficient, then the product is amended--the formulation is amended so you only have the half-- that half-rate which is now your rate?

A. Yes, yes, sorry.

Q. In this case, the data was not conclusive, and rather than requiring Syngenta to obtain conclusive data, they were allowed to proceed with the full rate? Is that what this paragraph is saying?

A. It was--it was common, it was required to have data, efficacy data, value data, that demonstrated the proposed rate, and data that examined the fungicide in field trials at the half-rate so that the lowest effective rate could be determined. And it was also quite common, if the lowest

16:46 effective rate could not be established, to register the low rate and require confirmatory data.

Q. You said register--

A. Pardon me. I'm misspeaking, to register the proposed full rate and to require confirmatory data at the half-rate.

Q. On this issue, was Syngenta required to provide confirmatory data?

A. I would have to go back to the letter granting temporary registration where all the conditions of a temporary registration are outlined, and I don't know--I don't believe I have that here as an exhibit.

Q. If we go to paragraph--

A. But it would be typically--typical to require that confirmatory data.

Q. If we go to Paragraph 90, now we are into--this is still in your first Affidavit.

A. Right.

Q. You're talking about Regulatory Directive 94-04.

A. Right.

Q. You're talking about Regulatory Directive 94-06.

A. All right.

Q. And you say, "Regulatory Directive 94-06 provides guidelines," and I think your--

A. That's right.

Q. Your earlier comment was, "this Directive is not

16:47 necessarily binding on PMRA;" is that right? You don't consider yourself bound by this Directive?

A. Well, it's not a regulation. It's not enacted in law, but it is a policy, and these are guidelines.

Q. You conclude Paragraph 90 by saying--you're summarizing Regulatory Directive 94-06, and the very last sentence there says, "canola seed treatments," you're saying, "Regulatory Directive 94-06 provides guidelines with respect to the color stands for seed treatment, pest control products and labeling of treated seeds under the authority of the Seeds Act and Pest Control Products Act specifies that rapeseed/canola seed treatments should be light blue," and you reference the Directive that's at Exhibit SC-67.

A. That's right.

I think the point I'm trying to make here is that under the Pest Control Products Act, there is no requirement that canola seed be light blue. There is only a requirement under the Seeds Act that treated seed or seed that has been treated with a pest control product be dyed so that it is conspicuous. And so our Regulatory Directive provides guidance on how it can be conspicuously treated because we were registering the products. Okay?

Q. Okay.

A. So I just wanted to make that clarification.

Q. Thank you for that.

16:49 It's just your--it's the paragraph summary 90 of the Regulatory Directive that I'm interested in, because it says, "Regulatory Directive specifies that canola seed treatments should be light blue," and if we go to Exhibit 67--SC-67, the bottom of Page 3, Section 2.0, "blue coloration standard," the second sentence says, "all seed treatment dressings intended for rapeseed/canola must be dyed a distinct baby blue color."

So the Regulatory Directive, in fact, is not permissive, whether the Regulatory Directive are binding--is binding or not, that's a different question, and I appreciate your earlier comment, but the directive itself says it must be dyed blue. You'd agree with me?

A. Yes, yes I would.

Q. Okay.

A. But I would just like to say that, in fact, the PMRA--yes, it does, okay, fine.

Q. And in 91, Paragraph 91, your first sentence on the second line, it says, "in 2002, it was generally agreed that Regulatory Directive 94-06 was out of date with evolving seed coating practices."

A. Okay. And what I meant by that was these guidelines, this Regulatory Directive from 94 was based on earlier trade memorandum, publications, guidance to industry from 1980 and 1986, and by 2002, seed treatment practices had changed, and, in fact, the PMRA was involved with harmonizing our seed

16:51 treatment Regulations with the EPA and were re-considering this Directive along with other seed treatment Regulations processes.

Q. If we could look at your second Affidavit, Paragraph 6, this is talking about work-share reviews and Joint Reviews.

A. Paragraph which?

Q. Paragraph 6 of your second Affidavit. It's on the second page.

A. All right.

Q. I'm not reading from Paragraph 6. Here you're describing Paragraph 6. You're describing work-share reviews and in Paragraph 7 you're describing work-share reviews. And in Paragraph 8, the last line, second last line of Paragraph 8 you say, "Helix was initially considered as a Joint Review but was ultimately conducted as a work-share." Why was it switched from a Joint Review to a work-share?

A. Well, I wasn't involved in those discussions, but we were working with the U.S. EPA regarding the registration of this product. The process that we used initially, we thought it would be a Joint Review, but the criteria for a Joint Review perhaps were not met.

Q. You're not certain why it was switched from one to the other?

A. I wasn't involved in that discussion.

16:53 Q. Okay, all right, fair enough.

Paragraph 9, you make a reference to the development of resistance to organophosphates and organochlorine insecticides. If we--

A. Paragraph 9?

Q. Sorry. Paragraph 9, yes.

In 1999, had flea beetles developed their resistance to lindane?

A. No, but Helix and thiamethoxim. Helix is just one of the end-use products that were proposed in this work-share, there were others as well for other use sites, Actara and Viridian, I believe. These were proposed for foliar use on a number of other use sites. In fact, resistance in Colorado potato beetle was a bigger concern at the time. The point I'm trying to make is thiamethoxim was proposed for a number of use, and OP replacements were required because organophosphates were under re-evaluation or soon to be under re-evaluation, and insecticide alternatives for a number of different use sites were required.

Q. Fair enough, so--

A. No.

Q. This paragraph doesn't really address lindane in any way or the potential of a resistance in insects to lindane?

A. No.

Q. No. And based on the way Helix works, in fact, if

16:54 you're going to compare Helix to lindane, Helix--flea beetles are more likely to develop resistance to Helix than lindane, would they not, because Helix is a single mode of action? I hope we don't have to get into what mode of action means, but is that a fair statement? You're not sure?

A. I think it's beyond the discussion here.

Q. And you don't have an opinion on whether flea beetles are more likely to develop a resistance to Helix than to lindane?

A. No, I don't.

Q. Okay. Let's go to the end of your second Affidavit. You have prepared an appendix--Appendix A, which starts at Page 12. And here you've prepared a detailed submission history; correct? For Gaucho CS.

