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

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In the Matter of an Arbitration Between:

CHEMTURA CORPORATION (formerly Crompton Corporation),

Claimant/Investor,

and

THE GOVERNMENT OF CANADA,

Respondent/Party.

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Volume 2

HEARING ON THE MERITS

Thursday, September 3, 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 8:58 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
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: So, I see everybody is ready.

I would like to say good morning to everyone and welcome Mr. Thomson, who we will hear first this morning.

PAUL THOMSON, CLAIMANT'S WITNESS, CALLED

PRESIDENT KAUFMANN-KOHLER: For the record, you're Paul Thomson?

THE WITNESS: Correct.

PRESIDENT KAUFMANN-KOHLER: You're presently Director in Charge of New Business and Technology at Chemtura?

THE WITNESS: I'll make a correction to that. Since the time I wrote that, I have a new title, and that's the Vice-President of Global Business Management.

PRESIDENT KAUFMANN-KOHLER: VP Global Business Management?

THE WITNESS: Correct.

PRESIDENT KAUFMANN-KOHLER: And before you have held a number of different positions at Chemtura?

THE WITNESS: Correct.

PRESIDENT KAUFMANN-KOHLER: You have given two Witness Statements in this arbitration?

THE WITNESS: Yes.

PRESIDENT KAUFMANN-KOHLER: You're heard as a witness, and you're under a duty to tell us the truth, and I'd like to

ask you to confirm this by reading into the record the Witness Declaration that is in front of you.

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

PRESIDENT KAUFMANN-KOHLER: Thank you.

You know how we proceed. You will be asked a few direct questions, maybe, by the Claimant's counsel, and then we will turn to cross-examination.

Mr. Somers.

MR. SOMERS: Thank you, Madam Chair.

DIRECT EXAMINATION

BY MR. SOMERS:

Q. Good morning, Mr. Thomson.

A. Good morning.

Q. I just ask you to adopt your statements for the record in the proceeding.

A. Yes. Those are my statements.

Q. I understand that there is one clarification that you would like to make, if I could turn you to Paragraph 56 of your statement.

A. Please.

PRESIDENT KAUFMANN-KOHLER: Of the first statement?

MR. SOMERS: Of the first statement, thank you.

THE WITNESS: Yes. Just in the first statement, the

very last sentence in Paragraph 56, there is a word missing from that statement that does significantly change the meaning. It should read: The HCH isomers found in the Arctic were predominantly the alpha and beta gamma isomers of HCH, not the gamma isomer, of which lindane is composed.

MR. SOMERS: Thank you, Madam Chair. We have no direct examination of this witness.

PRESIDENT KAUFMANN-KOHLER: Fine. Then let me turn to Respondent's counsel.

I must apologize, but I don't remember your name. And rather than...

MR. KURELEK: Kurelek, K-U-R-E-L-E-K.

PRESIDENT KAUFMANN-KOHLER: Thank you. You have the floor, then.

MR. KURELEK: Thank you.

CROSS-EXAMINATION

BY MR. KURELEK:

Q. Good morning, Mr. Thomson.

A. Good morning.

Q. I'm going to ask you some questions on behalf of Canada, as I'm sure you expect, and I'd like you to have in front of you three binders. One of them is the witness binder, which my assistant just handed up, and the other two are your two Witness Statements because I'll be referring to those just so you can refresh your memory.

09:02 A. Okay.

Q. So, I'll be dealing with roughly five substantive themes here.

The first one is just preliminary and wouldn't even be counted as one of the five, and it relates to what you just clarified in terms of your position.

Your current position with Chemtura is VP of Global Business Management; is that right?

A. Correct.

Q. And prior to that, your position was the Director of New Business Development and Technology?

A. Correct.

Q. And just if you need to refresher, too, by the way, I'm just referring to the first few paragraphs of your first Witness Statement.

Is it also true that from 1999 to the present you've held relatively--sorry, senior positions at Chemtura and its predecessor Crompton? I'm thinking of five positions that you mentioned in your first Affidavit; is that right?

A. Correct.

Q. Is it true that you held those positions with Crompton or Chemtura during the time period that is the subject of this NAFTA Claim?

A. Yes.

Q. Is it true that you received your Ph.D. in analytical

chemistry in 1989?

A. Yes.

Q. Would you say that you're familiar with the composition and function of Chemtura's crop-protection products, including lindane?

A. Yes.

Q. Are you familiar with both the PMRA's and the EPA's processes for registering pesticides such as lindane?

A. I have a general familiarization with the processes.

Q. Okay. I'm referring in particular to Paragraph 4 of your first Witness Statement.

Is it true that you played an active role for Chemtura during both the Special Review and what we have been referring to as the REN period, the re-evaluation periods?

A. I played a particularly important role during the REN process. I had a very minor role during the Special Review.

Q. What was your role during the Special Review?

A. At the time of the Special Review, I was responsible for the formulation development, so we were providing information on the products in support of the Special Review.

Q. Thank you.

So, I'm turning to my first substantive issue.

In your Witness Statement, you're critical of the PMRA's Special Review process; is that right?

A. Correct.

09:04 Q. I have some general questions for you about those criticisms to start off with, and in particular I'm referring to Paragraphs 74 to 78 of your first Witness Statement.

A. Okay.

Q. Is it true that in those pages you rely on several sources other than yourself to support your criticisms of the Special Review?

A. I'm sorry, could you just remind me of the Paragraphs again.

Q. Sure.

It starts at Paragraph 74, and it continues to 78, so maybe I'll make my questions more particular.

A. Okay.

Q. Is it true that one of those sources of support is a November 15th, 2001, letter to the PMRA that contains what you refer to as the "registrants' consolidated comments? Is that right?

A. Correct.

Q. Still in Paragraph 74, that letter was essentially a collaborative effort by lindane Registrants such as Chemtura; is that right?

A. Correct.

Q. Is it true that another source of support for your criticisms of the Special Review is Agsco, Inc., a lindane Registrant whom you describe as a distributor of seed and

09:05 fertilizer products? This is Paragraph 76.

A. Correct.

Q. Is it true that another source of support for your criticisms of the Special Review is IPCO, which is another lindane Registrant; is that right?

A. Correct.

Q. And finally, is it true that another source of support for your criticisms of the Special Review is TSG, or Technology Sciences Group, Inc., which is a scientific consulting firm that works with agrochemical Companies such as Chemtura and who sometimes, as you say, spoke on behalf of lindane manufacturers and formulators?

A. Correct.

Q. Turning more particularly to some of your criticisms of the Special Review, then, in your first Witness Statement--this is Paragraph 57--you allege that--we have talked about this meeting yesterday--the May 11th, 1999, meeting between the PMRA, the CIEL, which was described yesterday as a lindane lobby group. The PMRA indicated that--this is what you say--the political considerations were a significant reason for the Special Review. Is that what you say?

A. It is.

Q. Now, to substantiate that Claim you rely on Rob Dupree's notes from that meeting; is that correct?

09:07 A. Correct.

Q. I think it's Exhibit C-5 to your Affidavit, but in terms of your witness binder, it's Tab 1, so I'd ask you to turn to that, if you would, please.

A. Tab 1 of...

Q. Of the witness binder.

A. This one?

Q. Yes. And it will be the last page of that document, first full paragraph.

And at that point, we have Mr. Dupree talking about Wendy Sexsmith and her role at that meeting.

And Mr. Dupree says two things, it seems to me. First, he says, "Wendy Sexsmith, PMRA, made a brief appearance at our meeting and was clearly not interested in the canola residue data that was presented."

It goes on to say, "I suspect she will try and do whatever she can politically to try to derail any momentum to maintain uses of lindane."

Do you see that there?

A. Yes.

Q. Now, feel free to take a look at rest of the document if you want to refresh your memory, but I just want to make sure here. Mr. Dupree's comment here is not an attempt to quote Ms. Sexsmith directly, is it?

A. I'm sorry, could you repeat that?

09:08 Q. Sure.
In that paragraph that we just read--
A. Right.
Q. --Mr. Dupree is not trying to quote Ms. Sexsmith directly, is he?
A. No.
Q. Nor does Mr. Dupree explain the basis of his suspicion for Ms. Sexsmith's apparent political motivation, does he?
A. I mean, I think--I believe he does in the final sentence on that paragraph in terms of--
Q. So if politics concerning the Arctic situation heats up?
A. Correct.
Q. So, you believe that that's Mr. Dupree's motivation for making that second comment about Ms. Sexsmith, about the political motivations?
A. Yes.
Q. That's your evidence today?
A. I mean, I believe that was part of why he felt that this would--I mean, why he felt that there would be politics involved in this process.
Q. That's a slightly different question. What I was looking for was any reference here to why Mr. Dupree thought Ms. Sexsmith was indicating that there would be some politics involved, not whether Mr. Dupree thought that.

09:09 A. Okay. I'm sorry, then I misinterpreted the question.
Q. That's fine.
A. No, I don't believe that Mr. Dupree is saying that's Wendy Sexsmith's motivation there.
Q. I'd like to turn you to another document. It's at Tab 4 of the witness binder.
Now, this is a different set of notes, but they're arising out of the same meeting. These were notes written by Mr. Johnson of CIEL.
If you look on the first page of those notes, just under the dramatis personae, the attendees at the bottom, you'll see Wendy Sexsmith, which says, "part of meeting," which comports with what Mr. Dupree says earlier when he said, "Ms. Sexsmith made a brief appearance."
And then if you turn to Page 4 of Mr. Johnson's notes, you'll find at item 6, so midway down the page, "W. Sexsmith, PMRA, appeared briefly to discuss the voluntary cancellation program for canola seed treatment." Very generic line there.
Then on Page 5 of Mr. Johnson's notes, the top there, I think we read this out yesterday, Mr. Johnson concludes, "In summary, the PMRA staff was very open in the discussion and interested in our presentation on data and the canola tolerance. We will be able to maintain an open relationship and dialogue with them as the Special Review proceeds."
So, is it true now, in contrast to Mr. Dupree's

account of that same May 11, 1999, meeting, nowhere in Mr. Johnson's notes do we find him referring to either Ms. Sexsmith's apparent indifference to the data that was being discussed or to her apparent political motivations to ban lindane; is that correct? Feel free to take a few minutes to look at the document.

A. Yes, as far as I can see, there's no reference to that.

Q. Okay. And is it true that Chemtura has declined to call Mr. Dupree as a witness in this case so that he cannot be cross-examined on any statements attributed to him?

A. It is true that we have not called him as a witness. I don't believe that I can comment that that's the motivation.

Q. No, I wasn't suggesting a motivation. I'm just putting two and two together; that if Mr. Dupree is not here as a witness, then Canada cannot cross-examine him on any statements attributed to him; is that correct?

A. I can comment that he's not here; you're correct on that.

Q. Okay. Turning to the next substantive issue, one of your criticisms is that the PMRA did not notify Chemtura during the Special Review that it had serious concerns about the occupational exposure risks of lindane; is that correct?

A. Correct.

Q. If you could turn to Tab 2 of the witness binder, I

09:13 want to make sure. Are you familiar with this document? It's the March 15, 1999, Special Review Announcement of the Special Review of lindane?

A. Yes.

Q. And in particular, if you could turn to what I think was again referred to again yesterday, the bottom of the page, which would be one, there is no actual number at the bottom, but bottom of Page 1 of the text, in terms of scope, I'm just going to quote from that. "The scope of issues surrounding lindane is potentially broad. Initially, the Pest Management Regulatory Agency (PMRA) will examine the chemistry of existing Lindane Products registered in Canada and the extent to which these products may contribute to levels of various isomers in the environment."

Let me skip down to the bottom.

"The PMRA's current understanding of lindane suggests that--the issues are complex and merit a Special Review at this time. As a better understanding of the potential for adverse effects becomes known, the scope of this review may change."

My question for you is: Were you familiar with this document at the time that you swore your--I'm sorry, you didn't swear--when you wrote your first Witness Statement?

A. Yes.

Q. I will turn to Tab 3, if you will, of the witness binder. This is called a technical paper. It's a Science

09:14 Policy Notice that was released in December of 2000, and it was publicly available. It still is, I understand, on the Web site. I'll start--before I you to a particular page in that document, were you aware at the time that you--I want to say swear because all of our affiants swear, but you affirmed. Did you affirm your Witness Statements?

A. Yes.

Q. Okay. When you affirmed your first Witness Statement, were you aware of the PMRA's practice that it was standard practice for conducting pesticides re-evaluations that they simultaneously examined three things, three broad categories: Toxicity, exposure, and environmental impact? So, were you aware of that at the time you affirmed your Witness Statement?

A. Yes.

Q. So, would you agree that the evaluation of the exposure to the pesticide is a standard practice of re-evaluation?

A. Yes.

Q. In fact, if you turn to Page 2 of that document at Tab 3, you'll see there's a chart there, Figure 1, called decision framework, and under the decision framework or the way the PMRA attains the decision is to go through this analytical process. And you look at the third set of boxes down, you've got on the left side, "assessment of risk and value."

Now, value is not of concern at this point. They

09:16 talked about that yesterday. It's efficacy, but under the "assessment of risk" portion, we've got "risk to health" and "risk to the environment." And under both of those you will see there is "hazard identification," which is really analysis of toxicity, and the third bullet, "exposure assessment."

A. Yes.

Q. Now, do you agree that prior to its release in October 2001, the Special Review, do you agree that Chemtura was aware that PMRA had some concerns about occupational exposure?

A. I think that--I believed that, like all regulatory agencies, that PMRA had a concern about exposure to the extent that that was part of the evaluation.

Q. So, can I take from your answer that you weren't aware of any particular concern that the PMRA had prior to the release of the Special Review. Your understanding was the PMRA just might have a general concern, as any Agency would, going into an evaluation of that nature?

A. Absolutely. At the time that we were going through the Special Review, we were also going through a review of lindane with the EPA. The EPA was completing risk assessment associated with worker exposure, and we were dealing with EPA on those issues during this same time period.

Q. So, just so it's clear for the transcript, are you saying that as far as you know, Chemtura--sorry, PMRA did not

advance or show any particular concern about worker exposure prior to the release of the Special Review. Is that correct?

A. Correct.

Q. Okay. And turning to Tab 4 of the witness binder, again, this is a document I've already referred to, but it also appears as an exhibit to your first Witness Statement as C-4. And, in fact, in paragraph 55 of your first Witness Statement, you referred to this document as well. Again, this is Mr. Johnson's notes to that May 11, 1999, meeting.

Is it true--maybe you could turn to Paragraph 55 of your first Witness Statement, actually. That's where I'd like to start with this.

A. Okay.

Q. Is it true that you quote only a portion of this long document, Mr. Johnson's notes? Is that right? In your Witness Statement?

A. Yes.

Q. It looks like you start your quotation right at the line that says, "S. Fortner," if that's pronounced properly, "to send references." Is that right?

A. Right.

Q. Okay. Now, if you turn to Tab 4, which again is the same as your C-5, I think, in your Affidavit, Page 3. So, if we go to the portion of the document that you start to quote it.

09:20 A. Correct.

Q. Now, if you look there, I'm interested in the paragraphs that are three--the three paragraphs right above where you start quoting. If you look at the first paragraph, it reads, "PSD in U.K." under review. "PSD has raised some questions regarding operator exposure."

A. Correct.

Q. Now, PSD is, I understand, the Pesticide Safety Directorate. It's essentially the U.K. equivalent of the PMRA; is that right?

A. Correct.

Q. Okay. Now, is it true that two paragraphs later in that same document you see Mr. Johnson noting that the PMRA requested copies of PSD review when available; is that correct?

A. Correct.

Q. So, I'm going to return to a question that I asked you just before I turn to this document. I think it's slightly modified.

Do you agree that more than a year before the release of the Special Review--so, the release was in October of 2001--that Chemtura was aware of the PMRA's concern about occupational exposure? Do you agree with that statement?

A. I'm going to have to get to you read that one more time.

Q. Sure.

09:21 Do you agree that more than a year before the release of the Special Review in October of 2001, so we are talking before, what?--October 2000, or right around October 2000--Chemtura was aware of the PMRA's concern about occupational exposure? Do you agree with that?

A. I'm just having trouble with the word concern. PMRA, there was obviously an issue with PSD, and PMRA was interested in the evaluation. And I think it's safe--I mean, my interpretation is that they were interested in understanding the evaluation that went on with PSD. Whether that was at a level of the concern, I'm not sure that I would agree with that.

Q. So, you're not comfortable with the word concern, then; is that right?

A. Right.

Q. Okay. I'd like you to turn to Paragraph 62 of your first Witness Statement. You note there, you said, "At the October 4th, 2000, meeting between representatives of the PMRA and Crompton, the PMRA did raise the issue of worker exposure and indicated some concerns because the use pattern for seed treatments in Canada often differed from that of other countries," and you go on.

A. Did you want me to comment on that or--

Q. No. I think it speaks for itself there.

PRESIDENT KAUFMANN-KOHLER: Well, I think if

09:22 Mr. Thomson wants to give an explanation, he should.

MR. KURELEK: Sure. I didn't have a question, but that's fine.

THE WITNESS: I mean, my interpretation of that statement is that PMRA had concerns about the use pattern of seed treatments in Canada and the difference between how those were used in the U.K. versus Canada, not concern about worker exposure. I think that that was the concern that was being expressed.

BY MR. KURELEK:

Q. So, in your view, when you used the word concern, it was not related to the PMRA's concern about worker exposure; is that how you're parsing that sentence?

A. In that particular sentence.

Q. Okay.

If you'd turn to Tab 5 of the witness bundle. Now, this was brought up yesterday by Mr. Bondy, but I want to bring the point home again here in this context.

Is it also true that if you look at the last page of Mr. Ingulli's notes here, and if you look at the top right, it says notes from PMRA meeting held 10/4/00, so it's what, October 4, 2000. Right at the top there, it says, "PMRA meeting, concerns of PMRA, worker exposure."

Do you see those words there?

A. Yes.

09:24 Q. And if you could turn to Tab 6, please, of that same witness binder, you'll see again this is something I think Mr. Bondy referred to yesterday. This is an October 6th, letter, 2000. This was two days after that meeting that Mr. Ingulli was writing those notes about, and he sends a letter that includes a 1999--sorry, 1992 worker exposure study.

In the first paragraph, you will note that Dr.--this is Mr. Dupree talking--"Dr. Franklin indicated that worker exposure was an area that the PMRA had some concerns about."

Do you see that in the first paragraph?

A. I see that.

Q. You'll also see at the very bottom of that letter, the last paragraph, it sounds like Mr. Dupree is urging the PMRA to re-review the study, because I understand the PMRA already had the study, but he's saying, "If the PMRA has not already done so, I would encourage them to review this study to gain a better understanding of the exposure profile that workers can expect when treating canola seed with a seed treatment containing lindane."

Do you see that there?

A. I do.

Q. Okay. I'm going to shift gears here.

Turning now to the EPA--

PRESIDENT KAUFMANN-KOHLER: Can I just ask a question. Under Tab 6, I don't have this letter.

09:25 MR. KURELEK: Sorry?

PRESIDENT KAUFMANN-KOHLER: You were at Tab 6?

MR. KURELEK: Yes. Do you not have that?

PRESIDENT KAUFMANN-KOHLER: So, somehow I must have a different document under Tab 6.

MR. KURELEK: This is a--

PRESIDENT KAUFMANN-KOHLER: Yes, I have it under Tab 7.

MR. KURELEK: Oh. Tab 7 should be a big fat document. It's the 2000--

PRESIDENT KAUFMANN-KOHLER: The big fat document is under 6.

MR. KURELEK: Okay.

THE WITNESS: Can I just make some comments on those last two?

MR. KURELEK: If the Tribunal is interested. I didn't have a further question, but that's fine.

PRESIDENT KAUFMANN-KOHLER: Yes.

THE WITNESS: Just on the particular, the top one highlighted here, that the concerns again are about the use patterns and not the worker exposure. There is obviously an interest in worker exposure, but I don't believe that the interpretation is the concerns are the worker exposure. It's the use patterns for seed treatment.

PRESIDENT KAUFMANN-KOHLER: But how should we

09:26 understand this? It says worker exposure, so how do we understand that does not mean worker exposure?

THE WITNESS: I'm sorry. Dr. Franklin indicated that worker exposure area that the PMRA had some concerns about because the use pattern for seed treatments in Canada often differed. So, what the concern was was that the use patterns were different and that evaluating worker exposure in one scenario was different than the other, and so using that data was what the concern was.

PRESIDENT KAUFMANN-KOHLER: Thank you.

THE WITNESS: Is that okay?

And just can I go back to the one before, because that's all right, only I didn't get a chance to read the whole thing before I agreed to the statement. In terms of the concerns of PMRA and did, in fact, say worker exposure, but PMRA was informed that the EPA had reviewed the worker exposure, and so, you know, that was--our understanding was that PMRA would discuss that with the EPA since they had already reviewed worker exposure.

BY MR. KURELEK:

Q. So, if you could turn to Tab 7, please, of your witness binder, and this is the 2002 EPA RED. We're going to be referring to three EPA documents now.

MR. KURELEK: And I apologize to Madam Chair that they're out of order for your binder, but the 2000 RED in my

09:28 binder is Tab 7, and I'm also going to be referring to what, in my binder, is Tab 12, which I'll be referring to as the HCH Report, again from the EPA. This is February 8, 2006.

ARBITRATOR BROWER: Mine doesn't have a 12 at all.

MR. KURELEK: So, we don't have that for 12?

ARBITRATOR BROWER: No, it goes from 11 to 13.

PRESIDENT KAUFMANN-KOHLER: You are missing the Tab. This is the document.

ARBITRATOR BROWER: Ah, okay. Oh, that's 11.

There has been some mix-up here obviously.

(Pause.)

MR. KURELEK: So, what you should have, at least what I have in mind, and maybe most importantly, Mr. Thomson, I want to make sure you have the right binder here. Do you have under the Tab 7 the 2002 RED?

THE WITNESS: Yes.

BY MR. KURELEK:

Q. Okay. Do you have under Tab 12 the HCH Report dated February 8, 2006?

A. Yes.

Q. And do you have under Tab 14 the 2002--sorry, 2006 Addendum?

A. Yes.

Q. Okay. I understand the issue of the exhibit numbers has been clarified.

09:30 Now, in Paragraph 36 of your first Witness Statement, you say that Chemtura did not pursue a tolerance for lindane on canola in the U.S. because, "there was no financial reason to incur the cost to obtain the additional data that may have been necessary to maintain the ongoing U.S. registrations."

Is that correct? This is Paragraph 36.

A. Paragraph 36.

The statement is correct.

Q. And then if you turn to Paragraph 33 of your first Witness Statement, you say that Chemtura declined to pursue a U.S. tolerance because the PMRA had already terminated all of Chemtura's Canadian registrations; is that right?

A. And that's, sorry, Paragraph...

Q. Thirty-three.

A. It does state that the PMRA had already terminated, so I'm not--can you repeat the question?

Q. Sure. I just want to make sure that one of the reasons you say that Chemtura declined to pursue a U.S. tolerance was that the PMRA had already terminated all of Chemtura's Canadian registrations; is that correct?

A. Correct.

Q. And just put a date on that for the Tribunal here, we're talking about October 2001, when that Special Review was released.

And then in Paragraph 35 of your Witness Statement,

09:32 two paragraphs later, again on the same theme, you state that Chemtura declined to pursue a tolerance because Chemtura had acquired a company, Trace Chemicals, that held U.S. registrations for non-Lindane Products that fed the same market essentially as Chemtura's lindane-containing products in the U.S.; is that correct?

A. Correct.

Q. So, to put a date on that purchase, we're talking about March 2006; is that right?

A. Correct.

Q. So is it your evidence today that those are the two main reasons for Chemtura declining to pursue a U.S. tolerance for lindane on canola? If you want assistance here, again it's Paragraph 35--sorry, 33, 35, and then 39; again, you refer to it in your first Witness Statement.

A. I think that's--there's two issues. I believe there's two issues that we're dealing with here. One is the obtaining a tolerance for canola, and the other is maintaining the current registrations as part of the re-evaluation of lindane. The current registrations that existed at the time were not canola seed treatments, and they were--those products were being replaced by the products that we had acquired through the Trace acquisition, and therefore the cost to maintain the lindane registrations was the driver in that particular situation in terms of maintaining the registrations for the

existing products in the U.S.

Q. Okay. So, is it true, then, that Chemtura's decision not to pursue a U.S. tolerance for canola had nothing to do with the results of the EPA's 2002 RED, the document found at Tab 7?

A. No. In fact, we continued to invest in studies to support the application of a tolerance based on the 2002 RED.

Q. Indeed. In Paragraph 20 of your first Witness Statement, I think you referred to the 2002 RED as a favorable review by the EPA of lindane; is that correct?

A. Correct.

Q. By that comment, I take it that you've read and generally understood the contents of this complex document; is that right?

A. Correct.

Q. Is it true that while the EPA decided to retain the eligibility of Chemtura's six current registrations at the time, the 2002 RED did outline some concerns that the EPA had about lindane? Would you agree with that?

A. I would.

Q. For instance, if you could turn to Page 9 of the RED, so this is Tab 7, I'm looking at the paragraph under 1(a), toxicity. You see that there? You will find the following: "Lindane primarily affects the nervous system."

Also in that same paragraph, "In acute, subchronic,

and developmental neurotoxic studies and chronic toxicity oncogenicity studies, lindane was found to cause neurotoxic effects."

Now, just to unpack that language of it, is it true that neurotoxicity refers to the nervous system?

A. Yes.

Q. And is it true that oncogenicity, if I'm pronouncing that properly, refers to cancer or tumors?

A. I believe so.

Q. Is it also true that on the same page of the RED the EPA noted that lindane also appears to cause renal and hepatic toxicity; is that right?

A. Correct.

Q. Is it true that renal and hepatic refers--or hepatic--refers to the kidney and liver; is that right?

A. I believe so.

Q. Then again on the same page the EPA concluded that, "In addition, there is some evidence that lindane may act as a endocrine disruptor. However, further investigation is necessary to ascertain the relevance and impact of such findings on public health."

Would you agree that endocrine or hormone--hormonal disruption is something that would be of interest to the EPA?

A. Yes.

Q. Is it that last paragraph that I just or the last

09:36 sentence that I just quoted, does that also indicate that the RED was not a complete document and that further review steps still had to be undertaken by the EPA with respect to lindane, that further investigation?

A. Does that paragraph indicate that? Is that what you're asking?

Q. No, that last sentence, the, "However, further investigation is necessary."

A. Yes.

Q. If you could turn to Page 57 of the same document, please, I'm going to be referring here to quotations made on Pages 57 to 60 of the 2002 RED. Is it also true that in order to maintain its current non-canola registrations, Chemtura was required to make the following changes to manage potential occupational risks? And it lists, I think, four here. On Page 57, we've got two of them. There had to be a prohibition on on-farm lindane dust formulations on wheat, barley, oats, and rye. They had to reduce the maximum application rate for corn seed treatment. And then on Page 58, workers were required to double layer clothing, chemical resistant gloves, and a dust respirator when applying dust formulation on corn.

And then finally on Page 60, they require a 24-hour re-entry interval for all seed treatment uses. Do you see that?

PRESIDENT KAUFMANN-KOHLER: I'm confused because the

09:38 pages we have on the screen are not the pages we have under Tab 7.

MR. KURELEK: If I were you, I would just pay attention to the document binder, and what I referred to was Pages 57, 58, and 60 of Tab 7, the 2002 RED.

PRESIDENT KAUFMANN-KOHLER: Yes, that I understand, but then I need to see in these pages where you referred to, and on the screen I have a different highlight than what I see here. I'm confused.

MR. KURELEK: Okay, then, I will take you to those.

BY MR. KURELEK:

Q. If you go to my first point about the prohibition for on-farm lindane dust formulation, if you look at the second sentence under dust formulation--

PRESIDENT KAUFMANN-KOHLER: Yes. Sure.

MR. KURELEK: --that's the first point.

The second point about the maximum application rate.

PRESIDENT KAUFMANN-KOHLER: So, I'm under D, occupational risk, on farm seed treatment, dust formulation, and then it starts as indicated in Tab 12?

MR. KURELEK: Yes, but I'd like to refer you to the second sentence because of the rate.

PRESIDENT KAUFMANN-KOHLER: Because of the rate?

MR. KURELEK: Yes.

And then if you go to the next sentence, in response

09:39 to these risks--

PRESIDENT KAUFMANN-KOHLER: Yes.

MR. KURELEK: --that's the second point.

And then in terms of the third point about the PPEs or the protective clothing that had to be worn, that's at the very bottom of Page 58, "Therefore, to mitigate on-farm treatment of corn, and then you see, "the workers must wear."

PRESIDENT KAUFMANN-KOHLER: Yes.

MR. KURELEK: My apologies for going too quickly.

BY MR. KURELEK:

Q. And then Page 60, second topic, post application of risk, the second full paragraph there.?

PRESIDENT KAUFMANN-KOHLER: Yes.

MR. KURELEK: And you can start at the second sentence and continue on.

PRESIDENT KAUFMANN-KOHLER: "In accordance"?

MR. KURELEK: Yes. Okay.

Again, my apologies for going too quickly for you there.

BY MR. KURELEK:

Q. Do you agree, Mr. Thomson, that those four requirements, occupational exposure requirements, were issued by the 2002 EPA RED?

A. Yes.

Q. Does that shopping list indicate that the EPA harbored

some occupational exposure concerns about lindane?

A. No, it indicates that with mitigation they had no concerns.

Q. That's not exactly what I asked.

What I asked was whether the shopping list indicated whether the EPA, when it released this 2002 RED, harbored some occupational concerns. Do you agree with that?

A. No. By the time they issued the RED, they had dealt with the mitigation, so--I mean, part of the risk evaluation is to look at the risks, which we've identified, and then to determine if there is adequate mitigation that will eliminate the risks. So, they highlight in this document where those risks are and then provide the solutions to those risks that will lower the risks and, therefore, mitigate the concern. So, at the end of the day, when the RED is issued, the EPA has no concerns for worker exposure. And I think if you read, you know, at the ends of those paragraphs, you will see that the statements are the EPA does not feel that these are a concern.

Q. Okay. So, just so it's clear on the record, it's your evidence today that the EPA, with this document, had no occupational concerns at all; is that correct?

A. I mean, as far as the points that you asked me to look at, yes.

Q. Yes. Okay.

A. Turning to the points you asked me, I mean, you can

look at the last sentence under commercial seed treatment. "The Agency believes that PPE reductions are protective and will not result in exposures of concern." So, the document provides the mitigation to eliminate that concern.

Q. I'd like to take you to Paragraph 30 of your first Witness Statement, where you talk about this issue.

One of the things you note there, this is the third sentence in about halfway down the paragraph: "Significantly the RED indicated that there were no major concern--there was no major concern with occupational exposure." So, there you chose the word "no major concern," so, which is it? Is it no concern at all or no major concern in your evidence?