A. Yes, I have.

Q. And I believe you agreed with me when we looked at these dates, it was submitted--the submission in March--on March 27, 2000, it ultimately--well, PMRA responded to Gustafson with a Deficiency Letter July 27, 2000. So to get the initial checklist review was 118 days for Gaucho CS.

A. The original screening review, yes.

Q. Right, okay.

If we can flip and if you can hold your hand in that page so we don't lose it, but if you could flip to SC-74, Exhibit SC-74, this is the Helix--the original Helix

16:56 application, and if you'll--if you will accept my math, it was submitted November 25th, and it passed the B screening, the checklist review, December 18th, so 23 days. Does that look about right, give or take?

A. I think your math is good.

Q. Okay. And I know you looked at the Helix file but not the Helix submission, but for a new insecticide--I'm just trying to get a sense of what would have been involved with the actual submission. There would have been several quite significant studies with the Helix submission; is that fair?

A. There would have been a full data--supporting database required for a new active ingredient and end-use product.

Q. Which would be significantly greater than for a new formulation in terms of the number of studies--the complexity of studies; correct?

A. Yes.

Q. Okay. If we look at your table, and if we flip to Page 15 now, the box February 15, 2001, PMRA sent a letter to Gustafson, informing them that the submission is incomplete and provided a Deficiency Note, and you will see there Gustafson responded February 21 and then February 21 and 27, on the next page, there is a box with additional things that were provided.

Then, PMRA reviews that data from--February 27 date actually appears to be incorrect. I think it's actually just February 21st, but it doesn't make much of a difference.

16:59 A. Pardon me, I don't understand the last thing you're saying.

Q. Oh, that box on the top of Page 16 says February 21 and February 27, on February 21st, Gustafson supplied a letter, and then if you look at Footnote 46, that February 27 date is actually an internal PMRA document. So, my only comment was that Gustafson provided some information on February 21st and not February 27th. That was my only comment.

And let's look at that February 15 letter again, which is SC-48, Exhibit SC-48. This is PMRA writing to Gustafson, February 15, 2001. And if we go to the Attachment 1 as the list of deficiencies, so that middle part we read that required data before if the petitioner wants to register the higher rates of thiram and carbathiin, additional data will be required.

The next section says PRMA is looking for a storage stability study.

Then if we turn the page and actually look at the next page, so there is information on this Page 4, but Page 5 says the required data, submit complete Trial Reports for future submissions, and then they ask for a couple of other items there.

And Gustafson responded--well, CS-49 is the very next exhibit.

And they're really saying here, apart from the storage

17:01 stability study which will be submitted, they have given clarification was everything else. They have dropped certain things and described other things, but no data was provided. Is that--I know we sort of flipped through it, but this is your exhibit.

Would you agree with my summary?

A. Okay. It withdrew the high rate of Gaucho CS, so they didn't need to support it with any fungicide residue data--

Q. Right.

A. --and efficacy data.

They provided efficacy data for Gaucho CS, tank mix with Gaucho 480, and a revised label so that those use claims could be reviewed.

Q. It's in the nature of dropping some claims, as you've said, and clarifications; is that right?

A. That's right, so it's Gustafson's response to the deficiencies that went out, and we were addressing all the deficiencies that were in the Deficiency Note.

Q. Right.

That was filed February 21, and then there is nothing else from PMRA until an April 23rd, 2001, fax.

Correct me if I'm wrong, this term "Clarifax," that's when PMRA requests clarification data, so not new data--I shouldn't say clarification data, not new data, but clarification of what has been filed.

17:03 A. That's usually sent to the Applicant when evaluators are going through the data at Level C, the preliminary review, and the review the data, and there are questions regarding something that they find in the data, and they send the fax asking detailed questions, sometimes numerous questions regarding the data, to the Applicant and asks for their response.

Q. And those clarification faxes, according to the MOSP, don't stop a review. The review keeps on going. It's not just put on hold because of those.

A. Often, yes--yeah, you're right, they don't stop the review. The Applicant is given a short period of time to address those need for clarification.

Q. Okay. So April 23rd, 2001, PMRA asks for a honeybee study, if you will believe me that that's what that letter asks for. The next day, Gustafson provides the honeybee study.

And May 1st, we go into the Level D review. Do you see that there?

A. Yes, I do, um-hmm.

And the need for the honeybee study would have been established during the preliminary review. It was conditionally required data, determined at Level C that it was required and requested.

Q. Obviously, it was sufficient because a week later they move into Level D--sufficient to move into Level D.

17:04 It's these dates I next wanted to ask you about because we are in queue Level D as of May 1st, 2001, and then Level D-1 is started April 25th, 2002, so it's 359 days, give or take, before the Level D is started.

And if I understood your answer earlier, there would have been different evaluators or teams responsible for this Level D review.

A. Um-hmm.

Q. At least--do you know for this kind of submission how many teams or evaluators there would be?

A. You could tell by the data that are required, there would have been a tox evaluator, there would have been an exposure evaluator, there would have been an efficacy evaluator. In fact, there would have been two efficacy evaluators, one evaluating the insecticide efficacy, one evaluating the fungicide efficacy. Food residue evaluator. There would have been an environmental fate and environmental toxicity evaluator.

There are data to address all those different aspects of the product and its potential impacts. A risk assessment would have been done in all those areas.

Q. All those evaluators, even here when all of actives had already been approved for these uses, for these diseases and uses?

A. I believe so, yes, yes, there would have, and--yes.

17:06 And there would have been a chemistry evaluator as well.

Q. The vast--

A. There are data in all those areas that were submitted to support this new formulation and the new-use claims, and the tank-mix-use claims. So, all that data needs to be evaluated and a risk assessment, an integrated risk assessment, carried out.

Q. Where Gustafson--if there was no new use and Gustafson has provided evidence here that there was no new use, that was an error by PMRA, that would eliminate a team? You mentioned use. That's why I was confused on that point.

A. But this is a new use. This is a new product, and efficacy data were provided, both fungicide and insecticide efficacy data, on the performance of this formulation.

Q. Right.

A. There would have been acute tox data. There definitely were environmental fate data.

Q. Would there be the same number of teams or more for the Helix submission?

A. Those elements would be--

Q. It's the same elements for both?

A. Yes. Would have to be evaluated for that new technical active ingredient and end-use product, as well.

Q. So, one or more teams did not start their review for a

17:08 year after this product reached Level D; is that right? 359 days.

A. One or more members of the team.

Q. Okay. That delay could not have been attributable to Gustafson, once we are in Level D and it's the Level D review.

A. That's right.

Q. Okay. And once that one or more final team started to review, we see there in that same box, it passed Level D 20 days later, May 15, 2002.

(No response.)

Q. I believe in your prior answer you may--

ARBITRATOR CRAWFORD: What is your answer?

THE WITNESS: I didn't realize it was a question.

BY MR. BEDARD:

Q. I was just seeking your confirmation that once the final one or more teams began the review in Level D, it passed Level D in 20 days. That's what this box is telling us that you have prepared; is that right? Do I understand it correctly?

A. Right.

But it's not teams. It's the whole--it's an evaluator in each of those areas, just to clarify, and one or more evaluator had not started by May 1st.

Q. But whichever--

A. But the other ones may have started and carried out

17:09 their review during that time.

Q. Right.

And whichever one or more evaluators were missing completed their part of the review in 20 days?

A. That's right.

It could have been the chemistry reviewer.

Q. Environmental fate data would have been required for this product which consisted of active ingredients already registered for use on canola and mustard for diseases that had already been registered, pests and diseases that had already been registered?

A. Well, yes.

And, in fact, Gustafson addressed that by providing data on honeybees and on groundwater monitoring. Groundwater monitoring would be environmental fate.

Q. I believe in that last answer you may have mentioned--you may have said that this review involved new active ingredients, but I just want to clarify for the record, for Gaucho CS FL, there were no new active ingredients; correct?

A. It was a new end-use product.

Q. There were no new active ingredients?

A. No. Imidacloprid and the fungicide components were registered.

Q. Okay. In the Level I review or stage for Gaucho CS

17:11 FL--now we are on Page 17, we start Level I, and this is the final box, June 6th, and it's completed July 23rd.

A. Actually, we start Level I in May when we would have provided Gustafson with the annotated corrected draft label. So, we were asking Gustafson to provide us with a label corrected as a result of our Risk Assessment. So we would have provided that. It went "I pending label," "Gustafson, please make these changes to your originally proposed label." We require them as a result of our Risk Assessment and our review.

Then Gustafson came back in when the submission--when the submission went I in queue, that indicates, in fact, the label had returned to the PMRA for our review.

Q. Okay. So, from June 6th to July 23rd, your box says 47 days, that's a label review?

A. That's a label review.

Q. It took 47 days to review the label?

A. Yes.

Q. Okay. If I can actually ask you very quickly to look at Exhibit CF-25 to the Claire Franklin Affidavit. If you give me one moment, it's a letter dated November 18, '98. It's Tab 57 of the Joint Hearing Bundle. It's a November 18, 1998, letter from Claire Franklin to Mercia Moki (ph.). Do you have that?

A. Yes, I have it.

Q. We were looking at this letter earlier. If we flip to

17:13 the second page, it says, "You are probably aware that our respective staffs have a meeting with Novartis Canadian and U.S. representatives over several months." And this is about Helix.

A little further down, "There has been a great deal of consultation and planning invested in this initiative. The objective is harmonized registration decisions for Helix and thiamethoxim in a timely fashion, i.e., December '99, January 2000. Clearly, this is an ambitious objective with tremendous positive potential which merits our full support."

Would you agree that within PMRA a lot of resources were devoted to the registration of Helix? That's certainly what Dr. Franklin is saying in this letter to EPA.

A. It's true.

Q. It's true, okay.

If we could just look at exhibit--the Helix time lines, and let's start with Exhibits SC-74, which we had open earlier, which was the submission status history. And just to make one clarification, these are--these and the other Helix documents we are about to look at are a printout from a PMRA database of the status history; correct?

A. That's right.

Q. And the Appendix A that you prepared with respect to Gaucho CS had a lot of additional entries with data clarification and so forth.

17:15 If you had prepared a similar time line for Helix, there would have been a lot of entries similar to that for this as well? It's just that the two documents are different documents.

A. Yes, yes, you're right. The Gaucho would have been a bit longer, Gaucho CS, because they were three Levels B and two Levels C.

Q. And Helix would have certainly been a lot longer than this summary we are looking at now with data clarifications and so forth?

A. Pardon me?

Q. The Helix history would have been longer than this one we are looking at now if it included all of the correspondence and data clarifications. You think there might not have been any data clarification with Helix?

A. I wasn't saying that there isn't. That's speculation.

Q. You don't know?

A. I don't know.

Q. You don't know, okay.

If we look at the status here, and you go a few rows down, Level C goes in queue December '98. And then it, according to this, it's never started, completed or passed, and then we get to Level D. Can you explain that? It's unusual, isn't it? We would expect to see a pass and completion of Level C before we get to Level D.

17:16 A. Well, actually, no. This was printed from our database, and evaluators don't always put their status in, and coordinators are always having to ask them, especially at that point, asking them to put the proper status in, so...

Q. Okay. So, this document must be incomplete, is what you're saying?

A. No, I'm--

Q. Is it possible to get from Level C to Level D without Level C having been passed?

A. No, Level C passed. It would have had to pass a preliminary review to move from Level C to Level D.

Q. And Level D--this is the fifth entry--

A. Okay, go ahead.

Q. I'm sorry, did you want to finish?

A. No.

Q. Level D, the fifth line started or put in queue, rather, March 19, 1999. It gets completed--I'm looking at Row 7--August '99. And then Row 8 Level, D is in queue again September 22nd, 1999.

Wouldn't standard policy--so, do you have any explanation of why we have two Level D's?

A. No, I don't.

Q. Okay. Would one reason be that there was some major deficiency that prevented moving on past Level D?

A. No, that's speculation, same as my speculation that

17:18 one evaluator hadn't flipped it from D to--C to D, a similar type of speculation.

Q. Okay. Normally, if you had a second Level D, you would have had to have gone back to B and C to get to D?

A. That's right, but I wouldn't infer from this that that happened.

Q. Okay. We can't really tell much from this, I guess, your answer is that's correct? It's of limited use, given what you're saying? You have no explanation for the jump from C to D or in the second D?