A. I mean, there was no concern expressed in the RED.

Q. None at all?

A. No.

Q. So, that's your evidence today?

A. On those issues that we just outlined, there was no concern.

Q. Thank you.

Is it true that following the release of the 2002 RED, the EPA did not grant either a registration or a tolerance for lindane use on canola in the U.S.?

A. Correct.

Q. In addition to the concerns we just went through, is it true that the 2002 RED set out additional data requirements,

such as a plant metabolism study?

A. Yes.

Q. Is it true that the EPA would not grant a tolerance for lindane on canola in the absence of that study?

A. Correct.

Q. Is it true that generating such a study would take a substantial amount of time?

A. I guess it depends on the definition of "substantial." It's a plant metabolism study, so you need to go through the life cycle of the plant in order to do the metabolism. That takes time.

Q. I'll turn you to Tab 9 for a moment. These are Ed Johnson's notes, I believe.

In particular, I'm looking at the second to last page of this document, so we're looking at an E-mail from Ed Johnson to Will Cummings and Rob Dupree and others, and it's an update on the RED, and at the top of the second to last page, first full paragraph, it said, "There are, however, disturbing issues"--this is Mr. Johnson talking I believe--"with respect to the canola tolerance/registration. First, I was informed that the Metabolism Committee decided that no new tolerance could be issued before the plant metabolism study was submitted and reviewed. This is a significant delay since such a study will take a substantial amount of time to treat, grow, and analyze the crop."

09:45 Do you agree with that statement?

A. Yes.

Q. Is it true that Chemtura did not end up submitting the Plant Metabolism Study to the EPA until 2005?

A. Correct.

Q. Is it also true that EPA was still reviewing that study when it released its 2006 HCH Report?

A. That's as far as I'm aware. I can't tell you for sure.

Q. Sure. Well, maybe I can assist your memory here. If you turn to Tab 12, so this is hopefully for everybody the HCH Report, February 8, 2006. Page 1 at the very bottom of that document, second to last sentence, "The Registrants have also submitted an outstanding nature of the residue study, also known as the Plant Metabolism Study, originally required by the 1985 registration standard DCI for lindane, and these data are currently in review."

So, again, with that assistance, would you agree that the EPA in 2006, at least February 2006, was still reviewing the Plant Metabolism Study?

A. Yes.

Q. And therefore, at the time of the release of the HCH Report in February 2006, the EPA still had not granted either a registration or a tolerance for lindane use on canola in the U.S.; is that right?

09:47 A. Correct.

Q. If I could turn you back to Paragraph 41 of your first Witness Statement, despite that fact, despite the fact that in early February 2006, the EPA still hadn't granted a registration or tolerance, in Paragraph 41 of your first Witness Statement, you nevertheless say, "I would have expected that Crompton would have obtained this registration and/or tolerance by early 2003, in time for the 2003 planting season."

Is that correct? Is that what you said?

A. It's definitely what I said and, frankly, what I still believe.

Q. Okay. We will return to this issue. I'm turning now to the HCH Report itself, so this is again Tab 12. Would you agree that this Report presented the EPA's revised assessment of risks related to the continued registration of the insecticide lindane, also known as gamma HCH?

A. I don't believe I would classify it as a reassessment. It was an additional assessment based on an assessment of the other isomers.

Q. Sorry. Just to clarify, I don't believe I said reassessment.

A. Okay. I'm sorry.

Q. But just to assist you, I was quoting from Page 2 of Tab 12 of the HCH Report itself. It's the first full paragraph of Page 2. "As a result of the Agency's continuing review of

lindane, the Agency initiated the preparation of this document. This document represents the EPA's revised assessment of risk." So, maybe it's the word revised that made it sound like it said reassessment.

A. Okay.

Q. "The EPA's revised assessment of risks related to the continued registration of the insecticide lindane."

Do you see that there?

A. Yes.

Q. So, in other words, this document is part of the overall that the ongoing narrative that started with the 2002 RED; is that right?

A. Correct.

Q. Would you also agree that in this HCH Report, the EPA expressed some concerns about lindane?

A. Could you repeat that?

Q. Sure.

Would you also agree that this HCH Report expressed some concerns about lindane? This is the EPA's concerns. We're not talking about PMRA at this point.

A. I mean, as far as this document, and I can't recall specifically what the concerns may have been, but I can agree that there were likely concerns.

Q. Would you say that this document had a negative impact on your applications for a tolerance on registration in the

09:50 U.S.?

A. I'm not sure I would agree that this document had a negative impact. I mean, the review of the data that we had submitted for the tolerances was still being reviewed. That was the critical step.

Q. I'd like to turn you to Tab 13. This is an E-mail from John Kibbee, who will be the next witness in these proceedings, and he's writing to Will Cummings and others, C.P. Yip. And if you could turn--oh, and you are cc'd on this document as well.

If you turn to page, what I call Page 4, it doesn't have any page numbers, unfortunately, but back to front thing here, one, two, three, four, at the top, the title should say "Lindane."

A. Yes, yes.

Q. And then fourth bullet down, you see Mr. Kibbee saying, "2006 Risk Assessment of Lindane has had a negative impact."

Would you agree with that statement?

A. I agree that statement is there.

Q. Would you agree with the content of that statement, Mr. Thomson?

A. I think it's best to ask Mr. Kibbee, you know, what his--what he felt the negative impact was. Obviously, he feels that there was a negative impact. What that negative impact in

09:52 is in his mind, I can't tell from that document.

If you're asking me does that mean there's a negative impact on us being able to get the tolerance, I don't think that I can agree to that.

Q. Thank you. That was the question I had.

ARBITRATOR CRAWFORD: I'm not clear about that. What was your view of its impact?

THE WITNESS: I mean, I think that then--the negative impact was the inclusion of the isomers in the assessment and the--our ability to deal with that issue, you know. It presented the possibility that we would need to generate significantly more data to support any registration.

You've got to remember that this was an essence of discussion document where the EPA was looking at these. It wasn't making any particular rulings based on this document. So, there was the potential that there would be future data requirements because of it, but it doesn't necessarily imply that there would be any impact on getting a tolerance for canola since that was really essentially just being based on whether we completed the metabolism study.

BY MR. KURELEK:

Q. So, just going back to my question, just so I'm certain, is it true that you disagree with Mr. Kibbee's impression here that the 2006 HCH Report had a negative impact on Chemtura's application for a tolerance or registration in

09:53 the U.S.?

A. I mean if--you've added a lot into that sentence.

Q. I'm just trying to understand--let's back up, then.

A. Yeah.

Q. Do you agree that when Mr. Kibbee, because he doesn't call the HCH Report the same thing that I'm calling it here.

A. Correct.

Q. But do you agree in that fourth bullet that he is actually referring to the 2006 HCH Report and not to the 2006 Addendum. Is that correct?

A. Yes. Based on the date he wrote it. He couldn't have been referring to the--

Q. Yes, exactly.

A. So, yes, he's referring to that particular document.

Q. So, regardless of what Mr. Kibbee thinks, and I can ask him the same question, do you agree with that--with his impression there that that HCH Report has had a negative impact in particular on the registration application? It sounds as if--

A. You keep adding things to this.

Q. I don't believe I am. I think I'm asking exactly the same question. I asked you whether you agreed with Mr. Kibbee's statement or not. That was my original question, and that's--it sounds to me like you said you disagree with it. That's what I heard, but I just want to confirm that that's the

09:54 case.

A. No, I disagree if you interpret this as saying that the negative impact is on our ability to get a tolerance, and I disagree if that's what you feel the negative impact is.

Now, you'll have to ask Mr. Kibbee what he thinks the negative impact is. I'm not saying that the 2006 document is something that we, as a company, shouldn't be concerned about. There's a lot of issues that are being raised in that document.

What I am saying is that the issue around the tolerance, as far as I believe, will be based on whether we complete the metabolism study to provide the EPA with the data it needs to be able to issue a tolerance. This document I don't believe impacts our ability to complete the metabolism study review, so I don't want to tie the two things together. I'm not saying that this is a, you know, a glowing document that I shouldn't have any concern about. I have a concern about it, but I don't have a concern about it in terms of our ability to get the tolerances.

Q. Okay. Just so I understand this properly, your evidence here today is that if Mr. Kibbee in that fourth point is referring in his reference to negative impact to Chemtura's application for a tolerance or registration, then you disagree with it, if that's what he's saying, if that's what he's referring to?

A. I would disagree with that.

09:56 Q. If that's what he's referring to?
A. If that's what he's referring to.
Q. Thank you.
If you turn to Page 50 of the HCH Report, so I think we are back to Tab 13--no, that's wrong--Tab 12.
A. I'm sorry, what was the page?
Q. Page 50.
The top of that page is entitled, "Additional Concerns and Information Request." I'm not sure why it's not "requested."
Do you agree that there are five requests, it looks like there? One is infants' exposure to lindane and HCH isomers in breast milk.
A. Correct.
Q. Two is or B is carcinogenicity of lindane. Three is FQPA's 10 times safety factor.
A. Correct.
Q. Four is information on cultural practices and potential impacts of lindane on Alaskan subsistence population, and the last one is effects of lindane on the liver.
Would you agree that those are the five areas that the EPA was looking for information on?
A. Yes.
Q. And is it your evidence then that Chemtura's decision not to pursue a U.S. tolerance was unrelated to the results of

09:57 the EPA's 2006 HCH Report?

A. I think that Chemtura had, by this point, already started the process of requesting a tolerance. There is nothing that in here stopped us. The thing that was stopping was the evaluation of the metabolism study. Once the evaluation of the metabolism study was completed, regardless of what's, you know, being presented here, we would have been able to pursue a tolerance. It was clear that that was needed by the EPA before they would accept the application for a tolerance.

Q. So, going back to my question, then, is it true that the HCH Report itself did not lead to Chemtura's decision to stop its pursuit of the U.S. tolerance?

A. Correct.

Q. Again, is it true that with the release of the 2006 HCH Report, the EPA still had not granted either a registration or tolerance for lindane use in the U.S.? Is that right?

A. Correct.

Q. Turning to the final of these three documents, this is the 2006 RED Addendum, as it's called, even though it's got that 2002 on the front. This is Tab 14 in my binder.

A. Correct.

Q. Is it true that this document was released only a few days after Chemtura decided not to pursue a lindane registration in the U.S.?

09:59 A. I'm not sure if a few days. I can't tell you. It was around the same period. I believe that we had met with the EPA early in July, and this was released late that month, but that's just my recollection.

Q. Sure. Let me refresh your--

A. You might want to refresh me on that.

Q. Sure.

Tab 8 in my binder.

A. Tab 8.

Q. Maybe you could confirm whether that is Chemtura's Request for a Voluntary Cancellation. It's dated July 20th, 2006.

A. It is.

Q. So, again, would you agree that the 2006 RED Addendum was released certainly within a month of that July 20th, 2006, letter?

A. Within a month of the letter, you're correct.

Q. And in the months immediately prior to that release of the 2006 Addendum, was Chemtura expecting a positive decision from the EPA about lindane?

A. Chemtura definitely had concerns about what the EPA was going to decide on lindane.

Q. So, they had concerns about were they expecting a positive decision, a favorable one?

A. Chemtura was not expecting a cancellation of our

lindane registrations. We were concerned that it would be additional data requirements to support ongoing registration.

Q. Were there any concerns that it might not be favorable in terms of some of the statements that we made--what would be made by the EPA in the 2006 Addendum?

A. Now, I'm not sure--I'm not sure I know what you mean by "statements that would be made."

Q. Statements similar to the ones that we've already looked at in the other two Reports, statements about the EPA's concern about the toxicity of or the exposure concerns of lindane. What I'm trying to assess here is Chemtura's expectations going into the release of the 2006 Addendum. I'm trying to understand that.

A. We expected that there would be additional data requirements to address concerns that the EPA had.

Q. I'd like to turn you to the last tab. This is Tab 15 of your witness binder. This is an E-mail chain, and on the first page at the bottom, so this actually in terms of this document, at the top of the page, it says Page 7 of 13. At the bottom of that first page or Page 7 is an E-mail from Will Cummings to Paul Thomson and others, and so that's to you, June 14, 2006. So, this is Will Cummings. If you could turn the page, it says, "Paul, I would like to have an update on the status of the phase-out negotiations with EPA on this AI." And I understand AI is not "Amnesty International." It's "active

ingredient"; is that right?

A. Active ingredient, that's right.

Q. "Remember that EPA will make a decision on lindane before the end of August because of the FQPA deadline. It will not likely be a favorable decision. Therefore, if you intend to offer a phase-out, you will need to show your hand before the EPA shows their hand. The process needs to get moving."

Do you agree with that comment there that "it" being the Addendum will not likely be a favorable decision? Do you agree with that comment, or would you have agreed with that comment at the time?

A. I would agree that there was concern about whether that would be a favorable decision. I mean, I can't recall at the time when if I had a strong feeling that it would not be a favorable decision. Will did have a strong feeling it would not be, but...

Q. Was Chemtura aware of when the 2006 Addendum was going to be released?

A. There was a EPA time line that had to be met that we were aware of, so that they would have had to make some kind of decision, and I believe it was before the end of July, but I can't recall the exact date.

Q. Okay.

A. And, in fact, in that paragraph we just referenced, I think we're talking about the end of August, but I understand

it was the end of July, too.

Q. So, when--did the timing of Chemtura's withdrawal, and remember taking you back to that letter, that July 20th letter, I think it was, Tab 8--did the timing of Chemtura's withdrawal of its lindane registration have anything to do with the timing of the 2006 Addendum, the release of that Addendum?

A. I'm not sure what you mean by that. Did we affect that Addendum date?

Q. No, no, sorry. No. What I'm trying to ascertain is whether Chemtura's decision on July 20th, I believe it was--

A. Right.

Q. --to 2006, to withdraw its registration/tolerance applications, was that--the timing of that date, its application for withdrawal, was that affected at all by the expected release date of the 2006 Addendum?

A. Yes, yes.

Q. Okay. And in what sense was it related?

A. If we were going to do a voluntary withdrawal, it was beneficial for both us and the EPA to do that before they needed to issue their Final Report, which had to have been issued before, I believe, the end of July.

Q. It was beneficial to the EPA in what sense?

A. In the sense that they would not be required to issue a complete evaluation of lindane if, in fact, there was no registrations at the time. So, by coordinating the voluntary

10:06 withdrawal of all the Lindane Products, it meant that we did not--the EPA did not have to go through the process of a complete evaluation.

Q. And it was beneficial to Chemtura in what sense?

A. It was beneficial to Chemtura because if we did not voluntarily withdraw and therefore would need to support the registration going forward, we would have needed to have provided data to support any further registrations, and those data requirements would likely have had--would likely have appeared in any RED document issued in 2006.

Q. So, I'd like to return to that paragraph we just quoted from Will Cummings. It's a very interesting line here. "Therefore, if you intend to offer a phase-out, you will need to show your hand before the EPA shows their hand."

A. Correct.

Q. Is your understanding of what Mr. Cummings is saying there, is he essentially saying that Chemtura should quit the lindane seed--sorry, lindane scene in the U.S. to avoid getting fired from it by the EPA, to use the vernacular there?

A. It's your interpretation.

I believe that the interpretation and at least the interruption I had is that the continued registration was going to require significant investment by the company to support any further registrations, and that the data that was going to be required as part of this ongoing review was going to be

substantial for the company. And, therefore, the investment, the investment that we would need to make--I mean, we were doing a financial analysis at the time in terms of whether we were going to be able to justify continued investment in the lindane registrations in the U.S.

Q. Indeed. And that's how I started with quoting from your Witness Statement in terms of your motives, or stated motives in your first Witness Statement for withdrawing the application.

Turning to Paragraph 38 of your first Witness Statement--

A. I'm not sure I understood what you just said.

Q. Well, let me go back. What I started out with in this EPA section was, I quoted Paragraph 36 of your first Witness Statement. There was no financial reason to incur the costs to obtain the additional data that may be necessary to maintain the ongoing U.S. registrations. I asked you if that was correct, and I think you said yes. That's what I'm referring to.

A. Correct.

Q. Do you agree with that still?

A. Yes, yes.

Q. Okay. Now, turning back to Paragraph 38 of your first Witness Statement, you conclude that the EPA never banned lindane, nor did it identify any environmental, health, or

worker exposure concerns regarding lindane to justify cancellation.

Is that still your evidence today?

A. Yes.

Q. And turning to Paragraph 40 of your first Witness Statement, you suggest that, "Given the EPA's RED had found no unacceptable safety concerns"--so this is the 2002--"it is reasonable to expect that the EPA would have been prepared to register lindane for use on canola."

Is that right?

A. Correct.

Q. And then in Paragraphs 42 and 44, you say essentially the same thing in one respect in your first Witness Statement. You go so far as to say, "I have no reason to believe that the lindane registration"--this is by the EPA--"or at least an import tolerance, would not have continued indefinitely."

Is that right?

A. Correct.

Q. I'd like to take you back to the 2006 Addendum. This is again at Tab 14, so four passages I would like to refer you to. The first one is on Page 7. And this is, so everybody can follow along here, it's is the first full paragraph under subsistence diets, and it's the last sentence in that paragraph, where we find, "Lindane and other HCH isomers tend to accumulate in colder climates, such as the Arctic and

10:11 concentrate in the food chain. Thus, any manufacture or use of lindane, or any other HCH isomers, is a potential source of exposure to indigenous populations."

A. Correct.

Q. And turning to Page 8, similar issue, first full--this is under "Environmental Fate," similar location in the sense that it's the first full paragraph and it's the--or the second last sentence of that paragraph under "Environmental Fate."

"The fate characteristics of lindane, including persistent, bioaccumulative potential, and the potential for long-range transport, are key elements to understanding the extent and scope of exposures associated with the use of lindane. Lindane's toxicity in association with these fate characteristics results in risks of concern for the Agency."

Do you see that?

A. Yes.

Q. And the second last quotation, if you could turn the page--this is a short document here--Page 16, at the very bottom where we are winding up with the conclusion of the document. "The EPA finds"--last full paragraph are, "The EPA find the overall costs of continued registration of lindane for seed treatment are high. The seed treatment use will only add to the existing sources of lindane exposure. Ongoing releases of lindane into the environment are of concern due to the environmental fate characteristics of the chemical. Lindane is

10:12 persistent and mobile and will accumulate in human fat tissue. This potential for ongoing and future exposure to lindane is of particular concern for nursing infants because of the potential for exposure to lindane via breast milk."

Do you see that there?

A. Yes.

Q. And then finally at the top of Page 17, "In sum, the EPA finds that these costs of continued lindane registration far outweigh the benefits of the seed treatment use. Therefore, the lindane seed treatment uses are not eligible for re-registration under the FIFRA."

Do you see that there as well?

A. Yes.

Q. So, on the face of those unequivocal statements, do you still stand by what you say in Paragraph 50 of your first Witness Statement, that I'm not aware of any scientific basis upon which the EPA could base a decision to cancel a registration or tolerance for canola? Do you still stand by that today?

A. Yes.

Q. And do you still believe that the EPA would have granted an indefinite--

ARBITRATOR CRAWFORD: The witness wants to continue his answer.

MR. KURELEK: Yes. Sure.

10:14 THE WITNESS: Absolutely. I mean, the--the point of this document is highlighting some of the continued concerns that the EPA has, but if you look at the concerns, a lot of it is based on general concerns that could still be mitigated for a particular application. That was our fear going into this, is that there would be continued data to generate to mitigate the risks that were being presented to a point where they were acceptable. If we look at everything from the translocation of the gamma isomer, it's not clearly understood how much that contributes to what is being deposited in the Arctic. There is no clear indication that the use of a seed treatment in the planting of seeds would contribute significantly to that. And those are the kind of pieces of information that would still need to be generated.

The EPA, when it has concerns, usually works with the Registrant to conduct studies to determine what that level of concern actually is, and we would have, had we had a market for these products, continued to invest in generating the data to mitigate the concerns that the EPA was expressing.

So, I don't believe there is anything in here that the EPA would have been able to, from a scientific point of view, would have come out and canceled the registration, but there definitely is concern where they would have asked for additional data to understand those concerns and understand what the real risks were.

10:16 BY MR. KURELEK:

Q. So, then, is it still your evidence today that the EPA would have granted an indefinite tolerance for lindane on canola in the U.S.?

A. Based on where we were at that time, if the tolerance hadn't been issued, it would have been indefinite until there was a clear area of concern where they could have removed that.

Q. My final two questions on this topic. Is it true that with the release of the Addendum, the EPA still had not granted a registration or a tolerance on lindane; is that right?

A. Correct.

Q. And, in fact, is it true that the EPA never granted a tolerance or registration for lindane use on canola in the U.S. Is that right?

A. It is correct.

Q. I'd like to turn to the final topic, very short one, and this refers to--this topic refers to your statements made in your second Affidavit. If you look at Paragraph 32 of your second Affidavit in particular, which is Page 7, so I'm looking at the topic in your--sorry, I called it Affidavit, Witness Statement. "Chemtura has long-standing presence in the Canadian pesticide market."

Do you see that there?

A. This is my second statement?

Q. Yes.

10:17 A. Paragraph...
Q. Thirty-two.
A. Okay. I'm sorry, I was reading Paragraph 32, and that's not what you were reading. Okay. You were reading the title to paragraph--Section. That's why I couldn't find it.
Q. Sorry.
A. I thought I was lost here.
Q. We're almost done here.
In that paragraph, you say, "It must be understood that although Chemtura is a large company, the crop protection business was at all relevant times and is approximately 10 percent of sales of that company."
Is that your evidence today?
A. Yes.
Q. And Paragraph 35 of your second witness statement, page over, you say that, "The seed treatment business represented over 80 percent of the sales of the Crop Protection Division in Canada."
Is that right?
A. Correct.
Q. Okay. Now, what I'm trying to understand here is size, and you referred to various different designations, so I want to make sure I have this right on the record.
A. Okay.
Q. There is Crompton total sales which--let's say that's

10:19 the aggregate, that's the big pie. Sounds like what you're saying here is--correct me if I'm wrong--the crop protection business, the sales from the crop protection business represents 10 percent of the total Crompton sales; is that correct?

A. Total, yes.

Q. Yes.

A. Global, correct.

Q. And then again, just because you use a different phraseology here--

A. Sorry.

Q. --is it true that the seed treatment business, it sounds like it's 80 percent of that crop protection business; is that right?

A. Of the crop protection business in Canada, so we're talking just about the Canadian business with that 80 percent.

Q. So then, what percentage of the total Crompton sales do the seed treatment business sales represent? Is it 8 percent? Am I reading that right? It's 80 percent--

A. No.

Q. 80 percent or 10 percent?

A. No, because I can't recall off the top of my head. You'd have to look at what the total of the Canadian business represented, and then that's 80 percent of that. So, I mean, the Canadian business was a small part of the global business,

and 80 percent of that Canadian crop business was seed treatment. I know it's confusing. I'm confused as I try and tell you this.

PRESIDENT KAUFMANN-KOHLER: How much was the Canadian business of the total?

THE WITNESS: I'm sorry, I don't--I just don't know off the top of my head.

PRESIDENT KAUFMANN-KOHLER: No, if you don't know, then don't try.

BY MR. KURELEK:

Q. Okay. And I thought that may be the answer, but let me tell you where I'm going with this.

A. Sure.

Q. Because we've got the total Crompton sales, we've got the 10 percent crop protection business, and then we've got, it seems to me, a subset which is the seed treatment business.

A. Yes.

Q. And then what I'm really interested in is the nub, the lindane sales. I'm trying to figure out because I don't see it anywhere in your evidence here, what percentage of the total crops--sorry, yes, total Crompton sales was represented by lindane sales? So, not the generic crop protection or seed treatment business anywhere. Just lindane.

A. Yeah. I can't off the top of my head give you a number for that, and--I mean--and I'm not sure if it's in with

10:21 the financial numbers as part of the other submissions, but that couldn't off the top of my head.

Q. Okay. So is it anywhere that your counsel can point me to because I haven't seen it. The best I have seen is the crop protection percentage, the 10 percent.

MR. SOMERS: I'm not sure I follow your question. Is it--do you mean globally?

MR. KURELEK: Lindane seed.

MR. SOMERS: Isomer globally?

MR. KURELEK: Sales, yes.

MR. SOMERS: We will look for that number. I don't know where in the record where that would be.

THE WITNESS: I'm pretty sure we provided numbers on what the total sales for the Lindane Products are, and so hopefully somewhere in here we also--and it's public information--the sales of the Crop Protection Division for the whole company, and the whole company. So, it's not difficult to get those numbers from what we do have. I just can't do it on the top of my head.

PRESIDENT KAUFMANN-KOHLER: We also have the numbers for lindane in Canada. I assume so.

MR. SOMERS: Yes.

BY MR. KURELEK:

Q. Is it fair to say, then, that the lindane--without having the precise numbers in front of you, that the lindane

10:22 sales numbers represent less than the 10 percent that the crop protection business represents of the total sales?

A. Yes.

Q. Okay. Do you have a rough idea of what the percentage is. Is it half? Is it--

A. It would be less than half.

Q. So, it would be closer to 5 percent, then; is that right?

A. It wouldn't be more than 5 percent.

Q. Okay. Thank you. Those are my questions, Mr. Thomson.

PRESIDENT KAUFMANN-KOHLER: Any redirect questions?

MR. SOMERS: Yes, I do have, Madam Chair, and I think we could probably squeeze them in before the break.

REDIRECT EXAMINATION

BY MR. SOMERS:

Q. Mr. Thomson, at the outset of his cross-examination my friend took you to a report of a meeting written by Mr. Dupree in relation to a meeting with PMRA, and there was some question about Mr. Dupree appearing or not appearing at these proceedings.

Can you clarify whether Mr. Dupree is still with the company?

A. Mr. Dupree left the company. He does not work for the company right now.

10:24 Q. Is it your impression that he would have been prepared to assist the company in this proceeding?

A. Had he been an employee with the company, yes.

Q. In the course of reviewing those notes, and I'm going to refer to Exhibit C-5 of your statement, if I ask you to turn to that now.

A. So C-5 was the Tab 5?

Q. Of your first Witness Statement. I'm sorry, Exhibit C-5, which should be at Tab 5. That's right.

What I'm referring to are Mr. Dupree's notes of that meeting and the PMRA position on the politics of the issue. My friend turned you to the second page, but I would ask you to go to the first. It is not Exhibit C-5, as far as I can tell.

Or, I'm sorry, yes, the--and so if I could ask you to turn to the--since it was referred to in the witness bundle, I'll ask you to go to that instead.

MR. KURELEK: I think it's Tab 1 of my witness bundle.

MR. SOMERS: Thank you for that.

BY MR. SOMERS:

Q. He directed you to the second page of it, the second-to-last paragraph, which--and Mr. Dupree's statement, "I suspect she will try to do what she can politically to derail it," et cetera, and asked you for the basis, the possible basis for Mr. Dupree's belief in that.

Actually, turn to the first page, though, of that, and

10:25 ask for your comment on the part labeled PMRA position, the second bullet in particular. Could that have been the source of your employee's belief?

A. Yes. And I mean, again, there was the reference to the politics in there.

Q. In the push for a reassessment?

A. A reassessment.

Q. Would the push for reassessment have been to expand the uses of lindane or to just--

A. No. Oh, I'm sorry, yeah. I mean, it's the politics are pushing for the Reassessment of Lindane to essentially remove lindane.

Q. All right, thank you.

On the different issue about the concern for worker exposure, which the debate was about whether PMRA had communicated that or communicated an adequate degree of concern to the company about worker exposure, and you clarified that it was because of different use patterns between Canada and other countries.

A. And other countries.

Q. Could you explain what those differences in use patterns might be and how they might affect a concern about worker exposure or worker exposure data?

A. Well, certainly. I mean, the risk associated with the use of any seed treatment product is really if it's the same

10:27 active ingredient depends on the exposure. Seed treatment is the application of a particular pesticide to a seed, and there is many, many ways to do that. In the U.K., they had particular equipment that was mechanical in nature, was open, and generated a lot of dust in the process. It was very unlike the kind of closed systems that were used in Canada at the time, so the comparison of the two in terms of the exposure was vastly different, and it was really not possible to use the risks associated with the exposure we would get from a rather open and mechanical system to the ones that we had in Canada at the time. So, that's the concern about whether, you know, you can use that data in one application to infer anything in another.

Q. So, could I summarize your statement by saying it was concern about the reliability and usability of data and not concern over worker health, for instance?

A. Right. Right.

Q. Thank you.

My friend also took you to the 2002 Re-registration Eligibility Decision. That document was at Tab 7 of his witness bundle.

A. Right.

Q. In particular, he pointed you to a section there where the EPA was requesting additional data in terms of deciding that Lindane Products, your existing lindane registrations,

10:28 were eligible for re-registration, but additional data would be required.

A. Right.

Q. In your experience with re-registration documents, is that--is that an unusual requirement?

A. Oh, no, that's not unusual.

Q. Is that an unusual requirement?

A. No, that's a pretty standard requirement in most re-registrations. I mean, there are always issues that the regulators have that they may not have enough data to be able to make a decision, or they may have concerns, and they understand that the data is not likely to change the registration, but they would like to have the clarification of the data.

So, in terms of the metabolism study, they didn't have a metabolism study, though they weren't expressly concerned about the metabolism because in their calculations they had accounted for that, but they would like to have a clearer idea what the potential metabolites are, and so it was part of the, you know, a rather typical data requirement.

Q. In addition to that, you discussed the concerns or potential concerns about worker exposure being mitigated by additional protective measures to be taken by persons handling pesticide. Would that be an unusual requirement for a re-registration eligibility document to add?

10:30 A. No. In the EPA's regs they frequently want to see updated labels and improved especially worker protection, so even if there wasn't an issue, they would like to see those in the updated labels. But in cases where they do have a level of concern that they realize can easily be mitigated, they will request that those mitigation efforts be put on the label, so it's a standard practice to ask for those updates as part of the RED.

Q. You also discussed the metabolism study which the 2002 RED required of the company, and observations were made as to the length of time it took to obtain that metabolism study.

Were there alternative means available to the company to obtain a tolerance before that study was completed in 2005?

A. There were options available through the EPA to get time-limited tolerances, and we could have made the request for a time-limited tolerance, which would have allowed a temporary tolerance to be issued while the study was being conducted. It certainly was an option. It was not an option we pursued because the pressure for us to get that tolerance was, you know--had been diminished by the removal of our products from the Canadian market.

Q. Canada also took you to Paragraph 41 of your first Witness Statement, and I'll ask you to turn to that now. He asked you if it was your evidence or testimony, I believe the transcript will confirm, but that it was your evidence that you

could have obtained a registration or a tolerance in time for the 2003 season, and you answered a yes, "and, frankly, I still believe that."

I wanted to ask you if you could expand on your basis for belief.