A. No, no.

Q. Do you know whether the March 27, 2000, rejection date would be correct?

A. Yes, that is correct.

Q. That is correct.

If we go to your Paragraph 49--keep this page open, if you could--Paragraph 49 of your first Affidavit. I'm summarizing this paragraph, but PMRA and Syngenta met to discuss occupational exposure and occupational exposure reduction strategies in mid December '99. The PMRA provided Syngenta--I'm in the middle of the paragraph here. The PMRA provided Syngenta with a list of further information that it wished to see. That was mid December '99.

It looks like, to the extent we can rely on that exhibit, that this meeting happened during Level D. Does that

17:20 sound right?

A. I think that's speculation.

Q. You don't know, okay.

Do you know whether PMRA's concerns about Syngenta's occupational exposure were major? They were serious?

A. What I do know is that we were able to complete our Risk Assessment at Level D and make a decision to reject the product as a result of that Risk Assessment, and ask for the refined Exposure Assessment.

Q. As a result of these meetings and correspondence in December '99, do you know whether Syngenta was told that its occupational exposure was going to be unsatisfactory?

A. No, I wasn't at those meetings.

Q. Okay. If we look at Exhibit SC-77, just a couple of tabs ahead, this is a PMRA letter to Syngenta January 27, 2000. And if you look at the second paragraph, Syngenta applied for a Research Permit on January 10th, 2000.

Do you see that?

A. Yes, um-hmm. Yes, I see that.

Q. Okay. So, just keeping in mind the time line that we were looking at, it was still--its submission hadn't been rejected yet, but it is--because it was rejected March 27, 2000--it appears as though it's still somewhere in Level D in January 2000--but it's applied for a Research Permit to conduct a new occupational exposure study.

17:22 Would you--do you know, was Syngenta told your occupational exposure study that you filed with the initial submission is unacceptable?

A. It was eventually--Syngenta was eventually told that because the submission was rejected, and our Risk Assessment concluded that the surrogate exposure study did not--was not adequate. The surrogate exposure study, the original exposure study that was submitted.

Q. Going by the dates in this letter, and you can look at the second page of this letter, "Your request for a Research Permit has been granted." So, Helix--Syngenta applied for a Research Permit.

A. Well, it is--it was and is quite common that Research Permits are applied for and granted for research to be conducted before a submission is made to register a new technical active ingredient and during the submission process. Researchers, applicants, and manufacturers do apply for Research Permits throughout the process, before the process, to develop data to support ongoing and subsequent submissions to register.

Q. Right, understood.

Is it common for a Research Permit application to be approved in 17 days? Is that standard?

A. It's not standard. There are time lines provided in our Research Permit guidelines, but typically Research Permits

17:24 are applied for early in the season, and there is some urgency for researchers to get started on research in the growing season, and there is typically a lot of submissions for Research Permits completed in a short time, yes.

Q. Not many--

A. Now and then.

Q. Not many would be completed in 17 days?

A. Pardon me?

Q. Not many would be completed in 17 days?

A. I wouldn't say that.

Q. No?

A. I would not say that your statement is correct. In fact, there are a flood of Research Permit applications in early January, late December applying for planned research for the growing season which can begin as soon as March. Every year the PMRA has a large number of Research Permit applications, and they usually or they often are accompanied by requests to get the Research Permit completed, application completed as soon as possible so researchers can get in the field and conduct the application. And conduct the research, sorry.

Q. The second SC-75, Exhibit SC-75, is the submissions status history for Thiamethoxim Technical; is that right?

A. Yes, yes.

Q. I anticipate your answers, but I will ask: Level C we

17:26 have an entry for in queue but it's never completed or passed. Then we have two Level D's without it being sent back for a Level B screen and a Level C review.

I take it from your earlier response that you can't explain those events?

A. Not really, no.

Q. Okay. If we flip ahead to Exhibit SC-78--and I promise we are almost at the end--this is the submission history for the final Helix, the product that was ultimately approved; is that correct?

A. Yes.

Q. Okay.

A. I'm not sure whether this is for the--I can't tell by the submission number whether this is for Helix or Thiamethoxim Technical.

Q. I think if we go back to your evidence, and I think it's worth confirming--

(Witness reviewing document.)

PRESIDENT KAUFMANN-KOHLER: Can you just remind us what product was the history of SC-75.

MR. BEDARD: SC-75 was for Thiamethoxim Technical, so the active ingredient.

PRESIDENT KAUFMANN-KOHLER: Thank you.

BY MR. BEDARD:

Q. You're not certain whether this is for the final Helix

17:28 or for thiamethoxim?

A. It's for one or the other. It's probably for Helix, but I can't tell you from the submission number whether it's Helix, Helix Xtra, or Thiamethoxim Technical.

Q. Okay. If we look at the entries, Level B, it goes in queue September 8th, started September 12, it's completed September 12, it passed September 12, and so it gets through the screening in four days; correct?

A. This would have been the second submission. The Applicant would have been addressing the outstanding requirement for the refined Risk Assessment, so this submission, if it is for Helix Xtra, would have had one piece of data attached to it.

Q. Well, the other submission was rejected, so the submission--

A. It was rejected once we had completed a Level D review, so every aspect of that submission, all the data that were submitted to the PMRA would have completed and a risk assessment made in the initial Helix submission. Our Risk Assessment indicated that the surrogate exposure study was not adequate to allow a positive registration decision, and a refined exposure study conducted with thiamethoxim itself rather than an alternative active ingredient was requested.

So, when Syngenta came back in, they were addressing that one outstanding concern that the PMRA had identified in

its earlier submission. So, although this is not a Cag. A submission, the data that were submitted with the initial would have been reviewed, and we would have based our review of this study on our earlier Risk Assessment. We would have continued on from there.

Q. The screen would have--presumably that checklist for Category--and it's probably a larger checklist for Category A, I would think--in this case would have said, "See prior submission, see prior submission," is what you're saying?

A. That's right.

Q. Okay. That still requires a screen. Someone has to verify that all of the elements in the Category A checklist have been met.

A. It would have referred to the previous submission and our review in that, and it may simply have indicated all that data were previously submitted and reviewed by the PMRA.

Q. If we go on, Level C, which is a preliminary scientific review, so in this case you're saying it's a preliminary review of the occupational exposure study only; is that right? Because that's all there is to this submission.