A. I believe that if we--you know, if we had established that as a priority because we were--because the Canadian market was still there, then we could have pushed to get a time-limited tolerance. We could also have accelerated the metabolism study. Granted, it takes time to grow the plants, but we would have either farmed that out or put more resources into getting that done if we felt that we needed to be in the market in 2003. Unfortunately, we were out of the Canadian market at the time, so the pressure to do that was obviously not there, and, you know, in dealing with all kinds of issues at the company, we have to establish some priority, so it was not a priority for us at that particular time.

Q. Would it be fair to describe, then, that in the Canadian developments between the 2002 RED and the 2006 Addendum to the RED that that was--the developments in Canada were what were governing the company's actions in relation to the EPA?

A. Certainly, certainly. I mean, the big driver in even getting U.S. tolerance was to be able to eliminate this issue with the--the trade issue with the border, and so we needed to

10:34 have a registration in the U.S. But without any registration in Canada, where that was the larger market, the U.S. registration had significantly less value to us.

Q. And, finally, I just wanted to take you to--to the Addendum to the RED itself. That's Tab 14 of the witness bundle, and the last page of it, Page 17, which is an excerpt quoted by Canada in your examination.

A. I'm sorry?

Q. Page 17 of Tab 14 of the witness bundle.

A. Right.

Q. The top of the page, "In sum, EPA finds that these costs of continued lindane registration far outweigh the benefits of the seed treatment use."

Now, before this Addendum was issued, the company had withdrawn--

A. Correct.

Q. --its registrations.

Was the withdrawal of its registrations, did that have--did the withdrawal of your registrations have an effect on the cost-benefit analysis performed by the EPA?

A. I'm not sure I could answer that. Sorry.

Q. Just one more thing on that same document--no, I'm sorry, on the--I'm in the prior document. That would be Tab 12, the HCH assessment of lindane and other hexachlorocyclohexane isomers, the HCH assessment document.

10:36 Canada took you to Page 50 of that document and identified concerns listed on that Page 8 E.

A. Correct.

Q. And the transcript will correct me if I'm wrong, but I believe those were concerns were attributed to being EPA concerns.

A. These were, yeah.

Q. As I understand--could I ask you to read the first sentence of that page at the top?

A. Page 50?

Q. Right.

A. "Additional concerns related to lindane and the HCH isomers have been raised in public comments on the Lindane RED and risk assessment and comments on the draft NARAP. The Agency would like to obtain additional information from the public specific to the topics listed below as it makes its final determination on lindane."

Q. Is this an unusual thing for a Re-registration Eligibility Decision to solicit?

A. The EPA, when it issues REDs, always asked for public comment, and there is a public comment period on this. And so depending on what the public or the comments that come in are, they will frequently then go and ask for additional information. So, that's why I had mentioned earlier that this was more of a discussion document because it deals with the

10:37 comments that have come in and does some reassessment based on some of those comments, and then it is really looking for some more information or frankly some direction from the public in terms of the future assessment that it's going to do, so it's not total--I mean, the public comment is a standard practice with the EPA.

Q. Does their listing here imply an endorsement or an adoption of these concerns?

A. No, these are--well, I mean, it implies that they--there is enough concern being expressed by someone that they would like to get some more information so that they can adequately address the concerns that have been raised, I think is probably the best way to term that.

Q. I understand. Thank you. Those are my questions on redirect.

Thank you, Madam Chair.

MR. KURELEK: One point of clarification on something Mr. Somers prefaced that last issue about, and I think the record will bear me out on this. I was being very precise with my language in how I asked that question. And I don't know what that I used the word EPA concerns as a phrase. What I kept asking was whether the EPA requested further information on the following topics, and so it's just as long as we know that I wasn't attributing those concerns to the EPA, or that they were EPA concerns. Obviously the EPA wanted some

10:39 information on it, so that's what I wanted to distinguish here.

MR. SOMERS: Thank you very much. I appreciate that clarification.

PRESIDENT KAUFMANN-KOHLER: Thank you.

Do my co-Arbitrators have questions for Mr. Thomson?

QUESTIONS FROM THE TRIBUNAL

ARBITRATOR BROWER: My understanding of the administrative processes involved in the precise status or effect of the different documents we are dealing with is somewhat incomplete looking at Tab 7, which is the RED. Am I correct?

THE WITNESS: Yes.

ARBITRATOR BROWER: Page 64, at the top, what Registrants need to do, the result of this document, as I understand it, reading from the first couple of lines, is this: "EPA finds that the currently registered lindane seed treatment products would be eligible for re-registration, if the Registrants make the changes to the terms and conditions specified in this document."

So, that basically says re-registration of currently registered products will happen if you do the following.

THE WITNESS: Exactly.

ARBITRATOR BROWER: And at that time, your registered products included seed treatment but not for canola.

THE WITNESS: Correct. Correct.

10:41 ARBITRATOR BROWER: And included seed treatment with lindane.

THE WITNESS: Correct.

ARBITRATOR BROWER: But not for canola.

THE WITNESS: But not for canola.

ARBITRATOR BROWER: Okay. Now, what is the date of this document?

THE WITNESS: Tab 7?

ARBITRATOR BROWER: Yes.

THE WITNESS: It's September 25th, 2002.

ARBITRATOR BROWER: Okay.

THE WITNESS: It's just on the second page in that tab.

ARBITRATOR BROWER: What page number is that?

THE WITNESS: For the date?

ARBITRATOR BROWER: Yes.

THE WITNESS: Just on the second page at the top.

ARBITRATOR BROWER: Page 2 or page Roman?

THE WITNESS: It's not any of the Roman--it's in the Preamble to the actual--

MR. KURELEK: It's under note to reader.

PRESIDENT KAUFMANN-KOHLER: Back of this page.

ARBITRATOR BROWER: Oh, right. Exactly.

Then turning to Tab 8, the letter of July 20, 2006, withdrawing, as I understand, all of the then-registered

products of Chemtura involving lindane?

THE WITNESS: Correct, involving lindane.

ARBITRATOR BROWER: Right.

And in the last paragraph, however, appears on Page 2, you say, "Chemtura requests that the Agency complete a scientific review of the seed treatment worker exposure study submitted by Chemtura, formerly known as Crompton, to support the lindane seed treatment uses," et cetera, et cetera.

What is your understanding of what was hoped for as expressed in that paragraph?

THE WITNESS: We had submitted a worker exposure study as part of the ongoing review process to the EPA, so at this point they hadn't completed a review, and we were asking for cancellation of our registration, so there was no reason why the EPA would have reviewed that to support registrations that we had voluntarily canceled.

But for worker exposure studies, because you frequently use those studies to support other products, you can use surrogate studies, so you can use the worker exposure study for one product to support the registration of another product. By having that reviewed, we would have had that study available to us to support future registrations of other seed treatment products.

Does that make sense?

ARBITRATOR BROWER: I understand from what you say the

10:44 intention was not to work towards the re-registration of lindane.

THE WITNESS: No, no. It was to have a study reviewed so that we could use it for other purposes.

ARBITRATOR BROWER: Right. And at Tab 14, which is what's known as the Addendum which was issued in July 2006.

THE WITNESS: Correct.

ARBITRATOR BROWER: On Page 17, the last paragraph, prior to bibliography reads as follows. "In sum, EPA finds that these costs of continued lindane registration far outweigh the benefits of the seed treatment used. Therefore, the lindane seed treatment uses are not eligible for re-registration under FIFRA."

Did I understand you to say notwithstanding that, you felt you could ultimately have achieved a tolerance or a registration for lindane for canola?

THE WITNESS: Certainly, certainly.

In any evaluation of a pesticide, the EPA will look at a variety of factors, one of which is the benefits. So, regardless of what the risk is, if there are no benefits to having that product on the market, the EPA isn't going to approve it. It needs to have some benefit.

In this particular case, one we had withdrawn our application, our registration, so really there was no benefit to have a registration if there was no product. And we did

10:46 that because the benefits of our product in the marketplace were low because there was competition, some of it in terms of the products. Some of it was some of our own products, so really that benefit was gone.

So, for the EPA, when they look at the risk benefits, the benefits are very small. They're not saying that the risks are very high. They're saying their benefits are really small, so when you look at that risk-benefit, there was no reason to continue.

What I'm saying is that if we had a benefit, which would have been a canola market in the U.S., then that benefit would have changed, and we would have then been dealing with the risks and providing data to support mitigation of the risks that were of concern.

ARBITRATOR BROWER: Thank you.

ARBITRATOR CRAWFORD: Could I ask some questions?

PRESIDENT KAUFMANN-KOHLER: Yes.

ARBITRATOR CRAWFORD: I can quite see that the position in the U.S. where the canola was much smaller crop and there were other alternatives was the position in terms of the overall benefit was different, but where in this document at Pages 16 or 17 can you find that the EPA was taking into account your withdrawal application in terms of assessing the benefit? They seem to be saying the benefit of continuing lindane registration far outweigh the benefits of seed

10:47 treatment use. They're concerned with the question of continued registration.

THE WITNESS: Right.

ARBITRATOR CRAWFORD: You had withdrawn the registration, so in a sense this was moot. But they went ahead and made the Assessment anyway; isn't that accurate?

THE WITNESS: They did go ahead and assess. That was--I mean, I think part of the discussions we had always had with the EPA. You've got to remember that they are assessing the current registrations, so it wasn't an assessment of the canola situation. That wasn't part of--

ARBITRATOR CRAWFORD: No, I understand that.

THE WITNESS: So, we are just looking at the non-canola seed treatments that were in there.

ARBITRATOR CRAWFORD: Roughly.

THE WITNESS: I'm not sure that was still one, but you're right in the sense that, you know, we had voluntarily removed those labels, but they still did assess it because, you know, that was really the driver and in some of the discussions we had with them was the driver for this particular document. Really there was no benefit even for the seed treatments. Withdrawn or not withdrawn, there was no benefits for those seed treatments that they were looking at.

ARBITRATOR CRAWFORD: There's a big difference in the "time" (tone) between the 2002 and the 2006 EPA documents,

10:49 isn't there?

THE WITNESS: There is. I think it comes from the public comments that were--so, there were still considerable public concern that was being expressed, and so the EPA was re-evaluating it based on the input that they were getting. Not only--and that public concern was being expressed not only by the public at large and general interest groups, but certainly in other international agencies.

ARBITRATOR CRAWFORD: The EPA obviously listens to the public in the course of public information, but it is an independent authority which makes a scientific assessment.

THE WITNESS: It does, and--but it has a lot of accountability, so when--you know. They will--they publish the comments that come in, and they also publish their response to the comments, so they have--and when we looked at those lists of comments that they needed more information on in the 2006 HCH RED, they did publish the comments that came in on those and did deal with each of those issues before they issued the July 2006 RED.

ARBITRATOR BROWER: Following up on that question, at the time you withdrew all of your lindane registered products in the United States, what was your company's market share of sales of registered Lindane Products in the United States?

THE WITNESS: Our market share in the seed treatment business? I just want to make sure I've got your--I got it

10:50 correct.

ARBITRATOR BROWER: No. All registered lindane uses.

THE WITNESS: Of all registered lindane, and there would have only been seed treatment uses--I can't give you an exact number. I don't know off the top of my head, but we were--even though we were one of a number of Registrants, we were probably the only major active player in the market, so we would have had a high market share at that point.

ARBITRATOR BROWER: At that time in July 2006.

THE WITNESS: Right. We would have had a high market share of a small market.

PRESIDENT KAUFMANN-KOHLER: I'd like to go back to the PMRA.

You say in your second Witness Statement that the actions of the PMRA were not motivated by concerns for health and environment, and--but then you also say that Canada has defended the use of lindane in the '98 Aarhus Protocol, but it then decided to sacrifice lindane to induce other countries to discontinue other products, and I have some difficulty understanding what--how you perceived the motivation of the PMRA. I also see the mentions of political pressures in different places. I don't think I have seen this in your own evidence, but there are documents that say so by others.

Why would a regulator consider other aspects, other factors, that has an environmental concern, how do the

10:53 political issues fit in with this more international kind of bargaining, if I understand your evidence? Can you help me with that.

THE WITNESS: Well, I think that the PMRA, like pesticide regulators around the world, is under pressure from a lot of interest groups to effectively regulate pesticides in the country. So, I think there is outside pressures, whether it's from international organizations or domestic organizations.

PRESIDENT KAUFMANN-KOHLER: So, let's just identify the interest groups. There are international organizations that regulate--

THE WITNESS: Correct.

PRESIDENT KAUFMANN-KOHLER: That act like quote-unquote international regulators? They don't have the same powers.

THE WITNESS: Right.

PRESIDENT KAUFMANN-KOHLER: You have, you said, domestic groups.

THE WITNESS: Correct.

PRESIDENT KAUFMANN-KOHLER: What kind of domestic groups?

THE WITNESS: So, there's environmental groups within--within Canada--

PRESIDENT KAUFMANN-KOHLER: Yes.

10:54 THE WITNESS: --that frequently provide pressure. And a lot of times that will be targeted at a specific molecule, where there has been an increased awareness about issues relating to it, and so they may pressure the government.

There are, you know, other--I mean--

PRESIDENT KAUFMANN-KOHLER: Consumers?

THE WITNESS: Consumers may pressure government.

PRESIDENT KAUFMANN-KOHLER: Industry?

THE WITNESS: Industry, trade organizations. I mean, there could be a lot of outside organizations that will pressure them. I mean, it's a--and at times it can be a very high profile.

PRESIDENT KAUFMANN-KOHLER: So, what were the pressures here, as you see them?

THE WITNESS: The pressures here were from the international organizations. There was, you know, through the international agreements that had been signed. There was pressure to not just look at lindane, but lindane uses had been diminishing around the world, and so there was concern.

PRESIDENT KAUFMANN-KOHLER: Could you say that behind these international agreements there were motivations that were health and environmental concerns? I mean, the international agreement does not stand on its own. It has an objective.

THE WITNESS: Right. I mean, there certainly were health concerns and environmental concerns, and by no means do

10:55 I want anyone to have the impression that there are no health concerns or environmental concerns, but any time that there are concerns, anyway, and we associate those with the hazards of a compound, you have to do a risk assessment, and that risk assessment means you need to look at not just the hazard, but you need to look at the exposure involved with the particular application of interest, and also to look at the benefits of the use, and you need to combine all those three.

So, while it may be--you know, you may have a situation where a particular country is banning the use of lindane, and they're banning it because in their particular country they're using it for outdoor application in orchards, that's a significantly different scenario than we have in Canada where we are applying small amounts of lindane to seeds.

So. But, you know, because we have those issues and we have countries that are banning products, it generates a lot of interest and therefore pressure for Canada to do the same, to follow suit. Somebody else is banning it, we should ban it, too, and I think there is a lot of pressure on that.

PRESIDENT KAUFMANN-KOHLER: So, that's one type of pressure.

THE WITNESS: Correct.

PRESIDENT KAUFMANN-KOHLER: What are the others?

THE WITNESS: Well, that's on the international side.

PRESIDENT KAUFMANN-KOHLER: Yes.

10:57 THE WITNESS: You get the same kind of pressure on the domestic side with environmental groups who see other countries banning it, and they want to see Canada follow suit.

PRESIDENT KAUFMANN-KOHLER: I think that answers my questions. Thank you.

No further questions? Yes.

MR. KURELEK: Just an entirely pedantic point. I just want to clarify something. The question that Professor Crawford had, and ask the Court Reporter too, because this is on Page 76, Line 18. I think Professor Crawford said there is a big difference between the 2002 and 2006, the "tone," I think was the word he used because it showed up as "time." And I know you're doing a great job, but so it's clear, it's "tone," not "time" that you are--he's seen the transcript. He's doing a great job.

PRESIDENT KAUFMANN-KOHLER: Fine.

Mr. Thomson, that completes your examination. Thank you very much.

THE WITNESS: Thank you.

(Witness steps down.)

PRESIDENT KAUFMANN-KOHLER: So, now we will take 20 minutes' break, and then we will hear Mr. Kibbee; right? Good.

(Brief recess.)

JOHN KIBBEE, CLAIMANT'S WITNESS, CALLED

PRESIDENT KAUFMANN-KOHLER: Could I ask someone to

11:23 close the door in the back, please.

Mr. Kibbee, good morning.

THE WITNESS: Good morning.

PRESIDENT KAUFMANN-KOHLER: For the record, can you please confirm that you're John Kibbee.

THE WITNESS: Yes, I'm John Kibbee.

PRESIDENT KAUFMANN-KOHLER: You're Regional Technical Manager for seed treatment with Chemtura Canada?

THE WITNESS: Yes, I am.

PRESIDENT KAUFMANN-KOHLER: And before that, you've held positions with Gustafson and Bayer CropScience.

THE WITNESS: Yes.

PRESIDENT KAUFMANN-KOHLER: You have given two Witness Statements in this arbitration?

THE WITNESS: Yes.

PRESIDENT KAUFMANN-KOHLER: You're heard as a witness. You are under a duty to tell us the truth. Can I ask you to confirm this by reading the Witness Declaration that is in front of you.

THE WITNESS: Thank you.

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 against me.

PRESIDENT KAUFMANN-KOHLER: Thank you.

Now, you know how we proceed. You will be asked some

11:24 questions by Claimant's counsel, and then we turn to Respondent's counsel for cross-examination.

THE WITNESS: Okay.

PRESIDENT KAUFMANN-KOHLER: Mr. Somers?

MR. SOMERS: Thank you, Madam Chair.

DIRECT EXAMINATION

BY MR. SOMERS:

Q. Good morning, Mr. Kibbee.

My only question is, do you adopt the statements that you filed in this proceeding as your sworn testimony?

A. Yes, I do.

Q. Thank you.

PRESIDENT KAUFMANN-KOHLER: Mr. Kurelek.

CROSS-EXAMINATION

BY MR. KURELEK:

Q. Good morning, Mr. Kibbee.

A. Good morning.

Q. I'm going to ask you some questions on behalf of Canada, and I would like for you to have in front of you three binders. It looks like you have the first one, which is the witness binder that I've put together for you, but also if I could have--or if you could have a copy of your two Witness Statements in front of you, I think that would be helpful.

A. Thank you.

Q. Yesterday, Mr. Ingulli a number of times deferred to

11:25 your expertise, and so I'm going to tap some of that technical expertise this morning.

I'm going to deal with four issues that I'm going to ask you questions about, and I will signal every time I move to a different issue. The first one is somewhat technical, but I think we went fairly far down the road in trying to understand yesterday what the difference is between three Gaucho products. So I just want to confirm that we're talking about the same thing.

And in particular I'm thinking of the three that are called Gaucho 75ST, Gaucho 480 FL, and then Gaucho CS FL, which is the acronym--or the synonym for that is the all-in-one product. So you understand?

A. Yes.

Q. Okay. So that's where we're headed.

And in particular all three of those Gaucho products contain the same insecticide used to kill flea beetles on canola; is that correct?

A. Correct.

Q. We're talking about imidacloprid, I think it's called?

A. Imidacloprid.

Q. Yes. And.

Now, if you turn to your witness binder, that's mostly what I'll be referring to, I produced a number of documents there that are in the record.

11:26 Just to help you with dates, because the dates are going to be very important for this first issue. And so I just want to confirm the precise dates of what happened with these three Gaucho products.

So, if you turn to Tab 1, I just want to confirm, so the first Gaucho product I'm talking about is Gaucho 75ST.

Now, was that registered in Canada for export in August of 1998?

A. According to this document, yes.

Q. And that registration was made by Uniroyal, which, for the Tribunal's assistance, is Chemtura's predecessor company; is that correct?

A. Correct.

Q. And that 75ST registration was expanded for domestic uses and was approved by the PMRA in July of 1999; is that correct? If you want help with that, it's Tab 2.

A. Correct.

Q. And then if you turn to Tab 3, is it true that the certificate for registration was granted for 75ST for domestic uses in November of 1999? Is that correct?

A. This document confirms that.

Q. Now, I'm turning to the second of those three Gaucho products, 480 FL, which I understand stands for flow? Is that right?

A. Flowable.

11:28 Q. Flowable, as opposed to the dust formations, a liquid formation?

A. Correct.

Q. And these are--if you turn to the documents at Pages 4--at Tabs 4 and five--I think we'll start with 5 actually and go back to 4. I just want to confirm in--no, sorry, start with 4.

In October of 1999, Gaucho 480 FL was registered after being approved in July of that year; is that correct? The July letter is in Tab 5 and the registration document is Tab 4. Gaucho 480 FL.

A. Correct.

Q. And just to clarify again in terms of corporate structure, Gustafson was an equal partnership between Chemtura and Bayer at the time; is that right?

A. Yeah, but if you're referencing this letter, this references Gustafson LLC and not Gustafson Partnership. Gustafson Partnership was a Canadian organization. Gustafson LLC was the U.S. organization--

Q. Okay.

A. --which registration was held by Gustafson LLC.

Q. Okay, but in terms of the bottom line, Gaucho 480 FL was registered in Canada by Gustafson Partnership; is that right?

A. I don't believe so. I think this indicates that it's

registered by Gustafson LLC.

Q. Okay. But Gustafson was acting on behalf of what we now understand is the Claimant in this case, Chemtura, which used to be Crompton; is that right?

A. Gustafson LLC at that point in time was a partner, joint venture between Chemtura--or then Uniroyal--and Bayer, yes.

Q. And if you could turn to Tab 6, the document there, I'm not going to take you into too much detail with the Voluntary Withdrawal Agreement because I understand you weren't very involved in that, but this letter is in reference to that, in part.

And this is a letter from Claire Franklin to Tony Zatylny of the CCC, and they are discussing with reference to the VWA registration of replacement products. And if you look at the second paragraph, she says the following: "The Agency has currently registration submissions on hand for three active ingredients that may emerge as viable alternatives for lindane in canola seed dressing applications."

Then, if you skip down to the third paragraph, she says: "The Agency is cognizant of the trade implication arising from the current divergence in lindane's regulatory status, the U.S. versus Canada, and is interested in addressing this challenge in the most efficient and effective way possible. This will entail priority review of each of the

11:31 three current candidates and continuing to advance only those that have a complete and reviewable submission, with a view to having at least one lindane alternative available for the 2000 crop year."

Now, is it true that Ms. Franklin here is not talking about when she talks about the three current candidates, she's not talking about the three Gaucho products in this case, is she?

A. My impression of this is that she is looking at the larger picture of active ingredients rather than products that are applied to seed.

Q. So, is that a yes?

A. Restate your question, please.

Q. Sure.

Is Ms. Franklin in this letter, when she refers to the three current candidates, she's not referring to the three Gaucho products that we have been discussing, is she?

A. Not per se. The registration of active ingredients would be necessary for the registration of those three products, but they're not the same thing.

Q. Okay, I want to be very clear about this. My understanding is she's not referring to Gaucho--the three current--I'm sorry, the three Gaucho products we are talking about. Here we're talking about 75ST, 480, and CS FL.

Is your understanding the same as mine, which is that

when she says "three current candidates," she's not talking about those three Gaucho products?

A. I agree.

Q. Okay. Again, timing is important here.

If you turn to Tab 7, here is the minutes--

ARBITRATOR CRAWFORD: I'm slightly lost. Could you tell me what she is talking about?

MR. KURELEK: I'm getting to that, in the very next document, actually.

BY MR. KURELEK:

Q. Tab 7, these are minutes from JoAnne Buth of the CCC, and this is from a meeting that took place in June 1999 between the CCC, the PMRA, and the Registrants, and they were discussing the progress on registering replacement products.

Now, if you turn to Page 5--so in my book it's second-to-last page and they're actually numbered at the bottom--at the very top it says PMRA, "would give priority to three submissions as long as they were reviewable (complete) Helix, Gaucho, and Zeneca."

Do you see that there?

A. I see that.

Q. And do you agree that, if you refer to Page 4 on that same document, that although you don't appear to have attended that meeting, there were representatives of both Chemtura and Gustafson at that meeting; is that right?

11:34 A. In consideration Uniroyal was precursor of Chemtura, yes.

Q. Right. And Rick Turner for Gustafson.

A. Correct.

Q. Now, I understand from your testimony that your all-in-one replacement product, the Gaucho CS FL, is the replacement product that you say you were expecting to register through an expedited review; is that right?

A. Could you restate that, please.

Q. Sure.

Maybe I can him you by directing you to your Paragraph 12 of your first Witness Statement, just echoed like Paragraph 9 of your second one.

I just want to confirm that, in your Witness Statements, you talk about the CS FL Gaucho as being the replacement product that Chemtura was expecting to have registered in an expedited manner; is that correct?

A. Yes.

Q. And you Claim that this understanding was shared throughout Chemtura and Gustafson; is that right?

A. To the best of my knowledge, yes.

Q. And then the earlier products of 75ST and 480FL, the ones that didn't have a fungicide attached to it, you indicated in your second Witness Statement, Paragraphs 8 and 9, that these were merely stopgap pesticides; is that correct?

11:35 A. Correct.
Q. And that they--
A. Well, no, that's not the entire purpose. They were stopgap, plus they were intended to establish the use of imidacloprid products on canola, which results in future submissions being simplified because use of imidacloprid is already established on canola. In other words, the worker exposure would have been confirmed as being acceptable for those rates of imidacloprid. The residues in crops grown from treated seed would have already been confirmed as already being acceptable, et cetera, which simplifies future--just submissions that would be just for registration of other formulations that may contain imidacloprid for use in canola.
Q. Just so we can clarify the context in which you used the phrase "stopgap," in Paragraph 9 of your second affidavit, you say, in essence, Gaucho 480 FL and 75ST were stopgap products put into the market while Chemtura was working on its intended competitive product, Gaucho CS FL, in order that the canola growers would at least have something to use to control flea beetles.
So that's the context in which you used the phrase "stopgap"; is that correct?
A. Yes.
Q. Now, you have been talking to PMRA about developing Gaucho CS FL since sometime in 1999; is that right?

11:37 A. I reference to developing the specific product Gaucho CS FL beginning in about 1999, which does not encompass all development work on similar-type products for imidacloprid on canola.

Q. So, I'm now going to take you to an e-mail chain at Tab 8. It's going to take some explaining in terms of who is talking about what because there are certain levels to this.

So, this is the one that at the top of the document, it's Annex R-336, but if you could go to the second page to what is really the first e-mail in this chain, we've got C.P. Yip talking about attending a CCC meeting on June 24th in Winnipeg. The meeting was an update for all stakeholders about the status of lindane replacement products. Registrants PMRA, CCC, and even the North Canola Growers Association was present.

The first key point that he mentions there is Gaucho review with PMRA should be complete in one to two months, so this is, he's writing, in June of 1999.

A. May I correct something there?

Q. Sure.

A. You indicated it was C.P. Yip present, and the author was actually Rob Dupree, the author of that letter.

Q. Sure. Yes. So he's--right. Rob Dupree is writing to C.P.

A. Yes.

Q. You're right. Thank you.

11:38 And then if you turn back to the first page, and I'll take you to three more levels of this e-mail chain. Now, this one is from C.P. Yip, and he says, thanks.

Does this--and when we are talking about "this," I think he's referring to the first e-mail we just read--"Does this mean this is there no need to remind Franklin"--that would be PMRA's Claire Franklin--"about voluntary production cessation by December end 1999 in event of all conditions satisfied per our letter agreement."

Do you see that?

A. I see that.

Q. Okay. And then moving one level up again--this is Mr. Ingulli--"My interpretation of the cc mail"--again the Rob Dupree, the first one--"which follows is that Gaucho will be registered for canola before 12-30-99, December 30th, 1999, causing us to proceed with a voluntary cancellation of canola uses for RS. Is that correct?" That's what he says.

A. Can you point that to me again?

Q. Sure.

It's the second level down from the top, so this is--

A. Okay.

Q. Al Ingulli--

A. All right.

Q. --on, it looks like July 13, '99, 4:43 p.m.?

A. Okay.

11:40 Q. And then there is the top one: Al--sorry--Rob Dupree responds, "Al, this is correct. I was contacted by PMRA yesterday, and they informed me the review of the two Gaucho formulations is nearing completion."

Do you see that?

A. Yes.

Q. So, this e-mail exchange occurred in July of 1999, and I guess it started, didn't it, in June, I think? Yes. And this was eight months before your all-in-one Gaucho CS FL was even submitted to the PMRA; is that correct?

A. Correct.

Q. So, is it fair to say that it's the registration of the insecticide-only products--in other words, 75ST and 480--that your colleagues are referring to in this e-mail exchange?

A. Yes.

Q. And what they're saying here is that they are going to proceed with their lindane withdrawal because these products are going to be imminently registered; is that correct?

A. That forms part of the basis for that decision.

Q. I'm not--that's not quite the question I asked.

What I'm asking here is just to confirm what these Chemtura men are talking about here, and my question was that Chemtura--is it not true that Chemtura was going to proceed with the lindane withdrawal because these products, 75ST and

480FL, are going to be imminently registered? And when I say "imminently," I'm going back to the Rob Dupree's comment in the first e-mail about will be complete in one to two months. Is that what they're taking about?

A. I would say that's what they're talking about, but it doesn't cover all other assumptions within the organization about how things will proceed. It doesn't speak to Gaucho CS FL. Obviously, Gaucho CS FL development was in progress, and it was part of the plan for meeting market needs for the lindane withdrawal, and, you know, certainly it would show it's in good faith from PMRA in terms of their setting up groundwork for us to be able to have that registered to meet the entire market needs.

As I said, registration of these products were important in terms of establishing the use of canola--imidacloprid as a seed treatment on canola which should facilitate registration of Gaucho CS FL.

So, taking separately without consideration of other things in the organization, I think, is not appropriate because, you know, we were working on these other products for a reason. This is part of the whole picture, but it's not the entire picture.

Q. And I'm, I guess, leading to the entire picture, but at this point, all I'm asking about is this e-mail exchange, and all I'm asking--and I think I've got the answer. So all

11:43 I'm asking is whether these gentlemen here are talking about Gaucho 75ST and 480 and the imminent registration of that. It seems to me your answer is yes.

A. Yes, that's what they are talking about.

Q. That's right. Because, indeed, the CS FL application wasn't submitted until March 2000--sorry--yeah, March 2000, which was six months after this e-mail exchange; is that correct?

A. It was submitted March--Gaucho CS FL was submitted March 2000, correct.

Q. Now if we go to--

ARBITRATOR CRAWFORD: Before we leave that thought, could you just tell me what the abbreviation RS means in Mr. Ingulli's e-mail?

THE WITNESS: I can answer that, if you would like.

RS, our lindane contribution was Vitavax RS Flowable often referred to internally as "RS."

BY MR. KURELEK:

Q. If you turn to Tab 10, please. No, sorry, I'm jumping ahead here. Tab 9. This is a letter from Mr. Ingulli to Claire Franklin of the PMRA. This is the first in another series of letters on the same topic. Start with this one, where Mr. Ingulli wrote to the PMRA, and this is October of 1999, two-and-a-half months after the e-mail exchange we were just talking about. He's going to place conditions on the

voluntary withdrawal.

And condition number two, so this is at Page 2, point number two, he says: "Chemtura will only withdraw their lindane registrations if PMRA is granted a full or permanent registration of the imidacloprid insecticides-based formulations, Gaucho 75ST and Gaucho 480, for use on canola for planting in Canada at least three months prior to the expiration of their temporary registration by December 31, 2000."

Do you see that there?

A. Yes.

Q. And is it clear that Mr. Ingulli in this letter is talking about Gaucho 75ST and 480 and not Gaucho CS FL?

A. Correct.

Q. Feel free to take some time to read the whole letter, but is there any mention in that letter at all about CS FL, the all-in-one formulation?

(Witness reviews document.)

A. I agree there was no reference to it.

Q. If you could turn to Tab 10, please. This is the second letter in this chain. This is Claire Franklin's response to Mr. Ingulli. This is October 21, '99. If you go down to the bottom of that page, the last sentence, the first half of that last sentence, starting with "In addition, with respect to PMRA's commitment to facilitate access to

replacement products, Gaucho was registered for use in Canada in July, as a result of a priority review."

Now, would you agree with me that Ms. Franklin in this letter is referring, although she doesn't state it as Gaucho 480 and 75ST, would you agree with me that those are the Gaucho products she's referring to here and not CS FL?

A. I haven't seen this document before.

Q. Spend some time with it, if you want.

A. Sure.

Or not recently, I should say.

(Witness reviews document.)

A. Okay. Repeat your question, please.

Q. Is it true that Ms. Franklin, in this letter, even though she refers generically to Gaucho, that she was referring to Gaucho 75ST and 480FL? Is that correct?

A. Other than in some cases, such as in the previous communication, she referred to Gaucho more in terms of a Gaucho active ingredient usage rather than an end-use product usage. Specifically--let me check something.

(Witness reviews document.)

A. Since she references registered in July, yes, that does conclusively mean that she's referring to Gaucho 75ST and Gaucho 480.

Q. Thank you.

If you could turn to Tab 11, and I apologize for the

quality of this copy. We looked for a best copy, and we couldn't do any better than this but--and it's unfortunate because I'm going to ask you to review the whole thing, looking for an absence, in the sense that this is Mr. Ingulli's response to Ms. Franklin's letter, and feel free to take some time to read it.

Does Mr. Ingulli correct Ms. Franklin's October 21st statement about the commitment to register replacement products in a sense that does she say, oh, no, we're not talking about 480 and 75ST, we're talking about CS FL. Does Mr. Ingulli mention anything about that in this letter? I would like you to take a look at it and answer that question for me, please.

(Witness reviews document.)

A. No, I don't see a correction to that.

Q. Does Mr. Ingulli talk about replacement products at all in this letter, in his conditions there?

A. I don't see a reference.

Q. Okay. Turning to my second topic now, arising out of a different series of events. Let me start here with the document Tab 12 of the witness binder.

This is an e-mail that's internal to your organization dating back to the Fall of 1998, before the CCC even held their big November 24, '98, meeting between the Registrants, itself, and the PMRA to discuss the terms of the VWA.

And here, Mr. Dupree is passing on Bill Hallatt's

notes about a meeting with the PMRA that took place before that big November 24, '98, meeting. This is dated--it looks like October 20, '98, so about a month before. And you will see at the top there, this is Rob Dupree, and he's passing on, it says "Bill's summary" near the top there, and if I could take you to the bottom two small paragraphs in that document, where Bill--sorry, Mr. Hallatt is saying here, "I told Wendy," and that would be Wendy Sexsmith, "that we would not agree to a voluntary withdrawal at this time for the following reasons: A, there is no equivalent timeline as to when new replacement products would be registered, i.e., Gaucho or Helix."

Do you see that?

A. I see that.

Q. Now, I want to turn back to an earlier document that's related to this. This is in Tab 7--we have already looked at this. We are going to look at a different page. This is Page 4 of this Tab 7 document. Again, it's JoAnne Buth's lindane meeting minutes for the June 24th, 1999, meeting.

And in that--in those minutes, you see on Page 4, replacement products update. You see somebody from IPCO in attendance, somebody from Gustafson, someone from Uniroyal. They don't mention a name for Zeneca, but for Novartis we have Judy Shaw, and underneath that we have Helix. So, again this is under the heading: Replacement Products Update.

Now, Mr. Turner and Mr. Dupree from your organization

were at this meeting. Is there any indication in these minutes--and feel free again to take a look through them--is there any indication in these minutes that either of them protested the inclusion of Helix in the list of discussed replacement products?

(Witness reviews document.)

A. I don't find a reference.

Q. To the best of your knowledge, after this meeting, did anyone in Chemtura follow up with letters to the PMRA to register their complaint that Helix was being included as a replacement product?

A. I'm not aware of any, but with my involvement at the time, I wouldn't be aware of any.

Q. I ask you the same question now with respect to any complaints that might have been registered with either the CCC or the CCGA on the same topic, saying, what's Helix doing here in the topic of replacement products? Was there any complaint by Chemtura about that?

A. I would give the same answer: I'm not aware of it, but I wouldn't necessarily be aware of it.

Q. So, I would like to turn to you Paragraph 28 of your first Witness Statement. Page 8, I believe.

A. Seven.

You have a question?

Q. Yeah, one moment.

11:55 (Pause.)

My mistake. I was looking at the wrong witness statement.

So, yes, it's Witness Statement number one, Paragraph 28, and there you say: Helix couldn't be considered as qualifying as a replacement product as that term was used in the lindane withdrawal process because Novartis, the submitter of Helix, did not have a lindane product registered and therefore did not benefit from any commitments arising out of that process.

And yet, isn't it true from what we just looked at in terms of the letters in the e-mail chain that, while this process was being developed and implemented, your colleagues at Chemtura were referring to Helix as a replacement product and did not protest the inclusion of that reference in items such as the minutes we just referred to at Tab 7? Is that correct?

A. I do see the contradiction there.

Q. I would like to turn to my third topic.

How many years have you been working in the crop protection business, Mr. Kibbee? Approximately.

A. Let me add it up. It's been a few stints.

Sixteen years.

Q. Do you have a rough idea of how many applications you've made to the PMRA for pesticides? Just a rough idea.

A. I don't personally make the applications. I was never

11:57 the person making the applications but, rather, the manager of the person making the applications. My experience in that goes back to from about late 1999, I believe, with Gustafson when I became the registration manager, so I don't have--I have made submissions myself.

Q. But you've been associated with those submissions; is that right?

A. Yes.

Q. So is it accurate to say that you're fairly familiar with the PMRA's registration process?

A. Fairly familiar.

Q. And are you also familiar with the PMRA's management of submission policies? Some people refer to it M-O-S-P, or MOSP?

A. I'm familiar with parts of it but not its entirety. I don't consider myself an expert on it.

Q. Okay. Well, it's fairly short. If you turn to tab 13 of the witness binder. I see there is a copy of it there, dated June 7, 1996.

And I believe, correct me if I'm wrong, but I think that you attached this as an exhibit to your first Affidavit at Exhibit D-2. Am I correct in that?

A. I would have to check my--

Q. I think you have your Affidavit in front of you there. You should, anyway. Look at D-2. I think it's attached.

11:59 A. Correct.

Q. If you turn to--back to the witness binder, turn to Page 4, the second full paragraph: If major deficiencies are identified during one or more of the review streams of Category A, B, and C submissions at any time during the review, the review--sorry, the review of all streams stops.

Were you familiar with that policy at the time that you affirmed your first Witness Statement?

A. Yes.

Q. If you could turn to Tab 14, you've got an e-mail here from PMRA. This is dated October 13th, 1999, and this is with respect to the anticipated receipt of the Gaucho CS FL application, and this seems to me--correct me if I'm wrong, but this is the PMRA notifying Chemtura of the list of data that the PMRA wanted--or sorry, Gustafson, that the list of data that the PMRA wanted Gustafson to submit along with the Gaucho CS FL application; is that correct?

A. That appears to be what it is.

Q. So, my next question is: When Gustafson submitted its application for the all-in-one CS FL product on March 21, 2000, did it include in that package all of the data that is outlined in this October 13th, 99, e-mail?

A. I have reviewed that recently. As I'm sure you're aware, you could meet these data requirements either through--by submitting existing data, submitting new data, or

12:01 submitting a waiver or scientific rationale as to why it's not required. In reviewing the response from PMRA on our submission it did indicate it that we had submitted either one of those three options for each, and each of these required data elements, except for one exception, which I'll go into. And if you review the records on that, I think you will find that in the review all the required data elements were met. The conditional requirements were not necessarily met, but there are conditional requirements and may or may not apply to a given submission.

There was one that is listed as a requirement, specifically 10.2.3.4, which is efficacy operational trials. It is not, although it's listed as a requirement, it's not something that is submitted for seed treatment use. And there was no deficiency noted as a result of that, not including anything relative to that data element.

So, yes, you know, I consider things like we understand that we didn't submit acute toxicity studies, but we submitted a waiver on the basis of the--being a lindane replacement product, this is equivalent to Vitavax RS Dynaseal. We have taken it, lindane, we've replaced it with imidacloprid, and it's a reasonable scientific assumption. I don't know how much detail was given on that. I don't recall. I don't have the records to that, but that's the gist of what our argument would have been.

12:02 Q. Okay. That's a very detailed answer, and thank you for that detail. I'm going to break it down a bit.

My original question was whether, in March of 2000, March 21, 2000, when Gustafson sent in its application to PMRA for CS FL, my question was, did it include all of the data that was set out in this October 13, 1999, e-mail, recognizing, of course, there are some CRs and Rs, in other words, "requires" and "conditionally requires." But my question was: Was the data package complete when Chemtura--Gustafson submitted its application for CS FL? Yes or no.

A. That's what my answer was intended to convey. My position is that, yes, the submission included all that is required for as specified in here, because it's not just data that you can submit. You can submit reference to previously submitted data or you can submit scientific rationales.

Q. So, your answer is yes; is that right?

A. Yes, except for the one exemption for the efficacy operational studies.

Q. Okay. And did the PMRA agree with you? Did they view your--the Chemtura--the Gustafson application as complete?

A. I don't know what terminology they used. I do understand they didn't accept our rationales for not including acute toxicity and product chemistry. I appreciate that. We submitted on the basis that it would be treated similarly to Vitavax RS Fungicide, which was our understanding at the time

12:04 where we did not include product chemistry or Vitavax R--or acute toxicity, and it was accepted and approved on that basis. I understand there is a difference in opinion on what constitutes a replacement product. We recognize that this is a serious matter before the Tribunal here, and I really don't have an answer to that.

Q. Well, let me perhaps be of assistance here. If you turn to the letter at Tab 15, this is a letter from PMRA to Adam Vaughan of Gustafson, who seems to be a Registration Specialist. And you will find in the second paragraph, he says: "This submission"--the re-line tells us Gaucho CS Flowable--"This submission has been screened for equality, format, and completeness according to criteria established for Category B.2.6 New Combination of Actives found in Attachment 1, and was determined to be deficient. A list of screening deficiencies is contained in Attachment 2," and you will see that attached to that letter.

So, is it your understanding from that letter--take a while to read it if you want, you're the--as Mr. Ingulli says--the technical expert. Is it your understanding that the PMRA viewed Chemtura's original submission as deficient, slightly deficient, in data?

A. I will read it first.

(Witness reviews document.)

A. I do find reference to it being deficient, but not

12:06 incomplete.

Q. I will take you back to the document, the MOSP document, Tab 13, Page 4, which reminds us that "if major deficiencies are identified during one or more of the review streams of Category A, B, and C submissions at any time during the review, the review of all streams stops."

Do you see that?

A. Yes.

Q. I am going to take you to a document at Tab 17 now, and again I apologize for the quality of the top of the document, but this is a fax from PMRA again to Adam Vaughan of Gustafson?

A. Which tab again? Sorry.

Q. Seventeen.

A. Okay.

Q. And really it's the second page that matters here.

What the PMRA is seeking here is some additional studies again with respect to the flowable GS--sorry, CS FL product. This time they want some honeybee studies.

Do you see that in Tab 17?

A. Correct.

Q. And Tab 18 indicates that, boom, right away, next day, they got it. It looks like Gustafson must have had it on hand, because they--again this is probably the worst copy, but looks like very next day, April 24, 2001, those honeybee studies were

12:08 submitted.

Do you see that?

A. Yes.

Q. And again it's very hard to read top left corner, but it looks like it's April 24, 2001.

Now, is it true that that is more than a year after the Gustafson first submitted its CS FL application?

A. Yes.

PRESIDENT KAUFMANN-KOHLER: Now, if I could turn you to your first Witness Statement, let's see if I get it right this time, Paragraph 16, you make the following comments, or, should I say, complaint: "We anticipated approval"--this is of CS FL--"We anticipated approval within three months."

And then at Paragraph 22, two pages on, I don't recall any significant issues with the submission that would account for such delays or even any delays.

Do you see that?

THE WITNESS: Correct.

Q. Is that still your evidence today?

A. I would be happy to correct that statement. I did do my initial submission without the benefit of access to all the documentation and the communications between PMRA and Gustafson at the time. We had told Gustafson to Bayer CropScience and to a large extent I was relying on memory. I do appreciate that, in consideration of the submission of product chemistry and

12:10 acute toxicity later on in the process, that does account for some degree of delay in the submission. I would not agree that the information in Paragraph 17 in any way constitutes a delay in the submission, because, first of all, I don't see it as part of deficiencies in the earlier submission, and I really don't understand the reason why it was requested other than perhaps it was I new issue.

And in addition to that, in the Managements of Submission Policy in Tab 13, top of Page 4, refers to specifically this type of Request for Information: "During the review, evaluators may request clarification on minor points on submitted data. This is done by facsimile. Clarifications do not contain requests for new data elements. To facilitate clarification is recommended that the Applicant identify appropriate contact person for"--blah, blah, blah--"the Applicant has 10 days to respond to this request. The review continues during this time."

Q. I just want to go back to the first part of your answer there. And this goes to the letter at Tab 15. Are you suggesting--are you saying that you disagree with the letter from Sean Mira (ph.) that, in fact, it wasn't a Deficiency Letter? Is that what your evidence is?

A. Oh, no.

Q. That's what it sounded like to me. So, you're not saying that?

12:11 A. No, I'm not saying it's not a Deficiency Letter. I'm saying it's not an--

Q. Okay.

A. Incomplete submission.

Q. Sorry, could you repeat that last part?

A. I'm not saying that it's evidence that it was an--what tab is it again?

Q. 15, second photograph.

A. Yes, I'm saying it's a Deficiency Letter. It has been previously indicated that we had an incomplete submission that--in PMRA testimonial. I don't feel that this justifies that statement. As most submissions have, there were deficiencies within the submission, and these were identified and addressed.

Q. Thank you.

Moving on to my fourth and final topic which actually comes in two parts. Now we are going to look at comparison of your own registration of Gaucho CS FL, the all-in-one product we were just talking about, and the registration of Helix.

You talked about Helix registration in your Affidavits, and you suggest that the PMRA gave the registrants Syngenta, the Registrant of Helix, special treatment. So let's take a look at the letter, and this is Tab 19, and this is from Mr. Adam Vaughan again of Gustafson to the PMRA, and it's a request change the Gaucho CS FL submission to address some

12:13 formulation problems.

You know this is very technical stuff here, but in Paragraph 34 of your first Witness Statement, you say that the PMRA strictly prohibits changes to applications mid review.

Is that action, that changing applications mid review, is that what's understood as tailgating, in common parlance?

A. Some types of applications done during mid review are considered tailgating.

Q. Okay. Now, this one on Page 19, if you look at the bottom here, and we are talking about the CS FL, Mr. Vaughan is asking for proposed new label instructions would allow for tank mixing of Gaucho CS FL with Gaucho 480.

Now, at bottom of the letter he says, "We do not wish this tank mix submission to hinder the progress of submission number 2000-0706," which I understand is the original application for CS FL.

Is that correct?

A. I have no recollection of that.

Q. Okay.

A. That wouldn't--I can't say it. I don't know offhand.

Q. And then, in fact, that the very--in the next page, top paragraph, the last sentence of that top paragraph, "If this submission"--I assume the subsequent submission--"could possibly interfere with 2000-0706, we would also be willing to add this tank mix to the label after the completion of

12:15 2000-0706, as an amendment if necessary."

Do you see that there?

A. Yes.

Q. Okay. Now if you could turn to the document at Tab 20, which I understand was also--it's a document that's referenced in several place, but I also understand that you have attached this document to your first Witness Statement. Yes, it's--what are you? You're D--D-7, so it's the same thing, so obviously you're aware of the contents of this document.

If you turn to page, it looks like--well, there is the title page, and then one, two, three, so under the title types of tailgaters under Tab 20.

A. Um-hmm.

Q. It says "amendments to applications under review (formulation, label)."

Based on that PMRA document, would you agree that what Mr. Vaughan is asking for in the Tab 19 letter is what was commonly understood to be "tailgating"?

(Witness reviews document.)

A. I believe it could be.

Q. Are you aware of any documentation that indicates that Gustafson's request for tailgating here was turned down by the PMRA?

A. No, I'm not.

12:17 Q. So, now turning to the second part of the fourth issue that I'm discussing, and this is found at Tab 21 of the witness binder. I understand that in November 1999, about a month after Gustafson received its certificate of registration--and we are jumping back here to Gaucho 480 FL--that a submission was made to amend the registration to add some more pests. As Mr. Somers referred to in his Opening Statement, any time you add even a different application to a particular active ingredient, you have to apply for a registration for that.

And so, is this document at Tab 21, is this Gustafson's application to amend its original Gaucho 480 application to include new uses? If you could look at the first paragraph, it discusses that.

A. Yes.

Q. And if you turn to the last document at Tab 22, is it true that the PMRA granted that request?

A. Yes.

Q. Now, if we could just turn back to the document at Tab 5, this is something we referred to at the very beginning in the innocuous opening talking about the registration of G--sorry, 480 FL. And if you look at the bottom of this page, at the first page, it says, "This temporary registration will be 'time-limited' until December 31, 2000, conditional upon the submission, and acceptable review of PMRA, of residue data," blah, blah, blah.

12:19 Would you agree that the Gaucho 480 FL application received temporary registration from the PMRA? Is that correct?

A. Yes.

Q. If you could go to Paragraph 49 of your first Witness Statement, we will end off here. So, I think this is the last--I believe it's the last paragraph in your first Witness Statement. And there you complain that Syngenta was granted a new use for Helix even when the registration, the Helix registration, was only a temporary one.

Essentially you're complaining there about something that Gustafson itself received, a treatment that Gustafson itself received; is that correct?

A. I'm not sure the same policy would apply. I don't know the answer to that. The addition of new crop or new use site is different than the addition of a new Pest Control Claim, and I don't know that they would have the same restrictions or allowances.

Q. You would agree that the request from Gustafson was to change the use of that product; is that correct? I think your answer to that was already yes but--it's a document at Tab 21.

A. I, you know, that's different than on the use site. It's--yes, agreed, it's for a new use of the product in terms of controlling a particular insect. It's not for a new use site, which is a new crop or new type of application. They are

12:21 different. It's a different use. Terminology.

Q. But, indeed, you agree that the request for the different use was made of a product that had only a temporary registration on it. Is that correct?

A. Yes.

Q. Thank you, Mr. Kibbee. Those are my questions.

PRESIDENT KAUFMANN-KOHLER: Thank you.

Any redirect questions?

MR. SOMERS: Yes, thank you, Madam Chair, just a few.

REDIRECT EXAMINATION

BY MR. SOMERS:

Q. Nearer the outset of your cross-examination by--nearer, sorry--nearer the outset of your cross-examination by Canada, there was a discussion about replacement products, and I just wanted to clarify the industry's and Chemtura's understanding of what that word "replacement" meant in the context of the VWA discussions.

A. My interpretation, which represents Chemtura was that the replacement products were best defined in the November 1998 communication on--from--I don't know that I have a copy of the reference. It's the--

Q. For the Tribunal's reference, it's Exhibit B-12 to the Ingulli Affidavit.

A. Okay.

Q. For your purposes, it's the understanding of the

12:23 definition of replacement product that is important.

A. Okay. So, in that document, it was--there was description of discussing replacement products at a meeting to be held as a follow-up to that initial meeting, and there is four types of replacement products described. One was where products were removed--lindane was removed from existing products; a second where lindane was removed from existing products and replaced with a different insecticide; and two other categories relating to new insecticides. So, for the second category, we felt that several of our products qualified as applicable for that. We had Vitavax RS Dynaseal, which was a combination of active ingredients: Carboxin, thiram, and lindane. And our intent with Gaucho CS FL was basically take the lindane out of that product and replace it with imidacloprid. It was on that basis we developed and submitted for registration Gaucho CS FL.

Does that clarify it?

Q. Yes, it does.

So, as far as Helix was concerned, which of those categories would Helix have fallen into?

A. I believe that, you know, even though reading it we made the assumption that, I guess, that this would apply to people who were giving up their Lindane Products. Technically, that definition--one of those definitions could be applied to Helix. I think it was item C, where there's insecticides used

12:25 in Joint Review.

Q. But wouldn't there have had to have been a predecessor insecticide with lindane removed--

A. I think that's the reasonable assumption.

Q. He would like me to finish my question before you start, that's all. People interrupt me all the time.

Wouldn't there have had to have been lindane removed from an insecticide and replaced with thiamethoxim, to pick a number?

A. That would seem reasonable. Yes.

Q. To be--for it to be a replacement product? Thank you.

A. Right.

Q. According to the definition, as understood by everyone, was Gaucho, whether 75ST or 480, a replacement product?

A. I don't see that in the definitions that could be derived from that document that Gaucho 75ST or Gaucho 480 could be considered a replacement product.

Q. All right. The witness binder that Canada put in front of you is tabbed. Could I ask you to turn to Tab 15, just to do it quickly.

To speed things up, that's a data screening response letter from the Agency. Is that right? I'm talking about a letter addressed--

A. Yes, data screening response.

12:26 Q. All right. Could I have you comment on the date of that letter versus the date that the application was put in.

A. Okay. That was July 27th, 2000. The specific date--the submission was submitted March of 2000. That's about a hundred--it was about 122 days prior to--after the submission before we received this screening letter.

Q. Can you account for--given what the screening letter does or purports to do--can you account for that lapse of time in between the submission and response.

A. I really--you know, there is examples like that in the specific time frames, although they can, you know--there were several things happening. That's particularly stands out as--we had made a small submission for a, you know, stack of paper like of this order of magnitude thick, to get a new formulation submitted. It didn't include product chemistries or acute screening. Only looks at those studies and says, do they fill the requirements of this list? Are all these requirements met in that submission? Do they have something submitted for each of these elements? It's not a review of the methodology in the studies or the quality of the studies, the results or the conclusion. It's just checking off to see are all these elements in here.

So, it's, you know, for 118 days or 122--118 days for the actual screening process, 122 days after the submission, it took them that long to go through this stack of paper and look

12:28 at it relative to this checklist included in Tab 15.

Q. In your experience, would a data screening letter normally return to the Applicant in a faster turnaround?

A. Yes. You can--there is--there is ample statistics on that on and how long it takes to complete screening. That was included--some of that example data was included in my original submission that shows average screening times and target screening times. The target for submissions of that nature would be 45 days.

Q. All right.

A. Performance standard is a better term--that's the term that's used--performance standard for PMRA is 45 days.

Q. Thanks.

Given the data that was filed to obtain the Gaucho insecticide only, the Gaucho 75 and the 480 submissions, and given the data that was filed for the Vitavax fungicide-only formulation, and we understand that Gaucho CS was the combination of those two. Given that, and as the data that was filed to which that data screening letter under Tab 15 that we are looking at was a response, the Gaucho CS submission, could the PMRA have gone ahead and registered the product with the data that was provided without the additional deficiencies that they called for data on?

A. I'm afraid I'd have to see the actual deficiency list in front of me. I don't know what--that it's included in here.

12:30 Q. Under Tab 15. Would that not--

A. It doesn't--it doesn't list the actual deficiencies in here.

Q. At the--later on in the exhibit?

A. Okay. Let me go through it.

(Witness reviews document.)

Okay. There is some very minor corrections to the specification forms, corrections to the--or clarifications on the Confidential Statement of Ingredients. It does state that mustard is not an approved crop for the control of disease, seed rot, damping off, seedling blight and early season root--sorry.

It does say that mustard is not an approved crop for the control of seed rot, damping off, seedling blight and early season root rot. Our response to that one was that you're incorrect in that particular deficiency, and it's already been established through the registration of other products that these indeed are normal uses for carboxin, thiram, and imidacloprid, so that was erroneous on their part. So that's not a limitation.

We did include some pests on there which they found we didn't have sufficient data to support our--if it had been matter of accepting the registration at that point, we would have removed those from our label rather than generate new data, so that would not be a limitation.

12:32 Minor corrections to some other documentation, minor clarification of efficacy trials. I don't see deficiencies in that that couldn't be addressed quickly.

Q. In some order of magnitude of?

A. A month?

MR. SOMERS: That ends my redirect. Thank you, Madam Chair.

Thanks, Mr. Kibbee.

PRESIDENT KAUFMANN-KOHLER: Judge Brower, do you have any questions?

QUESTIONS FROM THE TRIBUNAL

ARBITRATOR BROWER: Directing your attention to Tab 7 of the witness binder before you, Page 4.

THE WITNESS: Tab 7?

ARBITRATOR BROWER: Yes.

THE WITNESS: Okay.

ARBITRATOR BROWER: In middle of the page, heading Uniroyal-Rob Dupree. Do you see where I am?

THE WITNESS: Yes.

ARBITRATOR BROWER: Right.

There is a reference to Gaucho. Do you have an understanding as to which Gaucho or Gauchos are meant?

THE WITNESS: I would generally say given that the situation at the time that would refer to Gaucho 480 FL.

ARBITRATOR BROWER: Okay.

12:35 That was my only question.

PRESIDENT KAUFMANN-KOHLER: Thank you.

ARBITRATOR CRAWFORD: No questions.

PRESIDENT KAUFMANN-KOHLER: Mr. Kibbee, in your second Witness Statement, you set out that, referring to Paragraph 14, it was apparent that the PMRA had additional political motivation to ban lindane-based product and register Helix in their place with a new Joint Review process. Then you explained that the PMRA was ready to allocate resources for an expedited review of Helix and also to accommodate the occupational exposure issues with respect to Helix, and if I read you correctly, that you--your perception is that there was discrimination between the two processes, Gaucho CS FL and Helix.

Is that a correct understanding?

THE WITNESS: That's correct.

PRESIDENT KAUFMANN-KOHLER: Now, what do you think would the PMRA's reasons be for favoring Helix and--to the detriment of Gaucho?

THE WITNESS: I think it would be speculative of me. We didn't have a good relationship with them. I mean, that's clear. They did seem to be very--the relationship between PMRA and Syngenta seemed to be much, much closer communication and dialogue and collaboration than with Chemtura.

What causes that? You know, are they impressed with

12:37 their--you know--their very large and very successful company, that they have the top--top scientists, you know. They have a lot of resources available. They're bringing a means to help them remove lindane from the market.

I mean, there is lots of speculation I could make. I don't know that it's--

PRESIDENT KAUFMANN-KOHLER: But Gaucho helps remove lindane from the market as well, so that cannot be the reason--

THE WITNESS: Well, okay. I will give you an example what really doesn't make sense, absolutely doesn't make sense. We talked about the 118 days for just screening this small, very small, submission. It's not like the Helix submission, which is the most complicated and biggest Category A submission you could make which I don't--I'm not sure could even fit in your average passenger van. It's like a huge submission, and we have this little stack of paper. So we submitted in March of 2000.

Well, the Helix, the initial Helix submission was review was completed in January of 2000. They had to withdraw--their submissions were withdrawn or rejected based on--the first submission was withdrawn or rejected.

So, we put our submission in for Gaucho CS FL, with which we explained the reasoning for it, we explained the importance. It's better for worker exposure, and we needed to get this simple submission approved.

12:38 So, it took them 118 days, or to do the Level B screening, which is enormously long for such a tiny submission. It's not that they were prioritized on Helix because Helix wasn't even in the process. Why--Helix was in the process of conducting a new worker exposure study to determine one way or the other whether or not they could be a lindane replacement product.

So, at that point in time, PMRA didn't even know that they had a viable alternative to lindane because Helix wasn't yet approved, and, you know, so, the other choice was to have the appropriate Gaucho CS FL product approved, and yet, still, instead of putting some priorities to that submission, they gave it an enormously long time frame just for the screening process. I just don't--you know, looking at the whole picture and looking at the consistent--we get these incredibly extended time frames for our simple submission, like 118 days. Like there was a Deficiency Letter in February of '01, where they sent us a Deficiency Letter, and we reminded them, okay, this isn't a deficiency. We already corrected that deficiency in September of '00, and so you know, we responded the next day. And following that, it goes back to the start of the lineup. They go through the preliminary screening again. They go through another relatively long Level C review taking another 70 days. It just doesn't make sense, that, you know, how could that happen? How could that, you know, with any consideration

12:40 of what we had given up for lindane product and, you know, the need for--to assure that there is the right products available for them to replace lindane for the upcoming ban. I don't know why it wouldn't have received priority. I just don't have an explanation. I don't know why it was in the Level C and D review process for 534 days when there was nothing exceptional about the content that would make it difficult. These were simple, like our submissions, like a product chemistry, that's like a cookie-cutter type of Report. Acute toxicity, I mean, you do that in every formulation that there's, you know--you have professionals do it, this standard type of Report, and it's not entirely complicated. So, we see all those extremely extended time frames.

And then I look at it, and I apologize that this isn't all laid out in my Affidavit. As I said, I didn't have the--all the documentation on the correspondence between PMRA and Gustafson, because we had told off for Gustafson business. But having had a chance to review all of--particularly Suzanne Chalifour's exhibits, I have a better understanding of everything that transpired, and there is things like, you know, when we submit something and say, okay, consider this if it doesn't extend the length of a review. And then they come back and say, well, the length of the review is your fault because you submitted stuff when--when they give us--some of the delays were due to deficiencies that they pointed out such as these

12:42 fungicides have never been used on mustard before. Well, indeed they had. We told you that. You don't have enough efficacy data to justify the high rate of fungicide. No, well, we--no, we dealt with that in September '00. We had to go back and explain those things to them.