A. Yes, that's all that remains.

Q. That Level C review takes three days; is that right? September 12 to September 15.

A. That's what's indicated, yes.

Q. And then Level D, which is the full review of the

17:32 occupational exposure study, takes, if you believe me, 32 days, from September 15 to October 17?

A. Again, it would be review of one Exposure Assessment study on that point.

Q. Which is not an insignificant study. Someone has to review it and review the data and make sure they're satisfied that it meets the PMRA standards; is that right?

A. That's right.

Q. And Level I, which is the label review--looks like the labels--like I can't tell. It says "pending labels November 17, registered November 27," so the labels either came in November 17 or November 23rd, so the label review took either four days or ten--is that right?--compared to 47 days to review the label for Gaucho CS FL.

A. That's right.

Q. Okay. Thank you, Ms. Chalifour.

MR. BEDARD: Thank you, Madam President.

PRESIDENT KAUFMANN-KOHLER: Any redirect questions?

MS. ELLIOTT-MAGWOOD: Yes, I do have a few. Thank you.

REDIRECT EXAMINATION

BY MS. ELLIOTT-MAGWOOD:

Q. Ms. Chalifour, when you were speaking about the Gaucho CS FL application and discussing with Mr. Bedard the various stages of discussion about various elements, is it--is it

17:33 common for--for a submission to have that much back and forth with an Applicant where some things have been requested and needs to be clarified?

A. It's not common for a Cag. B submission to go through two Level B, three Level B and two Level C and for there to be that much discussion, no.

Q. Okay. And could you just explain a bit. You talk about the multiple Levels B, the multiple Levels C's, exactly what this does to the time line as compared to kind of the perfect performance standard submission policy time line?

A. The perfect performance standard assumes that the submission will make one pass through Level B and one pass through Level C, and one pass through Level D, et cetera. And this submission had to make several passes through the screening for screening review and through preliminary review, and each time it goes through a screening review, the PMRA has 45 days to complete our screening review, and the Applicant has 45 days to address the concerns that have been identified.

So, it adds time, every time it goes through a B loop, as we call them or a C loop, and Level C, for example, it adds 90 days for the Applicant to address the deficiencies, and 60 days for the PMRA to review the response.

Q. Okay. And Helix was, we have discussed, conducted as a workshare.

A. That's right.

17:35 Q. And how does that bear on the time lines that PMRA was working under for Helix?

A. Because it was a Joint Review workshare, those were negotiated time lines, and the PMRA agreed with the EPA for NAFTA priority reviews to a negotiated time line of 18 to 24 months, so the MOSP does not actually apply to a submission that is a Joint Review or a workshare.

Q. Okay. Turning to temporary registration, you were discussing the fact that Helix was a temporary registration and remained as one for some time. Was that common for submissions to be in that pattern at that time period?

A. Yeah, it was fairly common for the PMRA to grant temporary registration, and it was also quite common to renew temporary registration on review on an annual basis, and sometimes for several years in a row.

In fact, when the new act came into force in 2006, there were 200, about 200 outstanding, I think I referred to that in my Affidavit, 200 outstanding temporary registrations that were converted to conditional registrations.

Q. Okay. And you were speaking about the seed coloration directive, and you didn't actually get with Mr. Bedard into the context of this discussion within your Affidavit. So, could you just explain to us--I understand this was an issue of a green Helix product contrary to the Directive's indication of baby blue as the color for canola seed treatment. How did this

17:38 issue arise?

A. Okay. In 2002, that Directive had been in effect since about 1986, when it originally came out as a trade memorandum.

But in 2002, there were two Helix registrations, two products, one with twice the amount of insecticide active ingredient. Canola seed is generally treated in commercial seed plants, and after consulting with a number of stakeholders, including the Canola Council of Canada, Gustafson, and Bayer, the PMRA was looking for a solution to the potential for these--for seeds treated with either of these two products to be differentiated visually, and in good faith we thought a different seed color for one of the Helix products would address that concern, and we consulted before we actually went about agreeing to this deviation, I guess, from the Directive. We consulted with a number of stakeholders, and none of them at the time thought that it would be a problem.

Q. Okay. And you were looking with Mr. Bedard at the label review for Gaucho CS FL, and he'd mentioned that it was 47 days. I'm just wondering what is the time line in the management of submission policies for label reviews?

A. Forty-five. I think it's 45 days.

Q. I believe you're right.

A. But I will look it up.

Q. Okay.

17:40 A. For Cag. A submission, okay.
I believe it's 45 days. I believe it's 45 days here.
Q. I believe it's in the chart at the back of your Exhibit SC-1.
A. Yes, it is 45. I'm actually looking at Page 6 of my Affidavit, 45 days for the review of the label.
Q. Okay. Thank you.
And just one more question. You explained that when Helix was resubmitted, you didn't review--re-review all of the data. You only considered the new data. And what is the policy rationale behind doing that?
A. We had completed our Risk Assessment in all the other aspects of the Helix submission, and there was no need to repeat a review that had already been completed. No need to re-review data. A decision was made at the end of the initial submission that the Risk Assessment with respect to the occupational exposure was not adequate.
Q. Okay. Thank you. Those are my questions.
MS. ELLIOTT-MAGWOOD: Thank you.
PRESIDENT KAUFMANN-KOHLER: Judge Brower, any questions? Please.

QUESTIONS FROM THE TRIBUNAL

ARBITRATOR BROWER: You remind me precisely what was the difference between the first Helix application and the second Helix application. What was the difference between what

17:42 was rejected in the first one and what was submitted in the second one?

THE WITNESS: The first Helix submission came with a full data package, all aspects of the product, environmental chemistry value, food residue data. That data, those data were reviewed in the initial submission, and a Risk Assessment conducted on all aspects of the product and the product's use in Canada. The Risk Assessment determined that the occupational exposure was unacceptable based on the surrogate exposure study that was submitted. It was reviewed and determined that it was unacceptable. So, the submission was rejected.

The Applicant Syngenta came back in, or Novartis at the time came back in and addressed that concern with a refined Exposure Assessment conducted with the actual active ingredient rather than a surrogate product.

Does that answer your question?

ARBITRATOR BROWER: So, the ingredients were different in the two applications?

THE WITNESS: The surrogate study was conducted with a different active ingredient than was being proposed.

ARBITRATOR BROWER: But the application was in both cases included identical ingredients?