So, it's all those sorts of things that, in order to really understand, it's important that you go through all the exhibits, particularly the Suzanne Chalifour's, and look at the actual review process and do that in consultation with somebody who really understands the review process to see if they're astounded at both the length of time for the Gaucho CS FL, as I am, and the brevity of the review for the Helix. Like Helix--I did an estimate in my first Affidavit that estimated something like the nominal timeline for the Helix review would have been 1449 days. That was a conservative estimate. With the actual information I now have from Suzanne Chalifour's, if you apply the normal time frames, it would be even higher than that. There is real, serious, unusual practices in those documents showing, for example, for Helix, there is two back-to-back Level D reviews, without having to go back to Level B and C for screening. That's, to my knowledge--that's unheard of. In the second submission, there is like a one day screening process--a zero day screening process, a four day Level C review, you know, and these are huge submissions. It adds up to, man, this is just not a world that I live in when I'm doing any of my

registrations at any time. It's--you know, I never--I can't believe that they could have went through that much information in the review time they did. It's just basically incomprehensible. And I did, for example, said in my first statement, it's not possible that they withdrew their submission and resubmitted it, because it would have been so astronomical that the time--you know, the timeline would have been so astronomical that it was--I just couldn't comprehend it, that it would have got approved when it did.

So...

PRESIDENT KAUFMANN-KOHLER: Thank you.

No other questions or follow-up? No? Then we can close out your examination now, Mr. Kibbee. Thank you for your explanations.

THE WITNESS: Thank you.

(Witness steps down.)

PRESIDENT KAUFMANN-KOHLER: And we can take a break for lunch of an hour, and we then we hear as next witness Mr. Johnson, right, absolutely. Good. Have a good lunch.

(Whereupon, at 12:44 p.m., the hearing was adjourned until 1:45 p.m., the same day.)

AFTERNOON SESSION

PRESIDENT KAUFMANN-KOHLER: Fine. I see everyone is ready.

Good afternoon, Mr. Johnson.

EDWIN JOHNSON, CLAIMANT'S WITNESS, CALLED

THE WITNESS: Good afternoon.

PRESIDENT KAUFMANN-KOHLER: For the record, can you please confirm that you're Edwin Johnson. Your microphone is not on.

THE WITNESS: Yes, I am Edwin L. Johnson.

PRESIDENT KAUFMANN-KOHLER: You're a senior consultant on global environmental regulatory issues at Technology Sciences Group, or TSG.

THE WITNESS: That's correct.

PRESIDENT KAUFMANN-KOHLER: And you have been with TSG since '92, and before that you worked with the EPA and its predecessor Agency.

THE WITNESS: Yes, that's correct.

PRESIDENT KAUFMANN-KOHLER: You have given two Witness Statements in this arbitration?

THE WITNESS: Yes, I have.

PRESIDENT KAUFMANN-KOHLER: You're heard as a witness today, and you are under duty to tell us the truth. Can you please confirm this by reading the Witness Declaration that is in front of you, please.

THE WITNESS: I am 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.

Now we will turn to Claimant's counsel for some direct questions, and then Respondent for cross-examination.

MR. SOMERS: Thank you, Madam Chair. Before I begin, just an observation and the Tribunal's indulgence. The witness is under some physical discomfort resulting from an injury, and is assisted from time to time by being able to stand up. And so if that happens, no one need take alarm, but I have invited the witness to do so as the need arises during the course of his cross.

THE WITNESS: My doctor misled me. He said if I took the pills he gave me, by yesterday I would be back to normal, but I'm as bad as I was last week.

PRESIDENT KAUFMANN-KOHLER: I'm sorry to hear that, but obviously you stand up whenever and you move whenever you feel the need to.

THE WITNESS: Thank you.

ARBITRATOR BROWER: Just take the microphone with you.

DIRECT EXAMINATION

BY MR. SOMERS:

Q. My only question to you, Mr. Johnson, is do you adopt the statements and swear them as true in the statements that

you filed in this proceeding.

THE WITNESS: Yes, they are.

PRESIDENT KAUFMANN-KOHLER: Thank you.

MR. LUZ: Good afternoon, Madam Chair, Judge Brower, Professor Crawford.

CROSS-EXAMINATION

BY MR. LUZ:

Q. Mr. Johnson, good afternoon. My name is Mark Luz. I'm counsel for Government of Canada, and I will have some questions for you today, as I'm sure you expected.

Before we start, I just wanted to make sure that you have with you copies of your two Witness Statements.

A. Yes, I do.

Q. And available to you also some of the volumes of the hearing bundle that contain documents that I will be referring to. Just access, and I'm sure they will be handed to you at some point, but do you--have distributed to the Tribunal and to everyone a list of documents that I plan on referring to. And if there are any others that come up that I don't plan on, then we will find them.

A. Okay.

Q. Just one other administrative note. We discovered that some of the copies of the EPA RED and the EPA HCH study that are in the joint hearing bundle are missing some pages. So, I think out of convenience for everyone and for the

Tribunal, since they were looking at those two documents this morning in Mr. Thomson's hearing bundle, you can just refer to those versions of it, so we won't be missing pages, and you will--we will make sure that you have the copies with all the pages that you need to refer to.

A. Thank you.

Q. Okay, great.

I'd first like to discuss your relationship to the Claimant Chemtura and the role that you played with respect to the United States Environmental Protection Agency or EPA. You said in your Witness Statement and you reaffirmed this morning that since you joined TSG, you have been advising clients on dealings with the EPA; is that right?

A. That's correct.

Q. And some of your clients are in the agrochemical sector; is that right?

A. Yes.

Q. And some of your clients include producers of lindane, such as Chemtura and others such as Inquinosa?

A. That's correct.

Q. And one of your tasks was representing the Claimant in this case before the EPA during the time of the events that are in dispute here; is that right?

A. Yes. I was one of the TSG employees that did that. Bob Stewart was another. It would depend on what the issue

was.

Q. Okay. And Bob Stewart is also at TSG?

A. Yes, he is.

Q. And what's his position there?

A. Managing Director and Director of the Pesticide Division.

Q. Okay. And so, you represented Chemtura before the EPA in its pursuit of a tolerance and registration for lindane use on canola?

A. Yes.

Q. And as part of that role, you assisted Chemtura in determining what types of data the EPA was seeking for those tolerances?

A. To some degree. We were sort of the liaison between Chemtura and the EPA, but on the data side they did much of their own work through their regulatory staff and their scientific staff and worked directly with EPA on many of those issues, so it wasn't a unilateral role that I had. It was a supportive role, I would say.

Q. Okay. So, you were liaising, as necessary, between Chemtura and the EPA?

A. Yes.

Q. And you were referring information back from the EPA to Chemtura as that need arose?

A. Yes. The extent that it was communicated through me.

In some cases it was communicated directly to Chemtura through the regular staff.

Q. Okay. And TSG is compensated for its services to Chemtura for providing this type of liaison?

A. Yes, it is.

Q. So, I'd like to discuss your role with respect to petitioning the EPA for a canola tolerance starting in 1999.

First, let's deal with some background information. In 1999, there was no tolerance for lindane use on canola in the United States; is that right?

A. Yes, that's correct.

Q. And in 1999, lindane was not registered for use on canola in the United States either; is that right?

A. Yes, that's correct.

Q. Okay. Just, if I could direct you to your first Witness Statement, Paragraph 18, so we get an understanding of registration and tolerance, right at Paragraph 18. I will read it out, and then you can just confirm what you have written here is correct. "In the case of a lindane-treated seed imported from Canada to be planted in the U.S., both a registration and a tolerance would be required: The registration to allow importation of the treated seed and the tolerance to cover maximum residues in the seeds, meal, and oil obtained from the crop grown from that treated seed. Canola seed imported into the U.S. for crushing requires a tolerance,

and canola grown from treated seed and processed into meal and oil in Canada requires a tolerance to cover the meal and oil that may be imported into the U.S."

Is that right?

A. Yes, that's correct.

Q. So, essentially, there was--in order to import seed, lindane-treated canola seed from Canada, both a registration and tolerance would be required?

A. Yes. The registration would have to be for the treated seed or the use of lindane to treat seeds, and the tolerance would be there to cover the crops that were grown from that treated seed. There didn't need to be a tolerance on the treated seed itself, but on the crops that were grown from it.

Q. Okay. Great.

Now, just below that, you talk about how in 1999, June 1999, TSG filed a petition for a tolerance for lindane residues on canola seed, canola meal, and canola oil with the EPA. That was on behalf of Inquinosa?

A. Yes, on behalf of another company.

Q. Okay. But as you note in Footnote 5 of your Witness Statement, a tolerance obtained by one company, since it was referable to lindane, would apply to all, including Crompton?

A. Yes. That's correct. Tolerance is not peculiar to a particular company as a registration is. It's generic. Once

it's established, it covers anybody who grows crops with that residue.

Q. Okay. So, in June 1999, the EPA had a petition for a canola tolerance before it?

A. That's correct.

Q. Okay. Did the EPA grant the requested canola tolerance in 1999?

A. Not at that time. They did what they called front end screening to make sure it was the complete application, and it was accepted for review, but it got tied in with the registration eligibility decision process, and EPA said they're not going to issue any additional tolerances or registrations for Lindane Products until they resolved the registration eligibility document. Decision, excuse me.

Q. Right. You're right about this at Paragraph 21 of your Witness Statement, saying that the EPA was, as you said, in the midst of a risk assessment for lindane in general; is that right?

A. I'm sorry, could you repeat that?

Q. At Paragraph 21, what you just were talking about, the application for canola tolerance got tied in with the re-registration process at the EPA. That's right?

A. Yes, that's correct.

Q. Okay. And you also say at Paragraph 21 that TSG wrote to the EPA asking for or urging a decision by spring 2001 so

that Lindane Products could be formulated and distributed in time for canola planting season in Canada; is that right?

A. Yes, that's correct.

Q. Okay. Well, let's look at that letter. It is at Tab 173, the hearing bundle which is Volume 5, and I also note for the record that this is Dr. Goldman's second Witness Statement, Exhibit 24, just so we all know multiple references.

Do you have it in front of you?

A. Yes, I do.

Q. Okay. So, this is the letter that you wrote to the EPA you are referring to in your Witness Statement?

A. That's correct.

Q. You wrote this letter in February 2001?

A. That's correct.

Q. And the letter asked the EPA to issue a canola tolerance as quickly as possible by spring 2001?

A. Yes.

Q. And you say in your Witness Statement that the EPA responded, and if I could take you back to your Witness Statement, Paragraph 121, and you have the quotation there from the EPA's response, "Canola seed treatment use will be included in the RED process..."We must include all uses in the RED process and must evaluate aggregate risk to reach our regulatory decision for lindane. While our decision need not wait until the RED is issued, we must finalize the risk

assessment." And then there is the rest of the paragraph.

So, that was the EPA's response?

A. That's a portion of the letter that came back. I would say that's one of the salient points that had been made to us.

Q. Okay. There might be another salient point where the ellipses are in the quote, so let's take a look at the actual letter that the EPA wrote. It's at Tab 180 of the same volume that in front of you.

And for the record, this is also at Dr. Goldman's Second Report, Exhibit 25. So, this is the letter that the EPA wrote back in response to your request to accelerate the canola tolerance; is that right?

A. Yes, that's correct.

Q. Okay. Well, let's take a look at where the language is from your Witness Statement where the ellipses were. You started off with the canola--it's in the middle of the second paragraph on that page, and you started your quote with, "The canola seed treatment use will be included in the RED process," and then there is the ellipses there in your Witness Statement, but the sentence that's in the letter that wasn't in your Witness Statement says, "Unfortunately, until the Agency has completed a comprehensive risk assessment for lindane, we will not be able to make a decision on your client's petition."

So, this is saying--the EPA is saying that there will

be no decision on the canola tolerance until it's completed a comprehensive risk assessment for lindane; is that right?

A. Yes, I believe that was part of my answer a few questions ago, that they told us that they needed to do the registration review, and they would include canola in it, but they had to finish the risk assessment. They said they didn't have to actually issue the RED, but they needed to do the risk calculations before they could take any action on canola.

Q. But here they're saying that there won't be a decision on a canola tolerance until it's completed a comprehensive risk assessment; is that right?

A. Yes, that's the analysis that goes into a RED.

Q. Okay. And just so I get the math right, this response from the EPA came almost two years after the June 1999 petition for canola tolerance was submitted?

A. Correct.

Q. Okay. Well, let's talk about the RED, and that I note again is at Tab 7 of the Thomson binder. If you could make sure that Mr. Johnson has it, and the Tribunal will return to it. I apologize that the version in the hearing bundle is missing some pages.

Do you have it in front of you?

A. Yes, I do.

Q. Great.

So, the EPA released the RED in July 2002; is that

right?

A. Correct.

Q. So, that's three years after the original canola tolerance petition was submitted; is that right?

A. Yes.

Q. Did the RED grant a tolerance for lindane use on canola?

A. No. The RED provided a calculation of what the risks were, the dietary and other occupational and so forth, which included canola, but they did not actually issue the tolerances.

Q. Okay. And did they issue a registration for lindane use on canola?

A. No, they didn't.

Q. Okay.

A. I should explain the process a little bit.

Q. Sure, go ahead.

A. When a RED is completed for uses that are already registered by EPA, they are already registered, and that goes through one place where they correct the labels and make changes that need to be--to mitigate things. Because canola was new, it would have gone through a different part of the EPA. It would have gone through the registration division as a stand-alone entity by using the risk assessments that were done in the RED.

Q. Okay. So, canola was a new use, so it needed a new tolerance and a new registration?

A. Correct.

Q. Okay, great.

Let's turn to Page--it's Roman numeral nine of the RED, ix, and I'm looking at the last full paragraph on that page, on the one that starts, "EPA notes that the establishment of new tolerances."

Do you see that?

A. Yes, I do.

Q. Okay, great. I'll just read it into the record. "EPA notes that the establishment of new tolerances for the seed treatment uses of lindane is conditioned on, one, the receipt and review of additional data to characterize lindane metabolites; and, two, EPA's ability to make a determination that establishing the new tolerances meets the safety standard in FFDCA. Because EPA does not know what the data will indicate about lindane metabolites and for other reasons, EPA is unable to determine whether it will be able to make a determination that new tolerances for lindane would be safe."

So, just to confirm what this says, here in July 2002, the EPA was not able to determine whether it could issue a new tolerance for canola?

A. Well, actually, that sentence pretty much applies to all of the uses that were registered--were eligible, because in

the old days they didn't set tolerances for the crop that grew from treated plants, and so therefore, there were no tolerances for any of the uses, and they all needed to be established for both the existing uses plus canola. And one of the requirements--in fact, the only requirement--in the RED toward a tolerance was a new metabolism study.

And we actually submitted a waiver from that requirement in about 2000, because EPA had extensive metabolism data in their files. In fact, they used it to do the risk assessment in the 2002 RED, and we felt that they didn't need another study or because we asked for a time-limited tolerance--in other words, it would be good for three years--and that was done purposely so that we could do any additional studies but have the tolerance on the books at the same time.

Q. Okay. You made two points in there, and I will want to get to both of them. The first one was submitting a waiver with respect to the Plant Metabolism Study.

A. Correct.

Q. And then you also talked about the time-limited tolerance.

A. Yes.

Q. Okay. Let's get to the time-limited tolerance petition later, and I do want to give you the chance to talk about that, so don't let me forget, but you said that you'd

submitted a waiver with respect to the Plant Metabolism Study. The EPA rejected that, did they not?

A. To my recollection, they never responded to it.

Q. So, the EPA nevertheless required Plant Metabolism Study?

A. Correct.

Q. As part of the RED?

A. Correct.

Q. And as a condition for the issuance of the tolerance; is that right?

A. Yes, that's correct.

Q. Okay. Well, let's talk about that Plant Metabolism Study that you said is a condition for the establishment of a tolerance.

Now, in Paragraph 25 of your Witness Statement, this is where you talk about it. You said, "The only data request of any significance was a request for a Plant Metabolism Study. Crompton worked with EPA to meet the additional data requirements and provided all of the data that was required."

Now, just before we get into the substance of that, can you just briefly and in layperson's terms describe what a Plant Metabolism Study is.

A. Seeds are treated with radioactive material, and then the plants, the seeds in this case would be planted, and when the crop grew, the radioactive materials would be traced

through the plant, and they would identify what percentage or what proportion of the original lindane broke down into various metabolites.

Q. And why would a Plant Metabolism Study be necessary in this case?

A. It's usually done to determine whether there are any metabolism of toxicological significance that should be included in the expression of the tolerance. In other words, should be measured simply as lindane or should it be measured as lindane plus metabolite A, and that's the main purpose of it.

The other thing is, if the metabolites are generally the same in plants as they are in animals, then it's presumed when the toxicological tests are done with the animals that they're also measuring the impact of the metabolism.

Q. Okay. Thank you.

And the EPA obviously considered this important enough to make it a condition before the establishment of any new tolerances; is that right?

A. Yes. As I said before, though, they had plenty of metabolism data, and they I think just wanted to get a confirmation.

Q. This study represented a significant delay to Chemtura's attempt to get a tolerance for canola in the United States, did it not?

A. I guess it depends what you call significant, but it did push things back a little bit because we couldn't get EPA talked out of it. However, I still say that we could have convinced them that they could give a time-limited tolerance to be in effect while we were doing the study.

Q. Sure.

A. And if there was sufficient action-forcing events going on, but apparently there were not at that time.

Q. Okay. And like I said, we will get to the time-limited tolerance. I think it's an interesting topic.

Did you tell Chemtura that this requirement was going on cause a significant delay to its petition--to its attempt to get a canola tolerance?

A. I believe I said it could.

Q. Okay. Let's take a look at Tab 249, and that's in Volume 7 of the hearing bundle. And for the record it's also at Dr. Goldman's Second Report, Exhibit 3.

Can you confirm that you wrote this E-mail July 26th, 2002?

A. Yes, it looks like I did.

Q. Okay. Now, if you could flip to Page 4, it's the fourth page on the E-mail, it actually looks like, if I could just go back to Page 2, just to make sure because that's the beginning of your E-mail there, part of the E-mail string, at the bottom you've got Ed Johnson, July 26, 2002, update on RED

And then the E-mail goes on, so I'm going to point you to the fourth page of that E-mail. Yeah. So, it's the page starting with "safety finding" at the top.

A. Okay.

Q. And I'm going to the first full paragraph where it says, "There are, however, disturbing issues with respect to the canola tolerance/registration. First, I was informed that the metabolism study decided that no new tolerances could be issued before the Plant Metabolism Study was submitted and reviewed.

ARBITRATOR CRAWFORD: Committee.

MR. LUZ: Committee. I'm sorry. That's right. Thank you, Professor Crawford. "Before the Plant Metabolism Committee decided that no new tolerances could be issued before the Plant Metabolism Study was submitted and reviewed. This is a significant delay since such a study will take a substantial amount of time to treat, grow, and analyze the crop."

BY MR. LUZ:

Q. So, again, the EPA told you that there would be no new tolerances before the Plant Metabolism Study was submitted and reviewed; is that right?

A. That's correct.

Q. Now, if you could turn to Tab 252 in your bundle, and that's Dr. Goldman's Exhibit 28 in her second statement.

A. I don't have it.

Q. You have the E-mail in front of you?
A. Yes, I do.
Q. Great.
And you wrote this E-mail on July 28th, 2002.
A. According to the header.
Q. And under the message contents, it says starting with, "There are a couple of problems which could arise from canola as I explained in an earlier E-mail." Number two, "the requirement for a new Plant Metabolism Study prior to the issuance of any new tolerances delays us at least a year."
So, in July 2002, you're aware that the study was not going to be ready until at least the middle of 2003; is that right?
A. Yes, that was my--I'm not an expert on how long it takes to do a metabolism study, but that was my estimate. I understand that they actually can be done faster in a greenhouse situation.
Q. Okay. Now, that means if it's the middle of 2003, that misses the early 2003 time frame that you said in your Witness Statement you expected a tolerance could have been issued by the EPA; is that right?
A. Yes, it does, and that is based upon waiting for the metabolism study. When I wrote the Expert Report, I was thinking about the situation as we saw then, and we felt that if there was an action-forcing event on EPA that they would go

back to what we asked for them to do originally, which was the time-limited tolerance. And one of the forcing factors could have well been the continued use of lindane in Canada because then you would have had the trade irritation again, and the EPA would tried to say, we've got to do something. Okay, let's do it and get the study later.

As I said, they had plenty of metabolism data. It's not like they had nothing and they just needed this one.

Q. But again, the EPA said that there would be no new tolerances until the study was done; is that right?

A. That's what they said.

Q. Now, notwithstanding this knowledge, Chemtura still undertook to complete the study; is that right?

A. Yes.

Q. Because, as you said, the EPA was not going to issue a tolerance without it; is that right?

A. The company agreed to support the tolerance and registrations and provide the required data.

Q. Okay. If you could turn to the document at Tab 259 of your bundle, and that's in Volume 9.

Do you have it in front of you?

A. Yes, I do.

Q. Okay. And this is an E-mail that you wrote in on August 15, 2003, so a year after the RED was issued, if my math is right.

A. August 12th?
Q. I'm sorry, did I say that? August 15th.
A. No, I said--oh, I see.
Q. Right there, August 15, 2003.
A. Right.
Q. And the subject line is, "Update on EPA and CEC activities," and you wrote at point number one in the middle of the page, just underneath the "EPA," "There is no activity on lindane in EPA."

Do you see that?

A. Yes.
Q. And if you go to point number four, it says, "EPA expressed interest in the status of the Seed Metabolism Study. They thought it might be done by now. I noted that I understood that a Protocol had been submitted by a response from EPA"--I think that word should be but, but "by a response by EPA had not been received as of a few weeks ago based upon my latest info. Mark Howard will check into that. He also said the metabolism study was going to be done on canola seed."

And then in large capital letters is Mr. Cummings' response: "I will be working with Jerry and Mark to get a status Report to EPA next week on this topic."

So, this indicates that as of the middle of 2003, the Plant Metabolism Study is still going on; is that right?

A. That's what it says, yes.

Q. Okay. If you could turn to Tab 264, that's still in Volume 9. For the record, this is also in Dr. Goldman's Exhibit 34.

This is looks like an E-mail from Michael Boucher at "McKennaLong.com," dated, and it looks like August 5th, 2004. You're copied on this E-mail you will see up in the Johnson, Edwin.

A. Um-hmm.

Q. Just before we go on, McKennaLong, that's McKenna, Long, Aldridge. It's a law firm; is that right?

A. Yes, it is.

Q. And what's the relationship between TSG and MLA, if I can use the acronym?

A. TSG is a wholly owned independent subsidiary of MLA.

Q. Okay. And was MLA also helping Chemtura on legal advice with respect to the canola tolerance petition to the EPA?

A. Yes, they were.

Q. Thank you.

Now, the e-mail says that it's an e-mail summarizing two conference calls that occurred with the EPA on August 4th, and indicates that you were on the call, you will see TSG, Ed Johnson, as being there.

Do you remember these phone calls, either generally or specifically?

A. Not really.
Q. Okay. Well, let's turn to the third page of this E-mail, and right underneath the divider, where it starts off, "In a second call, Chuck, Ed Johnson, Gary Burin, and I called Kim Nesci and Mark Howard." They're from the EPA; is that right?
A. Where are you?
Q. At the top of the third page, starts off, "In a second call."
A. Oh, I see. Yes.
Q. Right. So, you are on this call with Kim Nesci and Mark Howard of the EPA?
A. Yes.
Q. Okay. And the call was about Crompton's plan to expedite needed new tolerances for seed treatment uses of lindane by doing a probabilistic risk assessment of FDA uses. I know that's a different topic and we will get to that eventually, but I'd like to go down again to the second paragraph on that page. The second sentence says, "Even with a favorable aggregate exposure assessment of lindane, Mark Howard also clarified that EPA would not be in a position to establish new tolerances for lindane until the Agency had the results of the ongoing Plant Metabolism Study, which will identify residues of concern for the seed treatment uses and corresponding tolerances."

Is that right?
A. Yes, that's what it says.
Q. Okay. So ongoing means that the Plant Metabolism Study was still going on in August 2004?
A. Yes.
Q. Okay. And again, it confirms that the EPA is not going to issue any tolerances until this study is completed; is that right?
A. Pardon, could you say that again?
Q. It again confirms that the EPA said no new tolerances would be issued until the Plant Metabolism Study was finished?
A. Yes, that's what it says.
Q. Okay. Now, if you could turn to Tab 268 in your hearing bundle, it's again Volume 9. Do you have it in front of you?
A. Yes, I do.
Q. Okay. And it's an E-mail that you wrote to Will Cummings of Chemtura on December 12, 2004. It starts off, "Will, as we discussed last week, I'm sending you an E-mail proposing two things that I recommend for TSG to undertake with respect to outstanding lindane studies for EPA. Number one, Plant Metabolism Study. This is a critical study with respect to assuring that nothing but the parent compound is selected for the tolerance. If other metabolites are identified as being of toxicological significance, then additional residue

studies will be required."

And then the beginning of the next paragraph, it says, "I know that something must be submitted to the EPA by end of December."

So, this indicates that study was still going on at the end of December 2004?

A. Yes, I believe that was when a draft Report was completed and submitted to EPA.

Q. And do you know when the Final Report was submitted to the EPA?

A. I believe it was March 2005, if I'm not mistaken. I don't want to be held to that, but around that time.

Q. Okay. I'll take your word for it. It's early 2005, you think?

A. Yes.

Q. Okay. And the EPA required some time to review the Plant Metabolism Study; is that right?

A. Correct.

Q. Do you recall when they finished reviewing that Plant Metabolism Study data?

A. No, I don't recall when it was.

Q. Okay.

A. Those studies were handled by Chemtura and submitted through their regulatory staff. The communication back was to Chemtura, not to me.

Q. Okay. So, you're not sure when the EPA finished reviewing that data?

A. No.

Q. Okay.

A. All I know is that the study was apparently acceptable.

Q. Okay. Well, let's take a look at the HCH Study from February 2006, and that should be in your Thomson hearing bundle at Tab 12, just to make sure you have it. Again, I apologize. The version in the joint hearing bundle was missing pages or was the wrong document entirely. I'm not sure how that happened.

Do you have it?

A. Yes.

Q. If you go to Page 1, this is the February 2006 HCH Study. At the bottom of the Page 1, it says, "To address the second condition of the RED, Registrants have since provided all of the required data. The Registrants have submitted the required product and residue chemistry data, and the Agency has reviewed these data and found them to be acceptable. The Registrants have also submitted an outstanding nature of the residue study, also known as the Plant Metabolism Study, originally required in the 1985 registration standard DCI for lindane, and these data are currently in review."

So, does this suggest that in February 2006, the EPA

was still looking at the data submitted almost a year before by your rough estimation?

A. That's what it says, yes.

Q. Okay. Now, Mr. Johnson, you write at your Paragraph 7 of your second Witness Statement, "Impediments to obtaining a tolerance in 2002-2003 were the need to provide some routine studies assessed in the RED which when completed by 2005, were acceptable." So, everything that we've discussed about the Plant Metabolism Study suggests that and confirms what you said, that Chemtura did not have the requisite study in 2002-2003, and that is why the EPA did not issue a canola tolerance for lindane use on canola; is that right?

A. That's correct.

Q. Thank you.

Mr. Johnson, I'll just go briefly to a couple of other things. You said in your Witness Statement that there was only--the only data request of any significance was a request for a Plant Metabolism Study.

Do I take it to mean that when you say, "the only data request of any significance," it means there were other data requests?

A. There were requests for three studies. Plant Metabolism was the study that related to the tolerance.

Q. Right.

A. With respect to the registration, they asked for some

environmental studies. One was the Seed Leaching Study, and the other was Metabolism, Anaerobic Metabolism Study.

Q. Right.

And these were also prerequisites to getting a canola tolerance in the United States as well?

A. Well, I think you have to look at the process. I mean, the routine studies that are normally asked are those kinds of studies, but the process is really flexible. And if EPA has some reason to do it, they can give you a provisional registration. They can give you a time-limited tolerance while you're doing the studies. It depends on whether there is a good reason for it or not. And had lindane still be used in Canada, in order to avoid a continuing trade irritant, they would have had a good reason to do something. And then as far as the registration goes, I suspect that North Dakota, given their previous behavior, would have been on EPA to give a registration so that they could have a level playing field, and that would have forced the EPA to do something.

Well, the whole environment changed. There was no lindane use in Canada, so for them to rush through and do something would just have set up a reverse trade irritant, and therefore they sort of said, let's do this the regular way and just sit there and wait until they send the studies in because there wasn't that action-forcing situation.

Q. Okay. You said a lot which I appreciate. I just want

to go back to my question to get it on the record, that the Seed Leaching Study and the Anaerobic Aquatic Metabolism Study were prerequisites to getting a canola tolerance in the United States; is that right?

A. Not a tolerance. They were related to the registration.

Q. So the registration, okay. So, these needed to be completed in order to have registration in the United States for canola?

A. To get a final registration.

Q. Right.

A. As opposed to a conditional or provisional.

Q. Okay. Let's quickly talk about this Anaerobic Aquatic Metabolism Study. I think you said in your Witness Statement lumped in with the other routine studies, that this was not completed until 2005?

A. That's my recollection, yes.

Q. Okay. And were you aware of difficulties that Chemtura was having with respect to completing this study?

A. I wasn't personally aware of it. I mean, I'm not a scientist that works in that area, but I knew they were having some difficulty with carrying out the study, and we offered one of our chemists to help them.

Q. So, you were generally aware that this particular study was causing some trouble to Chemtura?

A. Yes.

Q. Okay. Let's take a look at one of the progress Reports for this particular study. It's at Tab 278 of the joint hearing bundle, which falls into Volume 10.

Now, you're not on this E-mail obviously, but it's entitled Lindane Progress Report, and near the top of the page it has study initiation date, preliminary study in progress, definitive study to begin in 2005, study due date December 31, 2005.

Then if we could skip to the last page, the last sentence on the last page, it says, "Work is in progress, and in spite of our significant technical difficulties at this point, we expect to provide a Final Report to the Agency by December 31, 2005."

So, this report of significant technical difficulties is what you were generally aware of at the time; is that right?

A. Yes.

Q. Okay. And if you could turn to Tab 268--that's back in Volume 9--it's an E-mail that we already looked at.

And number two, you've got Anaerobic Aquatic Metabolism Study. "Most recent progress Report in the Anaerobic Aquatic Metabolism Study indicated that there were some methodological problems with recovery. This is the same problem the previous lab had with the study, which was rejected by EPA."

And then it goes on. The last sentence of that paragraph, "EPA knows these studies are difficult, and we may be able to discuss results and work toward a conditional registration without a final study."

So, this was--and you're--again, what you're talking about knowing that the general nature that Chemtura was still having trouble with this study at the end of December 2004; is that right?

A. Yes.

Q. Do you know when the study was submitted to the EPA?

A. I think the due date was December 31. It was a few days, like December 24th or 23rd, somewhere in there.

Q. And like the Plant Metabolism Study, the EPA needed a bit of time to review this as well; right?

A. Correct.

Q. And do you know when the EPA completed its review of this study?

A. No, I don't.

Q. And are you aware that in February 2006, the HCH Report indicates that there were still undergoing a review of that study?