THE WITNESS: Yes, yes. It was only the surrogate study for occupational exposure, which was conducted with a

17:43 different active ingredient, and Syngenta would have submitted that to address the need to--the need for an Exposure Assessment for the thiamethoxim product, the Helix product, and with a rationale saying generally in seed treatment products this is the exposure from a use of a seed treatment product. And because it was not conducted with thiamethoxim, I presume a number of safety factors would have been applied to that Risk Assessment, and it was not--a positive registration decision could not be made based on that surrogate study.

Is that clear?

So, both submissions were for Helix. That particular data was conducted with a different active ingredient.

ARBITRATOR BROWER: And when CS FL was approved by PMRA, that was also a temporary approval?

THE WITNESS: Yes, it was.

ARBITRATOR BROWER: Okay. Thank you.

PRESIDENT KAUFMANN-KOHLER: Professor Crawford.

ARBITRATOR CRAWFORD: Looking at the I think it's the annex to your second Witness Statement you have got the time line for CS FL registration history.

And the outstanding factor which took so long is the fact that it was in the queue for level D from May the 1st, 2001 to April 25th, 2002. I'm making that statement, but if you disagree with it, of course, you're free to do so.

So my question is as follows... is that accurate? Is

17:46 that the reason because it's nearly a year?

Secondly, is it unusual?

THE WITNESS: First of all, the overall submission status was D in queue. That, however, doesn't mean, that one of the evaluators--one or more of the evaluators on the review team had not started their review. That means that at least one had not until that point.

ARBITRATOR CRAWFORD: Okay. Well, let me rephrase the question.

THE WITNESS: Okay.

ARBITRATOR CRAWFORD: The situation is that for purposes of Level D one, it entered the queue on the 1st of May, and it left--it had passed Level D one slightly more than a year later, in May 2002.

THE WITNESS: Yes.

ARBITRATOR CRAWFORD: Is that unusual?

THE WITNESS: Well, the time lines for review of a Cag. B submission for a new formulation would be 12 months for the review period, and this review was completed in slightly more than that time, and in only slightly more. It was 300 and some days rather than 365 days. So, the PMRA did nearly meet our time lines for that review.

ARBITRATOR CRAWFORD: Mr. Bedard didn't put this to you, but I'm going to.

THE WITNESS: Okay.

17:47 ARBITRATOR CRAWFORD: He was very meticulous in going through the detail, but there is a big picture question.

As I understand it, Chemtura's case is that in relation to a Category B submission, it really wasn't very difficult because it related to existing ingredients for which there was considerable experience for those particular crops sought. It took an unconscionable period of time to register the product. That's my understanding. That's their case. I would like you to comment on that.

THE WITNESS: Well, first of all, I don't agree that it wasn't--that the deficiencies were not significant and that the process was not necessarily complicated. There was a lot of back and forth with the Applicant, and we did have a--if you look at the data requirements for this type of new product, we did have a fair amount of data to review.

ARBITRATOR CRAWFORD: Judging from what was said by witnesses for Chemtura, by this stage the PMRA was really unhappy with Chemtura because of the difficulties that had occurred in relation to the voluntary waiver agreement, et cetera. And basically you went slow on this. You dragged your feet. Is that an accurate statement?

THE WITNESS: I don't think so. I think evaluators were working through the submission along with, I might add, a lot of other submissions at the same time. Typically, evaluators don't have a single submission to do, to evaluate,

17:49 and we worked through that, and there was just a lot of back and forth as evidenced by the Level B--numerous Level B levels and Level C levels with the Applicant to get a reviewable submission.

ARBITRATOR CRAWFORD: Chemtura sought accelerated status for CS FL. Mr. Bedard took you to that correspondence, and that request was denied, and we understand why, and I don't want to go into the merits of whether it was denied--of its denial or not. But let's assume that it had been granted and that you treated CS FL the way you treated Helix. What difference would that have made to the speed with which CS FL was finally approved?

THE WITNESS: Well, first of all, we didn't actually get the data we needed until May 2001, and there was a lot of back and forth. What difference--what was your question again?

ARBITRATOR CRAWFORD: My difference is if accelerated status had been given, all other things being equal, and the time taken to produce new data being the same, if you'd accepted Chemtura's request that it be treated equally with Helix, CS FL be treated equally with Helix, what difference would that have made to the eventual outcome in terms of the date of the CS FL registration?

THE WITNESS: If we had given it an expedited review?

ARBITRATOR CRAWFORD: Yes.

THE WITNESS: If we had given it an expedited review,

17:51 I guess evaluators would have gotten to that submission before they did.

ARBITRATOR CRAWFORD: But you can't tell us even a ballpark figure that it might have accelerated the process by six months or nine months or whatever?

THE WITNESS: No, I can't.

PRESIDENT KAUFMANN-KOHLER: Can I follow up on this a bit. If you look at your Appendix A to your second Witness Statement, and you look at the page where we have Level D, Level D lasts from May 1st, 2001, to May 15, 2002, and you have explained to us that it's one evaluator who may have been late and the others were working--whatever. That is speculation.

THE WITNESS: Duration.

PRESIDENT KAUFMANN-KOHLER: So, that is about 380 days, and that's approximately.

Now, if I look at your description of Level D in Paragraph 17 of your Witness Statement one, it's on Page 6.

THE WITNESS: Yes.

PRESIDENT KAUFMANN-KOHLER: I understand that Level D should take 180 days for the review, for the review to be completed; is that right? I mean, for Level D to be completed. Or is that wrong?

THE WITNESS: Well, actually, if you look at the management of submission policy, which I think is Attachment 1.

PRESIDENT KAUFMANN-KOHLER: Yes.

17:53 THE WITNESS: The review time line that the PMRA has set for itself for Category B submissions, the review is 365 days for a standard Cag. B.

PRESIDENT KAUFMANN-KOHLER: Yes, but I would like to have a standard Cag. B Level D.

THE WITNESS: That would be the review--the review would be--the review is that--is that period.

PRESIDENT KAUFMANN-KOHLER: So, where it says second review, is that Level D, or where do I find it? Now in Appendix 1 to the OSP, Category B, where do I find the standard days for Level D?

THE WITNESS: So, SC-1, the pages aren't numbered, but Page 6, Appendix 1, Category A, and presume it's Page 7, Category B.

PRESIDENT KAUFMANN-KOHLER: That's what I'm looking at. Now, which column is Level D?

THE WITNESS: The review is actually Level C and Level D combined, and we have allocated 365 days for us to complete that for a Cag. B submission.

PRESIDENT KAUFMANN-KOHLER: Fine. So, now back to my question: If you took for Level D 380 days, how many days too much compared to your standard? I had come to 200, but maybe I'm wrong.

THE WITNESS: Yes, we did. We didn't meet our time line for that submission.

17:55 PRESIDENT KAUFMANN-KOHLER: That is clear, but how much did you exceed it? That's what I'm trying to understand. If you exceeded it by 10 days, then that's certainly no issue. If you used double the time that you should have, then maybe there is an issue.

THE WITNESS: Right.

PRESIDENT KAUFMANN-KOHLER: Maybe not, I don't know. But I just tried to get to the facts.

THE WITNESS: Let me try to clarify that for you. This 365 days is for both the Level C, which is usually 60 days, and the Level D review, 305 days.

However, in this case, the submission had several loops added to it because it went on hold.

PRESIDENT KAUFMANN-KOHLER: I would like to come back to the loops afterwards, or do I have to address the loops now?

THE WITNESS: Well, if I could just finish, 365 days for the--both portions of the review, the preliminary review and the full review for an ideal Cag. B submission. But in this case, an extra 60 days was added for the second Level C review--

PRESIDENT KAUFMANN-KOHLER: Can I just stop you here because I would like to be clear before we go to the loops.

THE WITNESS: All right.

PRESIDENT KAUFMANN-KOHLER: Do I understand it correctly that in a standard Category B, I have 365 days for C

and D levels.

THE WITNESS: Yes, that's right.

PRESIDENT KAUFMANN-KOHLER: And that the C level is 60 days, so the D level is 305?

THE WITNESS: That's right.

PRESIDENT KAUFMANN-KOHLER: Fine.

Now--and then I can calculate how many excess days we have in this case.

Now, can you explain to me these--this loop story because why can't you finish one level and once this is done you go to the next one, and you simply don't move from one to the other before one is completed. Why do you go back? Why do you have three times B and two times C in Gaucho CS FL?

THE WITNESS: Okay. For the Level B screening--so, for the Level B, which is the screening review and not the full review, the screening review, screeners are looking at the submission to make sure that all the elements are addressed--

PRESIDENT KAUFMANN-KOHLER: That's clear, yes.

THE WITNESS: Okay. That takes 45 days for the PMRA to complete. If there are deficiencies, a letter is written to the Applicant, and they have 45 days to address the deficiencies. You didn't pay your fees, you didn't provide this piece of data, you didn't provide--

PRESIDENT KAUFMANN-KOHLER: And when they answer--

THE WITNESS: And when it comes back in--

17:58 PRESIDENT KAUFMANN-KOHLER: Restart 45 days?

THE WITNESS: Yes, because the screeners have to determine that here is the letter of deficiency, here is the Applicant's response, did they address all our deficiencies? We allow ourselves 45 days or a second loop through that process to screen the response.

PRESIDENT KAUFMANN-KOHLER: That's what you called the second B level, which is still the same but you had had a deficiency in between?

THE WITNESS: Yes, yes, that's right.

PRESIDENT KAUFMANN-KOHLER: Okay, fine.

So, then you wanted to explain why in this case you get to about 380 days.

THE WITNESS: Okay. The same thing happens when a submission has a Level C deficiency.

PRESIDENT KAUFMANN-KOHLER: That's clear.

THE WITNESS: PMRA initially has 60 days, the Applicant has 90 days, it comes back in, we take another 60 days.

So, that is added to the time it would take.

Ideally, it doesn't go through that second loop, and it completes its review in 365 days. But because we had those additional deficiency Level C reviews, we added more time.

PRESIDENT KAUFMANN-KOHLER: And you finished early. Now, if I add all the extra days that you're telling me now

18:00 because of additional B and C levels, we would have to do the calculation, but would we get--would we not get more than 380?

THE WITNESS: Yes, we would. We would get something if we add for all the extra times for the B and C reviews, we get a total of about 712 days.

And I think the PMRA, I did the calculation, but I didn't submit it here as an exhibit. I think the PMRA--

PRESIDENT KAUFMANN-KOHLER: That's probably in the record somewhere.

THE WITNESS: I think we took 750 days. So, we were late in addition, but we should have--we should have allowed ourselves about 712 days for this process and all the additional reviews that were required as a result of the deficiencies.

Sorry, it's a complex process.

PRESIDENT KAUFMANN-KOHLER: It's just a matter of understanding it.

I think I have covered my questions.

Yes, please.

ARBITRATOR CRAWFORD: When you get a--you made the point about the surrogate exposure study. I quite understand that with a new nonactive ingredient you might well think that a surrogate exposure study is not good enough, and you want an exposure study done with the active ingredient itself. That study comes in. You have got all the expertise in house to

review that. Have you, or do you send it out for blind review as you would with academic journal?

THE WITNESS: As we would do for what?

ARBITRATOR CRAWFORD: An academic journal, if you got a study of that sort for publication, you would send it out for blind review. Do you do that, or did you do it entirely in house?

THE WITNESS: No, actually, we would do the review at the PMRA. We would review what we have expertise to do that review, and there is a process--there is a review and an internal peer review, and in the case of the thiamethoxim exposure study, we were working with the U.S. EPA, and they also conducted a review, and the evaluators had a discussion as to whether or not that study was adequate.

ARBITRATOR CRAWFORD: Thank you very much.

PRESIDENT KAUFMANN-KOHLER: Maybe I should simply rectify before I spoke of 380 days, as if it was the overall duration. Of course, it's only the duration for the Level D process, where you don't have the loops of B and C, just that there is no misunderstanding on that.

THE WITNESS: Yes, thank you.

ARBITRATOR BROWER: We have been told that Helix was subject to the Joint Review procedure. That applies to both submissions, the one that was rejected, and the one that eventually was accepted.

18:03 THE WITNESS: Yes, that was all part of the same workshare project.

ARBITRATOR BROWER: And in your view, did the fact that this was the very first Joint Review exercise, as I recall; is that correct?