A. Yes, that's what it said at the page that we looked at earlier.

Q. That's right. Okay. So, we don't have to go back to it again, but that's what it says.

With respect to the Seed Leaching Study, do you recall when that was submitted to the EPA?

A. No, I don't.

Q. Was it also in 2005?

A. Pardon?

Q. Was it also in 2005?

A. I think--probably early 2005. Yes, I think most of the studies were submitted in 2005.

Q. Okay. Thank you, Mr. Johnson, for those study points.

And now I would like to go back to the second condition in the RED on that document that we--from that paragraph that we referred to before, and again the RED is in Mr. Thomson's witness bundle at Tab 7. We just go back to the language that we had read before about the conditions for the new tolerances. It's at the Roman numeral nine, little ix.

The second--the last full paragraph at the bottom of the page starts with, "EPA notes new tolerances for seed treatment uses of lindane is conditioned on one," and we've already discussed this data.

And two, "EPA's ability to make a determination that establishing the new tolerances meets the safety standard in FFDCA."

FFDCA, could you describe what the acronym is, because I always mix it up with other words of a similar nature?

A. Federal Food, Drug and Cosmetic Act, and it generally

regulates a whole range of drugs and things that are administered by the Food and Drug Administration. However, some of the sections, 408, 409, deal with pesticides, and those are the provisions that are administered by the EPA to set tolerance or maximum residue limits for pesticides.

Q. And that was made applicable partially by the Food Quality Protection Act? Is that the piece of legislation that amended the FFDCA to--

A. Well, tolerance petition--tolerance requirements were in there for years. I mean, they had been in there since the probably 1950s, but they were modified to some extent by the Food Protection Quality Act.

And, I mean, there are some changes, but I'm not sure if they're that much.

Q. Okay. Well, let's just get as clear as we can for this complicated legislation.

EPA is required to make a finding that residues in food are safe; is that right?

A. Yes.

Q. And safe means that there is a reasonable certainty that no harm will result from aggregate exposure; is that right?

A. Correct.

Q. And aggregate exposure includes both exposure to residues in food and, according to that legislation we were

just talking about, exposure from other nonoccupational sources; is that right?

A. Yes, that's what it says.

Q. Okay. So, the EPA has to aggregate all exposures to determine whether it fits into a particular risk cup. Is that a fair way of describing the EPA's role here?

A. Well, I would say they have to aggregate risk exposures that are relevant.

Q. Right.

A. That can be associated in a reasonable way of being put together.

Q. Okay. The EPA talks about this here in the RED, and if we could just go to Page Roman numeral 10, little x, it's the first full paragraph. It's talking about, "In light of these statutory provisions, EPA is considering whether the statute requires the Agency to include in its safety assessment those exposures resulting from the use of lindane in pharmaceutical products."

Just so we are clear, pharmaceutical uses of lindane includes treatment of head lice and scabies; is that right?

A. That's correct.

Q. Okay. Let's go to the next paragraph, the first sentence: "The existence of pharmaceutical sources of exposure to lindane raises questions of public policy and statutory interpretation that have not been resolved." It goes on to

say, "These questions include whether aggregate exposure encompasses exposures resulting from the use of lindane in pharmaceutical products, and if so, whether there is any reasonable statutory interpretation that could avoid apparently questionable public policy results."

And then, "The EPA is particularly concerned that the statute be interpreted and applied in a manner that yields results that are protective of public health and consistent with common sense," and here is the key sentence. "If Section 408 were interpreted to cover exposure from pharmaceutical uses, then EPA might never be able to establish new tolerances or leave existing tolerances in effect for a substance that is used both as a pesticide and pharmaceutical product if the pharmaceutical product caused adverse effects in humans."

Let's simplify what the EPA is saying here. At the time of the RED in July 2002, the EPA was uncertain as to whether or not it was statutorily bound to include pharmaceutical uses of lindane in the risk cup of its aggregate risk exposure; is that accurate?

A. That's what it says in the document, yes.

Q. Okay. And the reason--part of the reason for this concern was that the use of lindane for pharmaceutical treatment of scabies alone exceeds the Agency's level of concern; is that right?

A. Yes, according to the calculations that are in here.

Q. Okay. And this was obviously an issue that the EPA would have to discuss with the FDA, the Food and Drug Administration?

A. Yes.

Q. And according to this, the EPA wasn't quite sure or had not resolved the statutory interpretation in its public policy, so it's something that it would have to discuss internally before making a decision on new tolerances; is that right?

A. Yes.

There was a precedent on this, I believe it was malathion, also has pharmaceutical uses, and prior to the Lindane RED, it was determined that they would not accumulate them. They would keep them separate.

Q. The uncertainty here disturbed you, did it not? The uncertainty of the EPA's question as to its statutory responsibilities?

A. Certainly it was disturbing, but we had some information and EPA says it right in the RED somewhere that they think that it would be poor public policy--

Q. Okay.

A. --to put the pharmaceutical uses into the risk cup.

Q. But as you said--

A. Eventually, they didn't do it.

Q. Okay. You said eventually, they didn't do it.

A. Correct.
Q. Do you know how long it took them for to decide that issue?
A. No.
Q. Well, we will go through it and find out.
The--you conveyed this concern to Chemtura, and let's take a look at a document we already looked at. It's Tab 249. That's in Volume 7, and we are going back to the fourth page of that E-mail that you wrote, so I'm going to the second full paragraph there, where it starts, "Even more disturbing," so there we have, "Even more disturbing is that one possible solution to FDA use dilemma is to avoid making an FQPA finding. There is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.
And I will skip down to the next paragraph, where it starts, "This solution would retain existing uses, but OPP says they cannot issue any new tolerances without making the FQPA finding. This would put--this could put canola in limbo despite the fact there are no detectable residues in canola oil. However, I believe there are residues in meal which is used in animal feed."
So, here you're concerned that this issue is going to put the canola tolerance into limbo; is that right?

A. That's what I said in the E-mail. Yes.
Q. And you advise further to Chemtura that until the EPA made up its mind about this issue, it would be impossible for any new tolerances to be granted, including for canola; is that right?
A. I'm sorry, where are you reading now? Oh, I see.
Q. I'm just asking you if you did advise Chemtura that a new canola tolerance would be impossible until the EPA made this safety finding.
A. Yes, they had to make a decision as to what to do about the pharmaceutical uses and whether it included those or not.
Q. Okay. So, you don't know how long the limbo lasted at the EPA?
A. I don't recall, no.
Q. Okay. Let's take a look in Tab 259. It's an E-mail that we already looked at. This is in 2003. Tab 259 is in Volume 7--no, Volume 9. I apologize.
So, point three, you have, "There has been some discussion on the general issue of how to handle FDA approved product exposure in a cumulative risk assessment at top OPP management levels and OGC, but not much progress has been made."
OGC is the Office of General Counsel--
A. Yes.

Q. --of the EPA? Okay.

And then the next page, in the middle of it you ask at point one, "Should we try to press upper OPP management for closure on the RED comments, including the generic FDA issue?"

And Mr. Cummings replies, "I would push the FDA issue. The FDA issue is not resolved in our favor, there will not be any future lindane tolerances because the risk cup is full."

Did you continue to push the EPA, Mr. Johnson?

A. Yes, we did. We sent in several written comments, and we sent in some analyses by our toxicologists as to how to apply a probabilistic assessment to show that there is a problem that EPA is basically using the wrong analysis, and we continued to talk with people over there on the phone about getting this resolved.

Q. Okay. So, you put in a good deal of effort to try and convince the EPA--

A. Yes.

Q. --because Chemtura believed this was an important part of getting a canola tolerance in the United States?

A. Yes, that's correct.

Q. Okay. Let's skip forward to an E-mail in February 2006. This is at Tab 283 of the joint hearing bundle. And this is an E-mail or a chain of E-mails in February 2006. If we go to the second page of this E-mail, second full paragraph or the second full paragraph, "However, we do note

one significant change in the regulatory situation about which EPA notified us by telephone. In the 2002 RED, there was an FQPA issue based upon the FDA approved uses. Last week we were advised that the Agency had dealt with that issue, and the FDA uses were no longer an impediment to a positive FQPA finding since the FDA finding would not be included in an aggregate risk assessment."

So, it was in February 2006 that the EPA determined internally that it was not going to include pharma uses in its risk cup?

A. Yes, that's what it says in the E-mail.

Q. And that's four years after the issue was flagged in the RED?

A. Yes.

Q. And again, the EPA said explicitly that no new tolerances would be granted until that FQPA issue was determined; is that right?

A. I'm trying to think whether they actually said it that way or not. I guess you could imply that from what they said.

Q. Okay. So, in other words, given the three studies, the Plant Metabolism Study, the Anaerobic Aquatic Metabolism Study, the Seed Leaching Study, and this FQPA issue, no tolerances were actually possible between 2002 and 2006; is that right?

A. Yes, it is for full tolerances, but I keep going back

to the fact that there are short-term things that can be done while other issues are being resolved if there is a sufficient action-forcing event for them to look at.

Q. And I have not forgotten it. I promised you I would get back to the import tolerances. I promise we will.

Okay. I just--I'm done with that issue, and I just want to talk about one other item that you discussed in your Witness Statement, your second Witness Statement, the worker exposure study. You write at Paragraph 7 of your second statement that Chemtura needed to provide a seed treatment worker study of its own to satisfy the legal formality of having provided a worker exposure study for the canola registration.

Do you recall that?

A. Yes.

Q. You don't say when this required study was completed and submitted to the EPA. Do you recall when that happened?

A. I believe this study was submitted in 2004.

Q. 2004.

A. It was a study that they already had. They submitted to PMRA some time previous to that.

Q. Okay. But the EPA required that study as well?

A. Well, EPA didn't exactly require it. It's more of an administrative legal problem. In doing the RED, analysts that were doing the risk assessment used a study done with Helix,

which was owned by another company, and that company had proprietary rights to that study, and other people couldn't use it without paying them or getting their permission.

Q. Right.

A. EPA can use any study it wants to use to risk assessments, but in order to get a registration, you have to have your own study or use a study that is not protected any longer. And since this was protected, they needed to submit their own.

So, it wasn't a question of risk, and it wasn't a VCR kind of issue. It was more trying to meet the provisions of the data protection statute.

Q. But it was something that the EPA asked Chemtura to submit?

A. I'm not sure they asked them or they knew they had to do it. One of the two.

Q. So, it was considered a requirement, and Chemtura obliged?

A. Yes.

Q. Okay. Well, we've covered 2000--actually 1999 through 2006, so let's go up to February 2006 to the HCH Study that was issued by the EPA, and again, that's Tab 12 of Mr. Thomson's binder from this morning, and you should have it in front of you.

And I'd like to go to Page 2, and this is--I'm looking

at the first full paragraph on Page 2, and it starts, "As a result."

So, I will read that: "As a result of the Agency's continuing review of lindane, the Agency initiated the preparation of this document. This document presents EPA's revised assessment of risks related to the continued registration of the insecticide lindane, also known as gamma HCH."

So, this means that even in February 2006, the EPA was continuing its review of lindane; is that right?

A. Yes. That's not usual. I mean, pesticides are constantly under review, and as new information comes in, they will ask for new data. It's a continuing process. It's not a one time and that's it.

Q. Sure.

And so this--if my math is right, this came almost seven years after the initial canola tolerance was submitted in June 1999?

A. Yes.

Q. And this came almost five years after the EPA wrote in April 2001 that no decision would be made on a canola tolerance until it had completed a comprehensive risk analysis of lindane; is that right?

A. Yes, which I judged to be the 2002 RED as the comprehensive risk assessment.

Q. But here it says the EPA is the--presenting its revised assessment of risk, so that must also necessarily mean that the 2002 could not have been the comprehensive risk assessment.

A. Well, they dragged in alpha and beta and a few other considerations in here, which caused me a lot of problem, frankly. I mean, I think it's a hodgepodge, and we provided probably at least a hundred pages of comments on this, which generally weren't considered.

Q. So, you considered the 2002 RED to be the comprehensive risk assessment, but the EPA, apparently by this, did not share that interpretation; is that right?

A. Well, they were participating in the North Atlantic Regional Action Plan development, and one of the recommendations of that was that you not only consider lindane, but you look at the other isomers also, and I think this was a reaction to that recommendation that was working its way through the NARAP.

But I must say, as late as August 2004, there is a Press Release from a NARAP meeting where people were disturbed because the EPA was still pushing--it's their position that the 2002 RED, so I mean, it went on for quite a while. Even in 2005, EPA published the Federal Register Notice revoking some of the tolerances for the uses that were canceled, but they retained the uses on animals--I mean the tolerance on animals

because they were anticipating the possibilities of crops that would be fed to those animals, namely from seed treatment.

So, there's mixed signals on this, frankly.

Q. Okay. So, I just want to go back to my original question.

A. Yeah.

Q. You said that you considered the RED to be the comprehensive risk assessment, and I asked if you would agree that, according to the text that we read from the HCH Study, the EPA would not share that interpretation. Is that right?

A. EPA put this out as their new-cut risk assessment and their thoughts.

Q. Okay. So, the comprehensive risk assessment was not finished yet in February 2006?

A. That's what it says.

Q. Okay. Let's take a look at some of the key issues that were raised in the HCH Study, and we will just--you already had mentioned that you considered it a hodgepodge, I think you used the word.

A. Yes.

Q. I take it you weren't too pleased with this HCH Study?

A. It's not so much that I wasn't pleased with it, but I just thought that the workmanship wasn't very good.

Q. And you said that you submitted a lot of comments--

A. Yes.

Q. --after this was done, and this was obviously done--or about I should ask. Was this done at Chemtura's request?

A. Yes, and it was comments by several people, both at MLA, the law firm we talked about earlier, TSG, and it covered a number of the issues that are in here.

Q. So, Chemtura deployed the resources of yourself and lawyers and so on because--

A. Correct.

Q. --it obviously still wanted a tolerance and registration for canola, lindane use in canola products?

A. Yes, they were still interested in getting this.

Q. Okay. So, in February 2006 they were still interested in getting it?

A. Um-hmm.

Q. Let's take a look, and let's just confirm obviously no tolerance or registration had been issued at this point?

A. That's correct.

Q. Okay. Let's go to Page 50. Where it says additional concerns and information request, and the last sentence of that first full paragraph, the Agency would like to obtain additional information from the public specific to the topics listed below as it makes its final determination on lindane. And it lists a list of five different things, including infants' exposure to lindane through breast milk, cancer classification, and so on.

So, here, the EPA is looking for more information about these issues; is that right?

A. That's correct.

Q. And was there a deadline that the EPA had in order to determine when the tolerances were to be issued by the EPA?

A. Yes, August 2006 was the deadline that had been set for a final decision.

Q. Okay. So, we had August 2006 as a deadline. This comes out in February 2006.

A. Correct.

Q. Would you agree that the issues in this study flagged some potentially difficult hurdles that Chemtura would have to overcome in order to get a tolerance from the EPA?

A. No, actually, I didn't consider them to be impossible hurdles. We commented on all the things that are in the request.

We also--basically we commented on the fact that they just kind of discounted everything that was said about the waste system and assumed the alpha and beta just thrown out in the field to blow around in the environment. So, we reiterated that. They were given that process several times.

In the preparation for the Board of Review hearing in Canada in 2004, 5, I forget when it was, 2005, Chemtura and-and MLA, and we assembled a group of well renowned scientists to help advise on various issues, and they did an analysis with

respect to breast milk and determined that there isn't any problem. That was submitted to the EPA, which they totally ignored as far as I can tell.

They don't have any new data on breast milk. They say there is a dearth of information on levels in breast milk, but they just elevated their concern in words but not in data.

And then on the cancer classification, we thought that was settled in 2002 by the cancer classification group in the EPA.

I forgot what else we commented on. Oh, the indigenous population. That was covered in the 2002 RED, and determined that it wasn't a problem. It was considered in the North American Regional Action Plan. I went to most of those meetings, and there were presentations there that lindane was present in the Arctic, but not at levels that would be detrimental to the animals, the fish and the animals themselves or the people that consumed them.

So, I mean, there is a lot of data out there that I think frankly wasn't considered properly in this document. That's why I made my earlier comment.

Q. And what was the EPA's response to this obviously compelling case that Chemtura and your eminent scientists, group of--team of scientists and lawyers submitted?

A. Well, from what I saw in the reassessment, the next document--

Q. The Addendum?
A. The RED Addendum, I'm sorry.
Q. Right.
A. From what I saw in there wasn't compelling to them.
Q. Okay. Well, let's take a look at that document. It's at Tab 293 of the hearing bundle, and I'm hoping the copy in the hearing bundle is not missing pages; otherwise, this line of questioning will have significantly less interest for everyone.

ARBITRATOR CRAWFORD: Tab 14?

MR. LUZ: Tab 14, the date is 2006, July 2006, yes, you could see it. Sorry.

BY MR. LUZ:

Q. Okay. So, let's talk about one of the items. If you could turn to Page 13. You said that as far as you could tell, the EPA--I don't remember the word that you used, but if you said that the EPA ignored the comments--
A. I didn't say ignored, but they didn't buy them totally.
Q. Okay. Sorry. I didn't want to put words in your mouth. I just couldn't remember the word that you used.

Let's look at the last--the second-to-last full paragraph on the page, the last paragraph in the section, infant exposure to lindane from breast milk and resulting risk.

The last sentence, "However, EPA believes that because

of lindane's prior detections in breast milk, its physiochemical properties, and its continued presence in the diet, the potential for adverse effects to infants from consumption of breast milk cannot be dismissed due to lack of data."

So, this is in July 2006. Does this suggest that the EPA still has concerns about the presence of lindane in breast milk?

A. Yes, they still have concerns, but they have no data.

Q. Okay. So, this would require further data to be submitted?

A. In order to nail it down, yes, but as I said, we submitted an analysis that took into account the breast milk information that was around and modeled what the dose would be and predicted what the effect would be and found that it wasn't a problem.

As far as I can see here, that's not even mentioned.

Q. Okay. So, presumably the EPA would probably require further studies to fill the lack of data, as you said, to nail it down?

A. Possibly.

Q. Okay. And do you have any idea how long such a study or studies would have taken to satisfy the EPA?

A. No, I have no idea.

Q. And do you have any idea how long the EPA would take

to review such a study?

A. No.

Q. So, given what you just said, you're not--you can't say for sure if and when the EPA would have ever granted a tolerance for lindane use in canola; is that right?

A. I think by the time you get to this document, it becomes academic because the companies have already voluntarily taken it off the market because their big market that they wanted was Canada, and a lot of the things that were going on in the United States was to get a tolerance so that it wouldn't have a trade problem and could have it reinstituted in Canada.

But as that possibility kind of dwindled, there wasn't much incentive for them to continue to go on with this in the United States because that market wasn't that big.

Q. Okay. I just want to--you said a lot of information. I just want to make sure that you answered my question or heard my question.

You can't say for sure if and when the EPA would have ever granted a tolerance for lindane use on canola in the United States; is that right?

A. Yes, that's right, um-hmm.

Q. Mr. Johnson, I promised you we would get back to the time-limited tolerance, and I'm going to keep my promise to you.

Let's turn to your first Witness Statement,

Paragraph 28.

And you write, "based on the favorable review in the 2002 RED, it should have been possible for the EPA to grant a registration and tolerance for canola within months following the issuance of the 2002 RED, such that a registration and tolerance were available by early 2003." I think we already dealt with that.

And then the next sentence as well: "There was some data, such as the Plant Metabolism Study, which were required as a result of the 2002 RED, but TSG requested a time-limited tolerance which could have been granted while the remaining data were being developed and reviewed."

And you go on to write: "However, as a practical matter, given the situation in Canada, Crompton did not aggressively pursue this matter with the EPA."

So, there's a couple of points that you make here in your Witness Statement. First, you say TSG requested a time-limited tolerance, and then the next sentence you say that Crompton didn't aggressively pursue the matter. Let's get what's in between there. You said you requested a time-limited tolerance. What was the EPA's response to that?

A. The response was that they couldn't consider another tolerance until they did the risk assessment in the RED.

Q. So, their answer was no; is that right?

A. At this time.

Q. And this time was...
A. 1999.
Q. 1999. And did you ask at any other time after that with respect to a time-limited import tolerance?
A. Yes, we were constantly calling on the EPA trying to get them to move. We called them regularly, sent memos over to the managers at EPA--
Q. For an import tolerance?
A. Yes, to move on our tolerance action.
Q. And--but I'm talking about the time-limited import tolerance?
A. Yes. That's all we wanted right then.
Q. Okay.
A. We weren't looking for a final tolerance. That's why I keep saying that they could have given us that based on the information they had, and they had a lot of metabolism data because they even used it for the dietary risk assessment in the 2002 RED. So, this study was a follow-up, but it wasn't a crucial study. It was crucial in an administrative sense but not in a scientific sense, but we tried to move that, and it didn't get very far.
Q. Okay. So, just to clarify what you said, you've asked the EPA several times, you said, several memos, letters, meetings, and so on asking for a tolerance--
A. Yes--

Q. Go ahead.
A. They said we are looking at it.
Q. And they eventually just said no or said nothing?
A. They said nothing. They didn't say no. They said nothing, except that they're looking at it.
Q. So, when you say as a practical matter Crompton did not aggressively pursue this matter with the EPA, maybe you're not using the word aggressively, but it sounds like you certainly were pushing them and constantly asking them for a time-limited import tolerance?
A. Yeah, I wouldn't--let me interpret that sentence. I didn't mean that Crompton wasn't interested in pursuing the action in the United States, but they had a lot of activity now going on in Canada, and their resources were more being devoted up there, and we were kind of doing the calls to EPA and that sort of thing. I don't mean they didn't care about it.
Q. Okay. So, but the short answer is the EPA said no to your request for a time-limited import tolerance?
A. They didn't say anything, or they said not now.
Q. Okay. Thank you, Mr. Johnson. I don't have any other questions right now.
A. Thank you.
PRESIDENT KAUFMANN-KOHLER: Thank you.
Do you have any redirect questions, Mr. Somers?
MR. SOMERS: A few, Madam Chair, thanks.

PRESIDENT KAUFMANN-KOHLER: Please.

REDIRECT EXAMINATION

BY MR. SOMERS:

Q. At one point in your examination, Mr. Johnson--by the way, you were supposed to be physically uncomfortable. You look like you're enjoying this too much.

A. Took my mind off my pained muscle.

Q. Well, at least it did that, then.

MR. LUZ: We could keep going.

THE WITNESS: No, that's all right. Actually I took another pain pill that was scheduled before I came in here.

BY MR. SOMERS:

Q. Earlier on Canada was questioning you about the Seed Leaching and Plant Metabolism Studies, and the discussion was around whether they were required to get a final--to get a registration, and you said they were required to get a final registration as compared to a conditional or provisional registration, and I just wanted you to expand on what you meant by conditional or provisional registration.

A. EPA can issue a registration with conditions. In fact, almost every registration at EPA these days is provisional because you have to sign an agreement that says if we ever ask for more data on this chemical, you agree to provide it. That's the condition.

You can also--technically, and most specifically, it's

when somebody comes in with a new chemical and they don't have all the data because it was a new data requirement, and they didn't have the time to produce that data. That's the definition in the statute. So, if I came in with a new chemical, and yesterday EPA said you've got to have three cancer studies instead of two, well, I can't do the third cancer study in less than two and a half, three years. So they can say, okay, we will give you a registration, but you've got to do that test.

Well, practically, though, they add other kinds of conditions on as well. I know one of our clients in pesticide, they were concerned about environment, and they had a condition that they had agree to do a monitoring program in the field, so that's what a conditional registration is. We will give it to you, but you've got to do some things. If you don't do those things or if the answers turn out wrong to those tests, then you're gone. Otherwise, you can stay on. That's sort of the pragmatic definition of a conditional registration.

Q. Provisional, is that synonomous?

A. No, that's--I was using that pretty much for the same thing.

Q. Okay, okay.

Now, I'm going to ask you--this is about that point and about the time-limited tolerance that you were apparently not getting an immediate answer from EPA on in terms of the

line of questioning that I heard. If lindane--and I invite you to do a little bit of speculation, but if lindane had continued to be available as a seed treatment use in Canada, would you consider that the EPA might have focused more on whether it could grant a time-limited tolerance or this conditional registration? Would that have made a difference?

A. Yes, I do. I mean, I think I mentioned that several times, that if EPA had had something to force their action, then they would have done something different than if they had no pressure on them. So, if there was an imminent another trade problem, for example, then that with some pressure put on them to try to deal with that trade irritant, and they well could have--I don't know that they would have, but they well could have said, geez, this kind of changed the situation. Let's give them the time-limited tolerance so we don't get into all this back and forth with Canada again, and then they can provide the study, and then we will make a final decision.

So, the environment changed. That was the whole thing. There was a lot of impetus to do something when the petition was submitted and when the 2002 RED came out. But then after that there wasn't any lindane use in Canada anymore, so there wasn't much pressure to do anything. There was no trade irritant anymore. Guys in North Dakota were happy. I mean, they didn't have lindane, but neither did Canadians, so it was an even playing field again.

And so, there wasn't anything forcing EPA to do anything.

Q. Thank you.

In a discussion regarding the combination of pharmaceutical and agricultural uses in terms of the aggregating risk, you said in response to a question about whether they did--they aggregated or not, you said eventually they didn't do it. Eventually, they didn't combine those two use risks, I will say.

In fact, though, just from my understanding, they never did it in the first place. They considered doing it; is that right? They considered doing it, studied the matter, and decided not to do it?

A. Well, they looked at it, and they scratched their head, and they said, geez, this is a real dilemma, but they put a paragraph in the RED that said, you know, this is really poor policy, poor public policy to throw out all these tolerances for agricultural crops and effectively leave them with nothing because of this pharmaceutical use. It just doesn't make good public policy.

And they kind of invited comments to the effect that, yeah, it doesn't make sense, don't do it. We sent a tonne of comments in on that particular issue as well.

But in talking to the people there, they didn't think it made any sense. They were just worried about the

technical-legalistic aspects of it.

Q. So, that aggregation never was done?

A. No.

As I said, they had another situation before that with malathion, and in that case they didn't combine them, so there was a precedent, but apparently it didn't help on the lindane case. They forgot that the precedent was there, and it wasn't a precedent that was thought out. It was just something that was done in the RED.

Q. A factual precedent?

A. Yeah.

Q. Another line of questioning concerned the Addendum to the 2006 RED, which is located under Tab 14 of the Thomson witness bundle binder. I would ask you to turn to that, and I think--right. And it was at the bottom of Page 13--I'm sorry. The third full paragraph on Page 13. And you were directed to the sentence, "However, EPA believes that." Are you there?

A. I'm sorry?

Q. Were you there?

A. Page 13?

Q. Yes, Page 13?

A. Third full page, paragraph, nevertheless.

Q. Begins there, and I'm jumping down to the sentence four lines up from the bottom of it that starts, "However, EPA believes."

A. Um-hmm.

Q. "EPA believes that because of lindane's prior detections in breast milk, its physiochemical properties, and its continued presence in the diet, the potential for adverse effects to infants from consumption of breast milk cannot be dismissed due to lack of data."

In other words, they're looking--they don't have the data, like you said, I guess, did I understand that? And they need the data. Would that be one possible situation where they would issue, for example, a conditional registration or a time-limited tolerance and require this data to be brought in for further study?

A. That would be unusual. These are the kinds of studies that are done by the communicable disease center or university or something like that, and they don't just look for lindane in breast milk, but they look for a number of things. So, it's not normally the thing you would put on a company to do. It would be a public entity that would usually do that kind of study.

Q. Does that language in the Addendum here that we just read reflect the Agency's intention, had the--had the registrations not been canceled, an intention to continue to study that matter?

A. Yeah, EPA probably, if they could have gotten some data, would have reconsidered that issue. And they said in one

of the other documents that nobody seems to be collecting breast milk, lindane residues in breast milk.

Q. But would this type of absence, this absence--an absence of this type of data wouldn't preclude the issuance of a time-limited tolerance, for example?

A. No, I wouldn't think so, because they don't have the data. You need to have data in order to--I usually say the absence of data is not the precedent. It's a presence of risk. You got to have some data to show that the risk is there. Just because you don't have the data doesn't mean the risk is there.

Q. Fine. Thank you for that.

MR. SOMERS: Thank you, Madam Chair. That concludes my redirect.

PRESIDENT KAUFMANN-KOHLER: Thank you.

Are there any questions by the Tribunal? No?

My questions have been asked as well, so I would like to thank you very much for your patience and your answers.

THE WITNESS: Thank you.

PRESIDENT KAUFMANN-KOHLER: That closes your examination.

THE WITNESS: Thank you.

(Witness steps down.)

PRESIDENT KAUFMANN-KOHLER: So, let's take a 20-minute break, and then hear the first Respondent's witness, who is Mrs. Chaffey; is that right? Good.

(Brief recess.)

CHERYL CHAFFEY, RESPONDENT'S WITNESS, CALLED

PRESIDENT KAUFMANN-KOHLER: Now we are ready. Good afternoon.

For the record, can you please confirm you're Cheryl Chaffey, and could I ask you to push the button of the microphone. Now it's on, yes.

THE WITNESS: Yes, I am Cheryl Chaffey.

PRESIDENT KAUFMANN-KOHLER: You're head of the toxicology re-evaluation section of the--let me get this right--of the Health Evaluation Directorate at the PMRA.

THE WITNESS: That's correct.

PRESIDENT KAUFMANN-KOHLER: Yes. You've held this position since...

THE WITNESS: I have been with the PMRA since its inception and with Health Canada as a pesticide regulator since 1983.

PRESIDENT KAUFMANN-KOHLER: You have given two Witness Statements in this arbitration.

THE WITNESS: That's correct.

PRESIDENT KAUFMANN-KOHLER: You're heard as a witness, and as a witness you are under a duty to tell us the truth, so I would like to ask you to confirm this duty by reading the Witness Declaration that is in front of you.

THE WITNESS: Certainly.

15:58 I am 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.

You know how we will proceed? You will be asked a few questions by Canada's counsel, and then we will turn to Claimant's counsel.

THE WITNESS: Okay.

PRESIDENT KAUFMANN-KOHLER: Mr. Douaire de Bondy, are you doing the direct?

MR. DOUAIRE de BONDY: Actually, I pass the floor to my colleague, Christina Beharry.

MS. BEHARRY: Thank you, Madam Chair, Professor Crawford, and Judge Brower.

DIRECT EXAMINATION

BY MS. BEHARRY:

Q. Good afternoon, Ms. Chaffey.

A. Good afternoon.

Q. Did you have any involvement in the PMRA Special Review of lindane?

A. Yes. I and several members of my staff were involved in the toxicology evaluation.

Q. When was the Special Review launched?

A. The Special Review was officially launched in March of 1999.

15:59 Q. Prior to the Special Review, had any regulatory action been taken against lindane?

A. Yes. Lindane had undergone a retrenchment of many uses since the 1970s, such that by the time we undertook our reevaluation, all of the above-ground uses had been withdrawn and all that was left to be re-evaluated at that time were just the seed treatment uses.

Q. Why did the PMRA launch the Special Review?

A. It launched the Special Review in response to both domestic concerns such as those that were articulated in the Northern Contaminants Program Report on contaminants in the Arctic environment as well as international concerns that were specifically addressed through the United Nations LRTAP program.

Q. Was the Special Review initiated because of the Voluntary Withdrawal Agreement?

A. No, it was not.

Q. And to be clear, were you involved in the discussions leading up to the Voluntary Withdrawal Agreement?

A. No, I was not.

Q. So, when did planning for the Special Review begin?

A. The planning for the Special Review began in the Summer of 1998.

Q. You mentioned that you were involved in the toxicological components of the Special Review.

16:01 A. That's correct.

Q. How does the PMRA conduct a toxicological assessment?

A. We conduct a--

MR. SOMERS: Excuse me, I hesitate to interrupt at this point, but this is all material that is contained in the witness's statement, and I'm referring to the Procedural Order where, under Paragraph 54, a direct examination is considered necessary to complete the Witness Statement and therefore permissible, but otherwise what I'm hearing is actually--it's the Procedural Order Number 1, I'm sorry--but otherwise should not be conducted.

PRESIDENT KAUFMANN-KOHLER: You're saying this is not completing the Witness Statement.

MR. SOMERS: No, it isn't.

PRESIDENT KAUFMANN-KOHLER: It is repeating the Witness Statement.

MR. SOMERS: That's right.

PRESIDENT KAUFMANN-KOHLER: That's right.

Generally, I have no issue with a few introductory questions. It also allows the witness to start in an easier fashion, but obviously you can assume that we have read the Witness Statements, and therefore we don't need to repeat the contents. So, if you can keep it brief, that's what we really meant, to be brief.

MR. SOMERS: Thank you.

16:02 MS. BEHARRY: Yes, I plan to keep my questions brief. This wasn't anticipated to take very long.

PRESIDENT KAUFMANN-KOHLER: It is on your time, of course.

MS. BEHARRY: Exactly.

BY MS. BEHARRY:

Q. How does the PMRA--I will repeat my question. How does the PMRA conduct a toxicological assessment?

A. We undertake a review of the scientific literature as well as the Registrant-conducted studies to come up and determine the toxicological ends points we used in risk assessment as well as the application of the relevant uncertainty and safety factors in risk assessment.

Q. So what is an end point, briefly?

A. An end point is really the manifestation of a toxicity of a particular chemical and the dose level and the lowest dose level at which that is observed.

Q. And what is a safety factor?

A. A safety factor is a factor that is applied to the toxicology data, the animal toxicology data, to extrapolate down to a safe human exposure level below which no adverse effects would be anticipated.

Q. Could you please describe how the PMRA selects a safety factor.

A. We select a safety factor by looking at the weight of

16:03 evidence, and we consider not only what the database says, but also what deficiencies might exist within the database, and we account for those uncertainties as well as any special concerns that we might identify within that database.

Q. What was the safety factor applied in the case of lindane?

A. The overall safety factor that we applied for the Occupational Exposure Assessment was 1,000.

Q. Is it uncommon for the PMRA to apply a 10X safety factor?

A. No, it's not uncommon to apply that number.

Q. Has the PMRA applied a 10--

ARBITRATOR CRAWFORD: I'm sorry, you referred to a 10X safety factor previous to occupational exposure assessment 1,000. What's the difference?

THE WITNESS: The 1,000 really was comprised of what we call our baseline 100-fold factor. That is a factor that will be used in the risk assessment of virtually any chemical that's regulated worldwide, and that 100 factor is really to account primarily for the fact that we are extrapolating from animal data to humans and also to account for the fact that there could be variability in how humans respond to toxic insults.

In and above that baseline factor, we often employ different factors to account for data uncertainties as well as

16:05 concerns with that database, and that's the additional 10 that we are referring to in lindane. It's an additional 10-fold above the standard baseline of 100.

Q. And that leads to a thousand-fold margin of--

A. That's correct.

Q. Okay. Has the PMRA applied this additional 10-fold safety factor to other cases?

A. Yes. We have, certainly in many re-evaluation cases that I can think of. Chemicals that come to mind include phorate, turbevof (ph.), 2,4-D, and certainly in the case of new evaluations that we have looked at. The case of Helix, which I believe is one of lindane's competitor products, is a case where we also applied an additional 10-fold margin.

Q. And apart from the toxicological aspect which you mentioned, did the PMRA undertake other scientific assessments as part of the Special Review?

A. Yes. We undertook assessments of other areas that--besides the toxicology and occupational exposure included dietary exposure, environmental fate and toxicity as well as the value and chemistry aspects of a product evaluation.

Q. Were those assessments listed in the Special Review Announcement?

A. Special Review Announcement was indicated that the scope of the assessment could be quite broad. It certainly indicated that there were unresolved issues with respect to

16:06 both health and environment concerns.

Q. And what is meant by "health issues"?

A. Health issues typically encompass both an assessment of toxicology and exposure and that being occupational exposure and dietary exposure.

Q. What was the outcome of the Special Review?

A. The outcome of the Special Review was that we found unacceptable worker risk associated with the handling of either lindane or lindane-treated seeds.

Q. When the Special Review concluded, had the PMRA concluded all aspects of scientific evaluation?

A. No, we had not.

Q. Why didn't the PMRA wait until the completion of all studies prior to making its determination?

PRESIDENT KAUFMANN-KOHLER: I don't like interrupting, but now you are really going a little bit further than what I generally consider as introductory questions, and I think just out of equal treatment and fair play, the other side has really restricted itself in terms of direct examination.

If you could save your questions, if you have to, for redirect, unless you have some other really introductory question, but now--I mean, we know all these things about the special announcement, the scope, and the special announcement, the conclusions. I think it's not very helpful.

MS. BEHARRY: Just a few more minutes of your

16:08 indulgence.

PRESIDENT KAUFMANN-KOHLER: Yes.

MS. BEHARRY: Thank you.

BY MS. BEHARRY:

Q. In your Witness Statement, you mentioned that the PMRA had devoted certain resources to the Special Review.

A. That's correct.

Q. Could you please remind the Tribunal of what those resources were?

A. In my section alone, we spent approximately five working months on the re-evaluation on the toxicology aspect. I do know that the resource dedication in the other areas of the Assessment were equally substantive.

Q. And is this considered a significant amount of resources for the Agency?

A. Yes.

Q. Your Witness Statement has also discussed several meetings that had taken place prior to the release of the Special Review Decision. Could you please describe what was discussed at those meetings, once again to remind the Tribunal?

A. There were two meetings that took place between the Registrant and the PMRA. The first meeting which was held in May of 1999, there are a number of issues that were discussed and which included the scope of the Assessment, and it was indicated to the Registrant at that time that we would be

16:09 starting with the chemistry aspects first and proceeding with the health and environmental reviews in the Fall. We talked about the submission of the data. We talked about data protection, and the Registrant at that time brought to our attention the fact that the United Kingdom was finding unacceptable worker risk.

At the second meeting of October 2000, the items that were discussed included occupational exposure, environmental risk, and the registration of alternatives.

Q. Okay. And was there any follow-up from those meetings?

A. At the second meeting, a couple of days later, the Registrant sent in some data. There was an occupational exposure study, the Dupree study, that's referred to in my testimony and the testimony of others. This was a study that we already had in our possession.

Q. Was the PMRA satisfied with the study submitted by the Claimant?

A. The Dupree study had certain limitations, but overall we felt that it was still usable for conducting our risk assessment.

Q. Okay. Those conclude my questions, then.

PRESIDENT KAUFMANN-KOHLER: Thank you.

Now I can turn to Mr. Somers.

MR. SOMERS: Thank you, Madam Chair.

16:11 CROSS-EXAMINATION

BY MR. SOMERS:

Q. Good afternoon, Ms. Chaffey. My name is Greg Somers, and I will be asking you some questions on behalf of Chemtura Corporation.

A. Okay.

Q. I'll be referring to your two affidavits--

A. Okay.

Q. --that were filed in the proceeding, and I will be making reference from time to time to other documents that are located in the joint hearing bundle, a pile of documents that are put together for convenience.

Turning first to your first Witness Statement, your first confidential Affidavit, Volume 1.

A. Right.

Q. And I'm looking at--before I get to specific words--

PRESIDENT KAUFMANN-KOHLER: Could you speak a little closer to the microphone.

MR. SOMERS: Sorry about that.

BY MR. SOMERS:

Q. Before I turn to specific words in yours statement, I just wanted to clarify that you're not appearing here as an expert. You are a toxicologist, but you're appearing here as a witness of fact; is that right?

A. That's correct.

16:12 Q. Your training and your profession are in the field of toxicology?

A. That's correct.

Q. Would that include such things as studies of environmental effects of lindane? You mentioned volatilization at some places in your Report, accumulation in Arctic zones and that sort of thing?

A. Are you asking me if I'm an expert in those areas?

Q. Yes.

A. I would claim that I'm not an expert in those areas, but as a member of the lindane team, I had frequent discussions with the other team members which did have that expertise. And as a result of those interactions, I have a general understanding of those areas.

Q. I appreciate that.

Just turning to Paragraph 6 of your first confidential Affidavit, there you state at the outset--I will wait until you have it in front of you.

A. Paragraph 6?

Q. Right.

"When reviewing whether a pesticide is acceptable for use in Canada, the PMRA considers whether it has value." And I wondered what you meant by the word "value" there.

A. Whether we look at the value in a re-evaluation, typically what--and again, I'm not the person who conducts the

16:13 value assessment, but the scientists that conduct the value assessment will look to see what benefits the pesticide poses to the users, and this is often important when we undertake various risk-mitigation measures. So they will look at things in terms of whether there are alternatives available to the product in question.

Q. Before you condemn it and look for all alternatives to the product, while you're evaluating the product itself, and you evaluate its value, you're looking at things like its usefulness to the market, the economic benefits that it provides?

A. To some extent, we--with re-evaluation, if a product is out there in the market, we are assuming that there obviously is some value to the end-user; otherwise, the product would not be viable economically and not be in the marketplace at all. So, we assume that it has some element of value.

What we are really trying to do with our value assessment is to see really are there any other alternatives to these products for user groups because we are certainly interested that users have access to Pest Control Products.

Q. But again you're taking me too quickly into alternatives. I'm talking about when you evaluate a pesticide.

A. When these evaluations are undertaken, these are areas of evaluation that take place in parallel. So, while we are continuing to work on our toxicology and Environmental

16:15 Assessments, our value group usually will survey the user community to see what the use patterns are like: Is this a product that is used highly in that particular area? Are there alternatives? That is just a matter of routine practice at the PMRA.

And in many cases we don't need to take risk-mitigation measures, and so, you know, that's interesting information to have, but we don't take any further regulatory action on it. In other cases where risk mitigation is required, that's very, very valuable information to have at that point in time.

Q. My understanding of risk mitigation to be measures of review that could be implemented to reduce exposure to a toxic substance; is that not right?

A. Yes.

Q. So, before we get to that question, we are talking about the value of a product, and when--you called it the value team? Surveys of a user community to find out if this product has benefit?

A. That's right.

Q. Okay. Benefit. In other words, will it serve a useful purpose?

A. That's right. Is it of value to the user community.

Q. Will it improve yields? Will it increase the economic benefit of the agricultural product to which it is going to be

16:16 applied?

A. Our value group does not look at questions like that. Typically, the kinds of questions that they're answering is really whether this is a critical product in a particular use pattern. So, they will look to see if, say, the product was used on potatoes, are there other products that can be used on potatoes.

Q. Other products in terms of registered pesticides?

A. That's right.

And many times, if we do get to the point where a risk mitigation is required, which is not all the time, again this information can become very important for interacting with our user community to plan for the submission of new products.

Q. To plan for the submission of new products by pesticide manufacturers.

A. That's right. It gives us an idea of what user needs are and whether there needs to be any special considerations as to the prioritization of reviews that are coming in.

Q. I wanted to ask you about that, too. The prioritization of reviews that come in, is it not done on a first-come first-serve basis?

A. In most cases, it is done on a first-come first-serve basis. There are--

Q. But you'll make exceptions to that?

A. There are exceptions to that. An example of that, for

instance, is--a fairly well-known example is with organophosphates, and re-evaluation of organophosphates was undertaken in the late 1990s, early two thousands, and as a result of that activity, many organophosphates disappeared from the marketplace. So there was a concerted efforts by regulators to help the user communities by looking at replacement products.

Q. In the case of organophosphates, did you find one replacement product and then decide that the job had been done and move to the other applications not related to organophosphates substitutions that were in a queue?

A. Given that we were talking about a wide range of products, I mean there's probably--I think we have over 20 organophosphate products that are used in various niches in the marketplace. It would be impossible to just look at one particular niche with one particular product. Each product has its own regulatory plan and action, and we have to, say, look at the picture as a whole.

Q. When you say "niche," do you mean a particular crop, for example?

A. Yes.

Q. So, if an organophosphate pesticide was registered for use for six different crops, would one replacement product do?

A. It might; it might not. It depends on whether is has a similar profile in terms of what pest it controlled.

16:19 Q. You brought up organophosphates as a practical and real-life example of another situation where you had to come up with replacement products in a hurry and give them priority over the normal first-come first-serve approach.

A. That's right.

Q. In that case, you had said there were some 20 niche uses for--

A. No, I was talking about the overall number of organophosphates--

Q. I'm sorry.

A. --that we were re-evaluating. Not all of those required risk mitigation. I was just talking about the 20 as a--talking about the universe of organophosphate products.

Q. Fine, that's great.

Going back to Paragraph 6, then, and I'm picking up where we left off on that first sentence, the PMRA considers whether it has value and whether the potential risks to human health and the environment are acceptable.

So, is it fair to say that there is a risk benefit analysis carried out by you?

A. No, it's not fair to say that.

Q. All right.

A. In--with our legislation, a negative finding in any one of those areas is sufficient to warrant regulatory action. So, if we find unacceptable health or environment risk, the

16:20 value of a product does not trump that.

Likewise, if we have unacceptable value of a product, a positive or negative health or environmental finding has no influence on that. We would act on the basis of those considerations.

Q. I guess I'm wondering, it seems to beg the question a little bit to say if we find unacceptable risk then it's unacceptable. That seems to be your conclusion there. But I wonder how do you get to the point where you say now it's unacceptable and has crossed a line.

A. The determination of unacceptability comes down to our margins of safety and what we deem to be acceptable or not. That's the standard by which we decide whether something is acceptable or not.

Q. And you say that "we deem." Presumably that deeming is based on some scientific criterion?

A. That's right.

Q. Are we entering into that murky area of risk factors and uncertainty factors and that sort of thing?

A. You may choose to characterize it as a murky area. I'm sure many do, but certainly it's an area where we try to employ a very consistent approach and in terms of our consideration of risk factors, and we have documents that guide us in the application of those factors.

Q. Yeah, I wanted to turn to--I will in a moment, if I

16:22 may, but thank you. You have documents which guide you.
A. Yes.
Q. We will return to that theme.
A. Yes.
Q. So, now, I'm going on to Paragraph 7 of your statement, but the part that is found on Page 4, and the sentence that begins on that page: Risk is affected by both the toxicity and the potential exposure to a pesticide. To illustrate this concept, a product that is highly toxic with low exposure could have the same risk as a product with low toxicity but high exposure.
A. That's correct.
Q. That only makes sense.
And I suppose low exposure would be the place where mitigation measures come in.
A. That's correct.
Q. And so the fact that something is highly toxic wouldn't be enough for you to decide whether that is acceptable or entertains an acceptable risk for use; is that right?
A. That's correct.
Q. You need the whole story.
A. We need to make a determination on risk, which is a combination of both toxicity and exposure.
Q. And exposure itself is a variable that's determined or completely affected by mitigation measures.

16:23 A. It is affected by mitigation measure, yes, and how the product is used.

Q. Right. Right. Thank you.

And Paragraph 10, and you had tweaked me before when you said we have documents that help us. In Paragraph 10, the third sentence that begins: A document internal to PMRA was used at the time of the Special Review as a tool by scientific evaluators to conduct risk assessment in a standard manner.

Now, by "internal to PMRA," that means it was not available to Registrants or Applicants?

A. We had certainly communicated that policy to Registrants. I don't think Registrants were a stranger to the policy that we were applying with respect to occupational exposure at the time.

Q. But they were a stranger to the document.

A. We had not published that document.

Q. I wonder why that would be. You'd think that would expedite both their and your jobs if they knew the tests that they would have to go through in order to get by the gatekeeper, as it were. Can you help me out?

A. The publication of the--it was really a question of timing more than anything else. The document to which you refer in 2000 was a document that we specifically generated for our evaluators internally to make sure that we consistently applied uncertainty and safety factors. But it did not in any

16:24 way represent new practices. It really embodied practices that we had been using for a number of years.

And subsequent to that, we did not feel that we would publish that document at that time because we knew that we would be coming up soon to a point where new legislation would be put in place, and we may have to put out a document at that time on factors.

So, we were waiting actually for the legislation to be enacted, and that that was the time when we were going to publish a document on safety factors, and that's, in fact, what we proceeded to do.

Q. The document is footnoted in your statement as draft interim guidance on use of uncertainty and safety factors.

A. Yes, that's right.

Q. It reflected a practice you just said that had been in place at the Agency for many years?

A. For a number of years.

Q. It sounds provisional. "Draft interim" sounds as though you hadn't really come down hard on the methodology--

A. No, I would not characterize it that way at all. I think we put "draft" on it because obviously it was not a document that was written with the language of going out with a public document, as I'm sure you can appreciate that when you issue a public document, you spend a little bit more time and attention in terms of the language that you use and the

16:26 publication process. This document was really an internal document using very technical language for evaluators who are very familiar with the language that was being used.

Q. You're not suggesting, though, that a Registrant, a sophisticated registrant, would not understand that language?

A. No, but we usually--when we publish documents, we try to make the documents accessible to all stakeholders. We are not necessarily going to write that document just in a language that a Registrant can understand.

Q. Lindane is not banned in Canada, is it? You wouldn't say that now.

A. Sorry?

Q. Is lindane banned in Canada?

A. Lindane was the--was suspended. Certainly the Crompton products were suspended and the other products were withdrawn, just to be clear on the language.

Q. Well, I want to be even more clear than that because there are various points in the statement and in this proceeding one could be forgiven for going away thinking that lindane is banned in Canada, and in fact, lindane is on its way to being banned internationally.

But just to clarify, that's too general a statement. Neither of those statements are true, are they?

A. Well, certainly by virtue of the fact that lindane has been suspended or it has been withdrawn, I think, it's fair to

16:27 say that lindane is no longer in use in Canada.

Q. I'm not trying to build a trap for you, but my information, and I ask you to confirm it is that, in fact, pharmaceutically it is very much in use in Canada, and it is very much in use internationally as well. Is that not so?

A. I would have difficulty supporting the contention that it's well used internationally because I believe there are quite a number of countries that have taken regulatory action with respect to lindane.

Q. I can't dispute that. They have taken regulatory action, in fact, for many, many years. But that wasn't my question or my statement that I'm asking to you confirm.

My statement is that lindane, and I use the example of pharmaceutical use, is not banned in Canada or internationally.

A. I am not an expert in lindane and its pharmaceutical use throughout the world. I do know that it still does have registration in Canada for pharmaceutical use, but there are many caveats surrounding the use of that product, of the pharmaceutical use.

Q. Absolutely. And there were many caveats surrounding the agricultural use of lindane as a canola seed treatment as well, weren't there, on the label?

A. Yes. There are always caveats on labels.

Q. Thank you.

Does the PMRA conduct scientific studies of its own on

16:29 pesticides or on pesticide active ingredients?

A. If you mean the kinds of studies where we're going out into the field and doing laboratory studies, rarely, rarely.

Q. And in the case of lindane, were any carried out?

A. No, not by the PMRA.

Q. Right.

In Paragraph 27 of your first Confidential Statement, that is implied, if not directly stated, where on the second-to-last complete sentence in that paragraph on Page 9: Instead in deciding whether to allow--I'm reading from your statement--maintain registration of a pesticide, the PMRA relies both on publicly available scientific literature and on Registrant data. The PMRA bases its conclusions on its review of such information.

A. That's correct.

Q. So, that's how you arrive at your decisions on value, on risk, on risk mitigation; is that fair?

A. Yes.

Q. I'm going now down to Paragraph 29. You're given this data, as you explained earlier on, from Registrants, and you don't--as you say there, the PMRA doesn't simply take the conclusions of industry reports and studies at face value. Instead we review each Registrant study to decide whether or not its conclusions are reliable.

A. That's correct.

16:30 Q. A study that has been the subject--in fact, it was the subject of examination from your counsel a few minutes ago was the 1992 Dupree study. That concerned worker exposure.

Did you review that study to decide whether its conclusions were reliable?

A. Yes, PMRA did review that study.

Q. Did you conclude that its conclusions were reliable?

A. Yes. We felt that that study was usable. We certainly identified limitations with the study, but we felt that it was usable in terms of the evaluation of lindane and the commercial seed treatment.

Q. Are you saying that you weren't aware that that study was out of date?

A. Well--

Q. In terms of modern use practices?

A. First of all, I would have to clarify that in terms of indicating that study was out of date. At the time that we looked at that study, first of all, the use pattern, that study conformed to the use pattern that was indicated on the lindane labels that the PMRA had in its possession at that time. It was matched up with the lindane labels.

The second point that I wanted to make about that information--sorry, I lost the point there.

Q. If it comes to you, I invite you to just jump in and reiterate it.

16:32 A. Okay.
Q. So, you say the use pattern indicated in that study--did you remember it?
A. No, it's okay, carry on.
Q. The use pattern indicated in the Dupree study, you said, was also reflected on those labels.
A. That's right.
Q. But when you say in Paragraph 29 we review each Registrants' study to decide whether or not it's reliable, I assume you go beyond the label on a container of pesticide to decide whether a study is reliable.
A. Well, certainly we are aware of certain use practices and that actually did remind me of the other point I wanted to make. Thank you very much--
Q. --next question.
A. --and I just wanted to get back to the question about whether this was reflecting out-of-date practices. Our information at that point in time was that putting canola aside for a minute that, in fact, the Dupree study was actually representative of the seed treatment facilities in Canada for the smaller crops, the crops that were like the wheat and the oats. My understanding is that those seed treatment facilities for those smaller crops were not the high-tech facilities that were coming online in the late 1990s for canola.
So, we certainly were aware that for canola that there

16:33 were developments in terms of the technology for those seed treatment facilities, but we also knew that not every canola seed treatment facility was a high-tech facility. Certainly, there was a movement to that, but they were not all of the high-tech facilities that you speak of.

So, from our perspective, the Dupree study was not really an out-of-date study. It was relevant, but we do--did recognize that certainly it did not reflect a more sophisticated high-tech study, high-tech facility.

Q. To put a name on it, a more sophisticated facility and a study that would reflect that use practice, would that have been the case for Helix, the study--

A. That would have been certainly a study that reflected a more high-tech facility, yes.

Q. And you were aware of the Helix high-tech facility type study at the time of the Special Review?

A. Yes, we were.

Q. How come it was accessible to PMRA--and I will ask you this in a nonleading way--to use the Helix more sophisticated study in reviewing thiamethoxim, but not lindane?

A. Well, the lindane Registrants, first of all, never offered a study that was from a high-tech facility.

And, furthermore, the PMRA did not ask for that study because we had actually done, although we were not--we could not formally use the Helix study in support of a lindane

16:35 submission because of data protection issues, we did look at the Helix exposure numbers that came out of that exposure study, and we did a back-of-the-envelope calculation, and that calculation showed us that the exposure that we got, even with the high-tech facility, we still did not get acceptable margins for lindane.

So, from our point of view, it would have been negligent for us to have asked the company to have conducted a new occupational exposure study that we knew probably had very little likelihood of allowing the Registrant to continue registration of that product at the end of the day.

Q. I take it that napkin wasn't filed in these proceedings?

A. You're absolutely correct. It was not filed.

Nothing was written on that. As I mentioned, it was a calculation we did, which we recognized we could not formally do because of data protection issues, but it was enough to tell us that that was a risk mitigation measure that was not going to give us achievable margins of exposure at the end of the day.

Q. Not achievable because--in part at least because of that selection of uncertainty factor of 1,000. Is that fair?

A. Well certainly that's a factor in the risk assessment, yes.

Q. What I was kind of sort of, you know, revolving around

16:36 was, again in Paragraph 29, we just read the second sentence from it but--and then you go on, this is part of the practice of regulatory science. Fair. The PMRA can and often does go back to the Registrant that generated a particular study and ask questions. And perhaps even presents napkins. I'm wondering why in this case that didn't happen.

A. We made our regulatory decision and--or let's--we presented our regulatory assessment to Registrants in October of 1999. The Registrants at that point in time did not indicate to us that they were willing to undertake any new exposure study. They were still at that point in time telling us that the Dupree study was a relevant study for that Assessment. In fact, in response to our Assessment of October 2001, the Registrant submitted a new Occupational Exposure Assessment citing the Dupree study in support of their product. There was never any mention on the Registrant's part that another study would be forthcoming. And given what the Assessment that we had done, which showed that even using the Helix numbers for a highly refined seed treatment plant, that we were not getting acceptable levels with lindane, we did not feel that it was justified to ask for that information.

Q. I'm going to direct you to a memorandum now. I'm going to ask someone to put in front of you joint hearing bundle Volume 2, Tab 74. There is a document there called "Lindane Agenda" from 1999.

16:38 Do you have it?

A. Yes, I do.

Q. Good.

And I just wanted to--now, this would have been prior to the commencement of the Special Review or--

A. Certainly prior to the announcement of the Special Review.

Q. Right.

A. As I mentioned, we had sort of started the planning for it in 1998.

Q. Okay. And this was obviously before you had received the Dupree study or, frankly, probably anything since the Special Review hadn't been announced, any data from the field from, for example, Chemtura or other lindane Registrants. You would not have received any data from them yet; is that fair?

A. We would have had data on file for lindane that might have been submitted previously.

Q. But not in terms of or in preparation for or in contemplation of the Special Review.

A. That's correct.

Q. Turn to the next page, and these are notes that continue on. Part of this document, but they're handwritten notes. Maybe you recognize the handwriting and you can tell me whose they are. My guess was Wendy Sexsmith, but I'm not sure if you know.

16:40 A. They don't look familiar to me, I'm sorry.
Q. No. I see.
I'm looking at item 4 there. The third bullet under that says, no Data Call-In. Can you enlighten me as to why in the planning stages the PMRA anyway was already planning no Data Call-In for the Special Review?
A. I can't speak to that note and what was written by that person. I can certainly tell you my recollection of the events in terms of from my scientific assessment, what I thought was going on. And certainly at this point in time, when we were planning for the re-evaluation of--the evaluators were planning to do a review of the data, an initial screen to see what information we had, and to identify tentative data gaps at that point in time, and the thought initially was that we would communicate that information to Registrants.
And subsequently, in 2000, a decision was made by our management that we would have much closer collaboration with EPA. And because of that, since EPA had undertaken a Data Call-In the year before, we determined that it was not necessary to ask for further data at that time.
Q. In 2000.
A. In 2000.
Q. Yes, because I'm trying to back up the tape to all the way back to January 1999 when that decision appears to have been made long before the announcement even of the commencement

16:41 of the Special Review.

A. These are handwritten notes. I'm not sure this reflects a decision. I can certainly, as I say, tell you what my understanding was as a member of the evaluation team that we were working with, and at that point in time from my perspective, no decision had been made or communicated to me. I was certainly working under the impression that we were going to be doing that screen and that following that screen we would be asking for information.

Q. Did the PMRA ask for a--conducted a Data Call-In, in fact?

A. No, as I just mentioned, by the 2000, early 2000, we had made the decision to collaborate with EPA, which really rendered a Data Call-In moot because EPA had already gone through that exercise, so it was unnecessary.

Q. At that point, but the Special Review was already underway for nine months.

A. The initial stages of that evaluation, as I mentioned, were to do a screen of that data, and that screen took place during 1999, and the members of the team brought the results from that screen together at the very end of 1999, in November and December, the decision to use--to do that collaboration with EPA took place in, I believe, January and February of 2000.

Q. I understand. Thank you.

16:43 Turning to Paragraph 33 of your statement now, the nature of the Special Review, before that--sorry, before I forget, we had chatted briefly about organophosphates and the greater urgency that caused them to jump a queue in terms of having replacement products put in, if it made it available to the community.

Are there organophosphates that are actually still registered in Canada?

A. Yes, there are.

Q. For agricultural use?

A. Yes, there are.

Q. Could you estimate the number for me.

A. Oh, somewhere between 10 and 15, perhaps. We started off with the group of 27 different active ingredients in the re-evaluation program, and I believe we probably have left registered at this point in time somewhere between maybe 10 and 15.

Q. Are organophosphates POPs, Persistent Organic Pollutants?

A. No, they're not.

Q. What--are they classified in some sort of category like that--organophosphate says it all?

A. An organophosphate for most toxicologists would signify a product that was neurotoxic. That's their manifestation of toxicology.

16:45 Q. So, like--well, in that way anyway like lindane?
A. Yes, that's correct. They both interfere with neural transmitters.
Q. At Paragraph 33 of your statement, about halfway through it, you cite Section 19 of the Pest Control Product Regulations, and I'm just reading it from it again: During the period of registration of a controlled product, the Registrant shall, when requested to do so by the Minister, satisfy the Minister that the availability of the controlled product will not lead to an unacceptable risk of harm. The controlled product is, of course, in our discussion the pesticide under review or under examination for registration; correct?
A. Right.
Q. The availability that's referred to here would be the availability in Canada of the pesticide?
A. Yes.
Q. And unacceptable risk of harm, harm to...
A. That would be harm to either the human health or harm to the environment.
Q. Canadian human health? Do you undertake an examination of a risk to other than Canadians?
A. Canadian human health, yes.
Q. Paragraph 34 of your statement talks about increasing restrictions on the use of lindane since the 1970s in Canada.
A. That's right.

16:47 Q. For example, in the last complete sentence in Paragraph 34 on Page 12, you say: Canada first started restricting lindane use as early as the 1970s. And then you go on: The use of lindane on a range of fruit and vegetable crops and outdoor foggers and for the treatment of water for the control of mosquitoes was brought to an end in 1970. And then you continue: Technical HCH were banned, at the top of Page 13, no longer considered acceptable for registration. And the next sentence, by the mid nineties, most of the above ground uses of lindane were discontinued.

Were any, some or all of these as a result of withdrawals by Registrants as opposed to intervention by the PMRA terminating registrations? Can you tell me?