THE WITNESS: No, I don't think it was. No, it wasn't. Since 19--

ARBITRATOR BROWER: Oh, I'm sorry. Okay.

THE WITNESS: We have had about 35 Joint Reviews and about 10 workshares since about 1995, and I'm pretty sure that Helix was not the first one. It was early on in the process, but not the first one.

ARBITRATOR BROWER: All right. Thank you.

PRESIDENT KAUFMANN-KOHLER: Mr. Bedard?

MR. BEDARD: Madam President, I just have one clarification for the Tribunal's benefit, and it's on the record that the Gaucho CS FL application took 848 days. It's a matter of record.

PRESIDENT KAUFMANN-KOHLER: That's why I just checked on and that's why I made a rectification so that I'm not misunderstood. I misspoke there. That was in Mr. Kibbee's evidence in particular.

THE WITNESS: Can I add that the 800 and whatever days included Level B, Level A. It was the overall review time.

PRESIDENT KAUFMANN-KOHLER: Yes, it was 848, and it's

18:05 for the overall duration, is how I understand it.

Fine, if there are no further questions, this completes your examination. Thank you very much.

THE WITNESS: Thank you very much.

PRESIDENT KAUFMANN-KOHLER: You had scheduled to start with Dr. Franklin today, and to continue on Monday. What do you wish to do? It's a question to both, really.

MR. DOUAIRE de BONDY: Thank you, Madam Chair. I guess it depends on the length of cross-examination. We intend to do only a very brief direct, as per the procedure now, and it's five after 6:00, so...

PRESIDENT KAUFMANN-KOHLER: Can I ask the Claimant. You already packing.

MR. SOMERS: No, no, I was in fact unpacking. I was looking for the schedule to know how much time I had on Monday morning with Dr. Franklin because I might be able to shoehorn the whole thing into Monday morning. I don't have a copy of the schedule on me.

ARBITRATOR BROWER: You're on Dr. Costa.

PRESIDENT KAUFMANN-KOHLER: On Monday we have the continuation and end of Franklin until the break. Then Dr. Costa, and then Aidala and Goldman in the afternoon.

MR. DOUAIRE de BONDY: I suspect that may work on Monday morning, given that according to the Claimant they're expecting to cross-examine Dr. Franklin for two hours, and

18:07 Dr. Costa for one hour, and in both cases we weren't expecting to do more than a brief direct, but again we are in your hands.

PRESIDENT KAUFMANN-KOHLER: It may mean that maybe we cannot hear Dr. Goldman start on Monday. That may be the consequence. I don't think that's a problem. If you don't--depending on how long you want to examine the quantum Experts, but on the quantum Experts you have I think relatively--you have provided for sufficient time, I would say.

MR. SOMERS: On our behalf, I can even say generous time.

PRESIDENT KAUFMANN-KOHLER: That's what would seem to me, yes, but is this a shared assessment?

MR. DOUAIRE de BONDY: Yes, that's fine.

And I think if I may say so, may be kinder to the witnesses to just start the examination first thing Monday morning, start it tonight and leave her in limbo, or in Purdah.

PRESIDENT KAUFMANN-KOHLER: It's preferable not to cut examinations in the middle in any event.

Fine, so let's start with Dr. Franklin on Monday, and have Dr. Goldman available. She's your witness, in case we can start with her testimony on Monday late afternoon.

MR. DOUAIRE de BONDY: Fine. That's fine, thank you.

PRESIDENT KAUFMANN-KOHLER: Good. Anything else you wish to raise at this stage? Mr. Somers.

MR. SOMERS: One brief matter. There was a table that

18:08 was alluded to in Exhibit LC-22 of my friends, and I brought up a request for it, or requested it be looked for, you may recall, and I was inquiring about the status.

MR. DOUAIRE de BONDY: The search is ongoing.

ARBITRATOR CRAWFORD: Since we are talking about tables, advanced notice, you probably expected this, it would be very useful, I should think, if we could be provided with time lines for the various applications in the same form because they're in different form, but if an application that is not clear always which application or which product is subject of which time line, so at some point, if it can be agreed between the Parties, well and good. If we could have a consolidated table showing the time lines for the various products, that would be helpful.

PRESIDENT KAUFMANN-KOHLER: Would basically mean for the two Gauchos, for Gaucho CS FL, for Helix, for Helix Xtra, and it would help us also to have the situation in the U.S. but without all the details. I don't think that is what we need. I mean, here in the evidence of Ms. Chalifour, we have a lot of details. We don't need this. We need to know when it was filed and rejected, withdrawn, registered, basically.

MR. DOUAIRE de BONDY: We certainly would be able to generate that, yes.

PRESIDENT KAUFMANN-KOHLER: It may be somewhere in the record and we have missed it, but we have thought it could help

18:10 us, so we have a clear picture.

MR. DOUAIRE de BONDY: Right. I don't think that the kind of consolidated table that you're referring to is in the record, and we would certainly be willing to generate that.

MR. SOMERS: Rather than competing versions, would it be possible for counsel to prepare drafts, exchange, and then agree for submission?

PRESIDENT KAUFMANN-KOHLER: That would be perfect. Absolutely.

If there is nothing else, then I wish you a good Sunday, another relaxing one, but nevertheless a good one, and we will see each other on Monday morning.

MR. DOUAIRE de BONDY: Sorry, may I ask a clarification. One thing I missed was about the American aspect of this table, perhaps I missed this part of the early part of Ms. Chalifour's testimony, but--

PRESIDENT KAUFMANN-KOHLER: It may be helpful to know which product was registered in the U.S. when.

MR. DOUAIRE de BONDY: I see.

PRESIDENT KAUFMANN-KOHLER: Fine. Thank you, then. Good evening.

(Whereupon, at 6:11 p.m., the hearing was adjourned until 9:00 a.m. the following day.)

CERTIFICATE OF REPORTER

I, David A. Kasdan, RDR-CRR, Court Reporter, do hereby certify that the foregoing proceedings were stenographically recorded by me and thereafter reduced to typewritten form by computer-assisted transcription under my direction and supervision; and that the foregoing transcript is a true and accurate record of the proceedings.

I further certify that I am neither counsel for, related to, nor employed by any of the parties to this action in this proceeding, nor financially or otherwise interested in the outcome of this litigation.

_____

DAVID A. KASDAN