A. I have to think about this because I'm trying to recall some of the documents that were submitted. They were certainly not submitted as part of my testimony, but I do believe there were some documents that were Agriculture Canada trade memorandum documents that may have been submitted that might have talked about the discontinuation of these products. I'm--

Q. You're not sure.

A. I would suggest these issues be redirected perhaps to John Worgan because I'm not fully familiar with the details of the history in a detailed sense. You're asking a level of detail now that I'm not familiar with.

16:48 Q. Certainly in the last sentence you say: Sales of all products registered for use on livestock, et cetera, and on tobacco, were discontinued by Registrants at the end of 2000, so at least you're aware of that.

A. Yes, but I certainly could not tell you in 1970. If a product was taken off the marketplace right now, I couldn't tell you at this point in time whether it was a Registrant that withdrew it or, you know--

Q. It could be either one, then.

A. It could be, but I'd have to--someone else would have to. Perhaps John Worgan can answer that.

Q. At the bottom of Page 36, you quote from--I'm sorry, Page 13, Paragraph 36, you quote from the 2002 EPA Re-registration Eligibility Decision document.

A. Yes.

Q. And you cite, as we just discussed, the primary effect on lindane--of lindane is on the central nervous system, corroborated by published literature. In human exposure has been seen to produce neurological effects.

You go on to quote about the various toxicity aspects of lindane in that sense.

A. That's correct.

Q. Have you read--you've read the RED, the '02 RED.

A. I have read the RED, yes.

Q. And as I recall, and as I read that document, it

16:50 permits the re-registration of existing uses of lindane that it was examining; is that right?

A. The 2002 RED did declare the few remaining uses of lindane eligible for registration with certain risk-mitigation measures. Certainly the dry flowable--the dry formulations were to be discontinued because of occupational concerns as well as additional safety measures were required for those uses.

The canola use was also summarized in that document, although it was not a registered use of lindane at that time, and--in the 2002 RED, EPA had certainly identified occupational risk concerns with the canola use.

Q. So, notwithstanding those toxic roads (ph.) and toxic effects of lindane, this is just a reflection of the statement earlier in your--made by you earlier in your statement that even something that is highly toxic, if exposure is low enough, whether because of the use pattern or because of mitigation measures, can nevertheless be acceptable for registration.

A. Yes, risk is a function of both toxicity and exposure.

Q. And this is simply what the EPA was doing in its 2002 RED.

A. That's right. It found some se is acceptable, and it found others to present risk concerns, such as the canola.

Q. Fair.

I'm turning now to Paragraph 40 of your statement,

16:52 where you begin by talking about lindane production in North America, but then I'm jumping down now to: I attach to my Affidavit--about six lines from the beginning of Paragraph, 40, Page 15--I attached to my Affidavit a copy of the North American Regional Action Plan, NARAP, on lindane and other HCH isomers. Annex A of this report contains photos of mounds of toxic HCH waste sitting in warehouses in Netherlands and in Spain.

I will continue, so we are clear in the context.

Waiting to be buried in highly controlled waste disposal sites in the latter case at an announced cost of 30 million euros, were not disposed of in such secure sites, waste off and beta HCH-generated in lindane production travel through the atmosphere to the North--and you go on.

Obviously being in highly secure--highly controlled, I'm sorry, waste disposal sites, they're secure. This is not something that's going to travel through the atmosphere. You're using that to contrast to the potential situation where they are not in highly controlled sites; is that right?

A. I don't think it's a theoretical situation that they're in--some of the lindane is not in controlled sites. I think there was worldwide recognition that, in fact, a lot of the stockpiles were in sites that were not highly regulated, and therefore contributing to Northern issues in terms of environmental contamination.

16:53 Q. Is that what you're referring to in the next sentence, where you say: Although one Registrant has indicated it's possible to produce lindane and recycle the waste isomers into another chemical, stockpiles of uncovered abandoned waste isomers in Europe are evidence that, et cetera?

A. Yes.

Q. Do you--when a Registrant applies for a registration of a pesticide, do you investigate the source of the active ingredient for that pesticide?

A. Certainly the source of the active ingredient is information that the PMRA collects. We need to know where the product is manufactured. That's part of our standard processes and standard information requests of a Registrant.

Q. Is it taken into account in deciding whether a pesticide will get registered or not?

A. The PMRA has--because manufacturing information is information that the PMRA can and does request on a regular basis, that PMRA can exert some controls over that manufacturing process, for instance, what the level of contamination of the technical product.

So, from--to that way of thinking, I guess we do exert some control. For instance, if you look at products like maybe 2,4-D, we specify the amount of dioxins that must be--you know, that are allowed in the actual manufacturing process, so we do have some authority to regulate that.

16:55 Q. That's 2,4-D? Is that the pesticide you're referring to as an example?

A. Yes. Yes.

Q. In the case of lindane and the Special Review, were considerations of these sorts of issues, abandon waste isomers taking into consideration in reaching a determination?

A. In the determination of occupational health risk, which was what we ended up regulating on in our 2001 assessment, the isomers were a side issue and were not germane to the finding of unacceptable worker risk.

Q. Were they looked at?

A. They were looked at, I believe, by our environment group, but our environment group did not complete their assessment by the time that the Health Evaluation Directorate had completed their assessment of occupational risk.

Q. Were they taken into account or looked at in the Re-evaluation Note?

A. I believe they were.

Q. Are you aware what conclusion was reached in regards to them in that re-evaluation?

A. My understanding is that there was some level of concern expressed about the isomers, but I was not part of the re-evaluation team looking at the Re-evaluation Note, so I don't know all of the details.

Q. All right. I'm jumping ahead a little bit into the

16:57 section headed "International Trends" on Page 16 to Paragraph 46 on Page 17, Paragraph 46, which begins, "The NCP," which is, I take it, the Northern Contaminants Program, "published the Canadian Arctic Contaminants Assessment Report in 1997 which identified HCH." Whenever I see that, I know something is up because we--we are not talking about lindane anymore. Now we have changed to HCH.

Did you change the terminology there because that's obviously a different substance--it's larger, if you will, than lindane--because that Report doesn't discuss lindane specifically, but--

A. No.

Q. --but includes it in the--

A. No, that's not entirely correct. Much of the reporting in the CACAR Report, to make it easy, much of the reporting in that really talks about the collective of the HCH isomers, so that includes the lindane, and it includes the alpha and the beta isomers. But it also in places specifically addresses the isomers on their own. And, for instance, I believe in my second Affidavit, I make mention to the discussion with the Arctic ocean levels where it clearly indicates in the CACAR Report that while overall HCH levels are declining in the Arctic Ocean, that, in fact, the gamma form, the actual lindane, is actually at steady state in the Arctic Ocean, which suggests that there are still inputs into that

16:58 environmental compartment to maintain those ongoing persistent levels.

Q. Again, that was just to reiterate that the Report talks about all of those isomers as opposed to lindane specifically. It mentions lindane specifically in that terms that you're saying, that it's steady.

A. The Report is a collection of many pieces of literature. Some of that literature is looking at the collective of the isomers. Some of that literature is looking at lindane-specific levels or alpha-isomer-specific levels or beta-isomer-specific levels, so it's really a collection of all of that literature.

Q. I'm going down to the next paragraph, Paragraph 47, where you discuss the Joint Meeting on Pesticides Residue, the JMPR, as it's come to be known. The UN Food and Agricultural Organization and World Health Organization Joint Initiative, there you say that they used the safety factor of 500 in analyzing data from available studies.

That's the same safety factor as we have been talking about where PMRA uses a thousand?

A. That's right, and they applied an additional five-fold above the standard baseline that would be applied to any given chemical.

Q. So half as much as PMRA did, in other words?

A. Yes.

17:00 Q. So, the Special Review used a thousand. JMPR used 500. What did the EPA use in its '02 RED?

A. The EPA used a value of 300 for dietary risk, and they used a value of 100 for occupational risk.

Q. So, we've got 500, 300/100 for EPA, the Board of Review recommended something other than a thousand and something lower, obviously, because it made--are you familiar with the Board of Review Report? We will get to it in a minute.

A. Yes.

Q. And the PMRA itself at the Board of Review recommended--I'm sorry, stated a lower safety factor than a thousand would have been considered adequate by toxicologists.

A. I think we were recognizing the fact that within the four corners of scientific debate that one can take a different point of view on the selection of safety factors, and that we were acknowledging that, yes, a toxicologist could come to that decision of using a 3X instead of a 10X. That's not outside of the realm of possibility. But given our health protective role, as a health regulator, we felt that that additional 10-fold was justified.

Q. We will get to that, the justification of that, when we get to the Board of Review, so I will leave that for now.

On Paragraph 48--I'm turning to that now, so Page 18--at the North American level, you state, "In 1997, the

17:02 Great Lakes Binational Toxics Strategy listed lindane as a Level II substance," and you give as support for that Exhibit CC-16, which is attached to your Statement. I turn to it, and I don't find lindane in there, so I was wondering if I'm missing it or you could help me out. I'm turning to Exhibit CC-16, which is attached to your statement. Do you have access to it there?

A. Yes. And I think here probably correctly alluding to the fact that lindane is not specified in here, it's really talking about the hexachlorocyclohexane entity, which includes lindane.

Q. Right. But it also includes alpha, beta, delta, and epsilon?

A. That's correct.

Q. All isomers of hexachlorocyclohexane.

So, it's not lindane that was listed as a Level II substance. It was that salad--

A. It was that collective that includes lindane.

Q. Thank you.

I'm turning to Paragraph 69 of your statement now, if I could ask you to--just keep that aside for a moment, and this sort of concerns regulatory science, as well.

If I could ask that a volume from the joint hearing bundle to be put in front of the witness as well, it's Volume 2, and I will be referring to Tab 41. Do you have that

17:05 one? It's a document dated October 2nd, 1998.

A. Yes.

Q. Called "Lindane Seed Treatment Update." This predates, of course, the Special Review, but it does--it does refer to at least a proposal for the EPA and the PMRA to work together, and the reference in your Paragraph 69 about a management meeting, a Briefing Note recommending that U.S. and Canada work more closely together is what made me think of this.

I guess what I'm wondering about is, your job is risk assessment, risk mitigation, deciding whether risks are an acceptable level or not and so on, and therefore whether a pesticide should be registered. I put that over here.

I look at document of October 2nd, '98, at Tab 41 of the joint hearing bundle, and the third paragraph it says, "The resulting proposal has emerged after follow-up to this issue both with the Canola Council of Canada and the EPA staff." And the third bullet says, "Commitment between EPA and PMRA to work together to phase out all uses of lindane."

Now, there has not been any Special Review science done yet, but the outcome there appears to be fairly well plotted, and I'm wondering how your--your job as a toxicologist interfaces with this program. In other words, do you receive a direction from whoever negotiates these arrangements that you're looking for a certain outcome, or do they take the

17:07 results of your work as to, if I apply a safety factor of this and if I look at that study and I do this and that and call in data, and they do their thing with it and decide whether they're going to allow it or not? Does someone else have sort of an executive say over what happens to your Report? I'm asking for your help on understanding that.

A. Yes. As far as the Scientific Risk Assessment is concerned, I receive no direction from our management in terms of how to proceed with that Assessment or in terms of what finding to come up with. The Scientific Risk Assessment stands on its own merit on the basis of science.

When we have concluded our Scientific Risk Assessment, it's standard practice for scientific evaluators to present that information before a level of senior management, and we will indicate whether the exposures met the targets that we had established. So, if we had established a target of 1,000 for occupational exposure, we would clearly indicate to management that it's not reaching that target. In other words, there is unacceptable risk associated with that product.

It's then up to management to make a decision as to what regulatory action is then required on the basis of that scientific assessment.

Q. Right.

And it seems to me you have put the horse before the cart in the way you just described it, but this is the cart,

17:08 and it came before the horse. It's October '98--you haven't done your Special Review, much less your Risk Assessment yet, and it says "phase out all uses." And this is PMRA. This isn't phase-out of all uses in terms of the Minister of Health or some other department just decreeing that this material is illegal, like some narcotic or something. This is the PMRA, the pesticide agency, deciding, planning, proposing that it phase out all uses before they have seen the science, as far as science for prohibition anyway. The science to date has allowed registration for seed treatment use of lindane at this date.

So, I'm wondering how those two things can come together. First they decide to phase it out, and then they ask you to go do a rigorous scientific analysis.

A. Mr. Somers, first of all, I can say that with respect to this memo, this really--this memo here is talking about some interaction that had taken place between obviously some individuals in the PMRA and the EPA.

Q. Right.

A. It's not a document or a meeting that I had taken any part of. I can only tell you what I know as a scientific evaluator and a scientific assessor, and I could tell you that I received no direction, that there was no preconceived outcome to the re-evaluation of lindane. We conducted our assessment in good faith, and that assessment showed unacceptable worker

17:10 risk. That was not predetermined. I have no vested interest in terms of whether an assessment comes out acceptable or unacceptable at the end of the day. My only interest is that we conduct our assessments with scientific integrity.

Q. I accept that, of course, as to whether something comes out as acceptable or unacceptable at end of the day, isn't that exactly what you're out to find?

A. We are charged with the responsibility of making a determination as to the acceptability of risk, yes.

Q. I'm turning to Paragraph 78 of your Statement now.

A. Seventy-eight?

Q. Yeah, at Page 28, where you're describing a step in the Occupational Risk Assessment, and you begin, "The third step of the Occupational Risk Assessment was to use all relevant identified data to estimate the unit exposure values. That is the amount of anticipated exposure per kilogram of chemical handled for each exposure scenario."

So, in this situation or for this particular assessment step, the Dupree study would have been pertinent because it is the use pattern described in that study that would determine the exposure per kilo of chemical handled; is that fair?

A. Right, yes.

Q. So, this is where sort of the rubber hits the road in terms of that study coming to affect the outcome--

17:12 A. That's correct.
Q. --at least one aspect? Okay.
I will jump ahead a fair amount here to Paragraph 131 of your Statement. That's the Board of Review, at least your take or your interpretation of the Board of Review's conclusions.
In the second bullet of that, you say, "The Claimant suggests the Board"--that's us, the Claimant, suggests the Board--"criticized the PMRA's use of uncertainty factors."
Well, and as I recall it--perhaps instead of recalling it, I will take you to it. It's in the joint hearing bundle. It's at Volume 9 and at Tab 275. Joint hearing bundle Volume 9, Tab 275.
Do you have it?
A. Yes.
Q. The PMRA was--well, step back. The Lindane Board of Review was staffed by scientists; is that right?
A. Yes.
Q. Maybe you're not aware, I don't know, but was the PMRA consulted in the scientists that were chosen to staff that Board?
A. I believe the--actually, I--I don't know. I'm not an expert in that. I believe that question would be better directed to John Worgan.
Q. All right.

17:15 So bear with me. This will really speed things up when I find what I'm looking for.

A. That's okay.

(Pause.)

Q. The Board of Review recommended that, as I mentioned earlier, that the PMRA take into account a different uncertainty factor. It didn't tell you which one. It suggested some. It pointed out what other agencies were doing, but it didn't tell you which one. But in the re-evaluation the PMRA continued to use the same one; is that right?

A. Certainly, the Review Board directed us to reconsider, and we did reconsider. And my understanding of the REN is that the evaluators applied our new policy on the application of uncertainty factors and safety factors and, following that consideration, came up with a conclusion that a 10X was still warranted.

Q. I guess all I wanted to do was determine how the PMRA justified its use of the 10X. Was that made part of its determination? Because as I recall the Board of Review, the Board felt that the PMRA use of that additional 10 creating the thousand, creating the unpassable obstacle for lindane to get to the level of acceptable risk was not justified, and therefore I'm wondering--I'm asking you to--

A. Sorry, I didn't mean to interrupt.

Q. I think you understand the question.

17:18 A. My reading of the Review Board Report was not that they found that our selection of the 10-fold to be unreasonable, they certainly indicated that the selection of the additional 10-fold was conservative. But I could certainly cite Section 115 of the Review Board Report where they--where they conclude that the Risk Assessment conducted by the PMRA and the conclusions reached were generally within acceptable scientific parameters. That suggests to me that they did not think that we were wrong in our assessment, but they certainly had a different view.

(Pause.)

Q. I'm just reviewing my questions to see if I have any more, but it won't be much longer.

A. That's fine.

(Pause.)

Q. I just have a follow-up question on that volatilization aspect of things that we were talking about that's mentioned in your second statement at Paragraph 34. The Waite study is what that's about, your second Affidavit, Paragraph 34.

My understanding is that data on volatilization was offered to PMRA in 1999 by Environment Canada, and it was rejected, and I'm wondering if you are aware of that and if you can confirm it for me or not.

A. No, I can't speak to that level of detail, I'm afraid.

17:21 Q. Earlier in your testimony as well on a similar theme, you mentioned that while alpha and beta isomers were declining in the Arctic--I think you called it the CACAR Report, the Arctic Contaminants Report--the level of lindane was steady.

A. In the Arctic Ocean, yes.

Q. Over time, the level of lindane would decline, would it not, if no more was being added to the system?

A. If no more was being added, that's correct.

Q. And so it would decline at a rate that was proportional to what is called the "half-life" of the substance?

A. That's correct.

Q. Were you part of the group that was offered information on lindane half-life by the Chemtura? Do you recall that situation, where half-life information on lindane was offered to you by Chemtura?

A. No, I'm sorry, I don't recall specific details about environmental data and its offering to the PMRA. That goes beyond the scope of my expertise, I'm afraid.

Q. It wouldn't be something offered to me?

A. Not to me in the health group, no.

Q. If it was offered in the course of the Special Review, would you have come to be aware of it? Would it form part of the data that was used to arrive at your conclusion in the Special Review?

17:23 A. I would venture to say it would depend upon the quality and the nature of the data, one would have to assess it to decide whether it's usable. I don't know if this is information that falls into that category or not. It's outside, as I say, of the scope of my expertise.

Q. But since no Data Call-In was made, and since I think you testified at the beginning of 2000 the idea--the agreement or the accommodation had been reached to work with the EPA, that no data at all would have been received by you in 2000 in relation to this or anything else from Chemtura; is that fair?

A. Could you repeat that question, please?

Q. Sure, that was badly put.

A. Sure.

Q. You testified earlier that PMRA decided by the beginning of 2000 to work with the EPA and, therefore, Data Call-In was not necessary because you had so much data available from the EPA; isn't that right?

A. Or we had a significant amount of data available to us, and we were of the opinion that any data that we did not have available to us would be made available to us through our collaboration with the EPA.

Q. So, if a Registrant like Chemtura had approached you with data in 2000, you would have turned it down because you had enough?

A. I don't know that we would have turned it down and

17:24 completely shut the door.

Q. Oh, no?

A. In fact, the occupational exposure study that was sent to us in 2000 from Chemtura we took in. We didn't say, "No, we are not going to take that." We accepted that, but then found when we looked at that information that it was, indeed, information that we already had. So, I would not say that we were shutting the door. I think that's an overstatement.

Q. But you're not aware of any other information in terms of--that you can't cite directly any other information you would have relied on from Chemtura in 2000 in reaching your--

A. I think you will have to ask that question again. I find that question--

Q. Do you recall--sorry, go ahead. I interrupted you.

A. No, please.

Q. You recall to me that you received the Dupree study from them, but it was already in your materials?

A. Yes.

Q. It was a duplicative.

You recall receiving that?

A. Yes.

Q. Do you recall receiving any other information from Chemtura?

A. On the health side, I don't recall receiving anything further directly from Chemtura. I was aware that Chemtura was

17:25 certainly making data submissions to EPA during that period of time, and EPA was reviewing that information and providing those reviews to us, so we became aware of new information that Chemtura had been submitted.

Q. Had submitted to the EPA?

A. That's right.

Q. All right. You're not aware of Mr. Ingulli submitting information to Claire Franklin?

A. Mr. Ingulli submitting information to Claire Franklin?

Q. That's right.

A. I'm not sure what data you're referring to.

Q. Okay. Thank you very much. You have been very helpful. Thanks. I'm done with questions.

MR. SOMERS: Thank you, Madam Chair.

PRESIDENT KAUFMANN-KOHLER: Thank you.

Any redirect questions, Mr. Douaire de Bondy?

MR. DOUAIRE de BONDY: Thank you. I do have just a few questions on redirect.

REDIRECT EXAMINATION

BY MR. DOUAIRE de BONDY:

Q. In the first place, Ms. Chaffey, you were asked about the risk factor that was used by the PMRA in its assessment, and Mr. Somers compared that with the factor, with the 100-level factor that was used for the Occupational Risk Assessment by U.S. EPA.

17:27 What would lead one agency in one country to use a different risk factor than another national agency?

A. Their own policies would dictate what relevant risk factors would be applied. So, in Canada we have a policy, for instance, that says if a additional level of protection is afforded to the general public in a risk assessment, as was the case with lindane, that we would afford the same level of protection to the working population. This is a policy that's in contrast to that in the EPA that basically has an approach where they do not afford their workers the same level of protection as the general public.

Q. Thank you.

Going back to this issue of the additional factor 10 used that led to the thousand uncertainty factor in the case of the Lindane Special Review, can you clarify who selected the additional safety factor, the additional factor 10.

A. It would be the scientific team; that is, my evaluators and myself.

Q. All right. Going back to the beginning of Mr. Somers's examination, he was talking about different criteria for review, and I think they mentioned safety, merit, and value, certainly talking about value.

Are these requirements set out in any governing document for legislation of the PMRA?

A. Absolutely. They're specified both in our old

17:28 legislation as well as our new legislation.

Q. So, the value criteria is set out as a basis for review in your governing legislation?

A. That is correct.

Q. Thank you.

I just had a few questions to ask about the environmental report Mr. Somers referenced. I'm wondering if you could turn to your first Affidavit. It's Volume 1 of 2.

A. Okay.

Q. And if you could turn to Exhibit CC-16B.

A. Yes.

Q. Are you familiar with this document?

A. Yes, I am.

Q. Can you explain what this document is.

A. This document was a document that was prepared by our Environmental Assessment Group back in 1998. It was part of again the scoping exercise that was being undertaken to prepare for the eventual re-evaluation of lindane.

Q. All right. And if you could turn to Page 3 of this document, top of Page 3, it says, "In a personal communication (D. Waite, Environment Canada to K. Curren, PMRA) September 4, 1998, it was reported that lindane volatilized from canola seed within the first week of being planted," and they go on to talk about the results of this field study.

So, is it fair to say that the PMRA was already aware

17:30 of Mr. Waite's study in 1998?

A. Absolutely.

Q. All right. I would like to turn to your second Affidavit--it's only one volume in this case--and I would like to look at Exhibit CC-49.

Now, you see this is another study by Don Waite. Was this study considered by PMRA in the context of the Special Review?

A. Yes, it was.

Q. And what was the date of this study?

A. This study was January 31st, 2000.

Q. So, how does the study relate to Mr. Waite's earlier study in 1997?

A. It was a publication of his earlier findings.

Q. So, you had been aware of his unpublished findings, and then you became aware of his published findings?

A. That's right. And they were subsequently incorporated into our Environmental Assessment that was undertaken both during the Special Review as well as during the REN consideration.

Q. Okay. Why don't we turn to the next tab in your Affidavit, your second Affidavit, CC-50. This is a document dated the 7th of August 2001.

Please go to the second point.

What do you see at the second point?

17:32 A. I see that there is a brief overview of Don Waite's data was given at that conference call. He participated in that conference call and provided information to us in August 7 of 2001.

Q. All right. Let's go to the next document. It's a document the 7th of August 2001. Again, it seems to be more detailed minutes of this conference call.

Can you go to the first agenda Item 1 under discussion.

A. Yes.

Q. What is this suggesting with regard to Mr. Waite's study?

A. It suggested that his data that he generated was pivotal to the Environmental Assessment.

Q. Can we just to complete this turn to CC-52, the next exhibit. This is an e-mail by Derrick François, the 10th of July 2001, it looks like. He said, note--this is in the first paragraph: "Note, I have included a table that outlines the estimated amounts of lindane that would volatilize from seed treatment based on Waite's estimates."

So, what would you take from this e-mail?

A. I would take we took into serious account Waite's findings, and we incorporated those into our assessment.

Q. Okay. All right, just to finish this off these three questions, can you please turn to CC-53, if you could turn

17:34 to--first of all, what is the document at CC-53?

A. CC-53 is the Environment Assessment that had been conducted by the time our occupational exposure review was completed. It is not a complete assessment. It was a document that was--still needed to go through a peer-review process, so in that regard it could be considered a draft document, a draft evaluation.

Q. Okay. And could we turn to Page 6 of this study, please.

A. Yes.

Q. And if we look at the second paragraph under the heading "Mobility," it says, "A field study conducted by Waite et al. 2001 in Saskatchewan demonstrated volatilization of lindane from fields." Feel free to read the entire paragraph, if you need to.

Now, what would you take from the fact that this was referenced in the study?

A. I would take it to mean that this was a critical study in the Environmental Assessment of lindane.

Q. Thank you.

The Claimant has suggested that the PMRA was--that Mr. Waite proposed his study to the PMRA and that the PMRA was not interested in considering that data. What's your view based on these documents we have just looked at?

A. I would say that that's certainly a false statement

17:36 from the Claimant. We certainly took Mr. Waite's research into serious consideration. And, in fact, incorporated it into both the Assessments that we were undertaking on behalf of the Special Review as well later on in the REN document.

Q. Thank you. Those are my questions.

PRESIDENT KAUFMANN-KOHLER: Thank you.

Any questions from the Tribunal?

Judge Brower.

QUESTIONS FROM THE TRIBUNAL

ARBITRATOR BROWER: Looking at Volume 2 of the joint hearing bundle, Tab 41, I think you were taken to this document previously. If we have the right document, it's dated October 2, 1998, in the upper right, and your attention was called previously to a line about the middle of the page, "commitment between EPA and PMRA to work together to phase out all uses of lindane."

I ask you to look at the paragraph above that begins, "EPA is concerned about the continuing use of lindane on canola in Canada, apparently with a view to seeking cancellation of the use. 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."

17:38 Do you know what CEC means?

THE WITNESS: I'm remembering what it is, I'm just trying to--the CEC was a group that was established under NAFTA that dealt with the environmental aspects.

MR. DOUAIRE de BONDY: If I can assist the witness, the Commission on Environmental Cooperation.

ARBITRATOR BROWER: I had "council," but it was the same thing.

In other words, that's a bilateral Canada-U.S. body of some sort?

THE WITNESS: Yes, it is.

ARBITRATOR BROWER: All right. Now--and was there in due course a North American Regional Action Plan under the CEC that dealt with lindane in some way?

THE WITNESS: Yes, there was. I tried to get my dates correct on this. I believe in 1999 the U.S. nominated lindane as a candidate for the NARAP process; and, by 2006, that NARAP was issued, and I believe I have it as one of the documents attached to my Evidence Statements. I would have to go through the indices to tell you where that is, if you would like me to do that.

ARBITRATOR BROWER: Do you recall what the bottom line, as it were, was of that NARAP with respect to lindane?

THE WITNESS: Well, the whole purpose of the NARAP was to restrict the uses of lindane and recall that the remaining

17:40 uses were identified, that being the pharmaceutical use in Canada, the pharmaceutical use in the U.S.

ARBITRATOR BROWER: We talk about pharmaceutical use, but this is basically to combat lice and scabies; right?

THE WITNESS: That's correct. That's correct.

ARBITRATOR BROWER: Thank you.

THE WITNESS: And there were basically a series of actions that were recommended by the NARAP plan to try to mitigate exposures to those products.

ARBITRATOR BROWER: You have been with PMRA since it was established and before that with what you might describe as the predecessor authority in the Canadian Government?

THE WITNESS: That's correct.

ARBITRATOR BROWER: Are you surprised by the language I have just read out and the line ending, "phase-out all uses of lindane"?

THE WITNESS: As a toxicologist, I'm certainly not surprised. Again, I can tell you from my perspective as the evaluation team, I was not instructed to reach any conclusion, but as a toxicologist, I think you would be hard-pressed to find a toxicologist in the world that didn't know that organochlorines as a chemical class are without problems. These certainly had been implicated for many years as being problematic for human health and the environment.

So, if you're asking me if that kind of statement

surprises me, I would have to say on a scientific level it does not surprise me.

ARBITRATOR BROWER: If you would turn to the previous page at the same tab, the cover page, as it were, of facts, you know who is Anne Lindsey, whose name appears at the bottom?

THE WITNESS: She was a Senior Manager at the Environmental Protection Agency.

ARBITRATOR BROWER: Right.

And can you confirm that Céline-Renée Arbique did work in the Executive Director's office of PMRA at the time?

THE WITNESS: Sorry, could you repeat the beginning of your question. I didn't quite hear it.

ARBITRATOR BROWER: Do you see the name in the box Céline-Renée Arbique?

THE WITNESS: Actually, I can't. There's many people at the PMRA. I don't know necessarily all the administrative staff. I--that might have been one of the administrative staff, and I'm afraid that name actually doesn't ring a bell with me.

ARBITRATOR BROWER: Okay. But this looks regular, as it were?

THE WITNESS: It certainly looks like it's a fax cover sheet from the PMRA.

ARBITRATOR BROWER: Okay. I will just add underscoring your reference to Anne Lindsey that Area Code 703

17:43 is Virginia, which is you're going to tell me is where the EPA is located across the river from the District of Columbia?

THE WITNESS: That's right.

ARBITRATOR BROWER: Thank you.

Now, turn to your first Witness Statement, Paragraph 82 on Page 30. On the previous page, Page 29, in the middle, there is a heading "Five reasons for Delay to the Special Review."

THE WITNESS: Correct.

ARBITRATOR BROWER: And the next page, Paragraph 82, the first and last sentences read as follows: "However, it was the linkage of the PMRA's process to that of the EPA that was the primary source of delay," and this is referring to the Special Review.

And the final sentence in the paragraph is, "Consequently, our dependence on the EPA time lines ceased at this point." You're referring to October 2001, "and we were able to conclude our review prior to the U.S."

So, I take it that whatever you were doing in the Special Review was somehow linked to activity or progress in the EPA activities relating to lindane.

THE WITNESS: That's correct. We were actually waiting for data reviews by EPA of information that the Registrant was, indeed, submitting, and the Registrant did not submit that information to EPA until, I believe it was,

17:45 June 2001. So, EPA's own delay was actually precipitated somewhat by the Registrant's delay in submitting that information.

ARBITRATOR BROWER: Thank you. Those are my questions.

THE WITNESS: You're welcome.

MR. DOUAIRE de BONDY: Judge Brower, or Madam Chair, if I may jump in with a clarification just for a moment, just with regard to the documents to which Judge Brower brought Cheryl Chaffey from the hearing bundle. The clarification is simply this is a document at Tab 41 of the hearing bundle. We had advised the Claimant prior to the hearing--I believe it was about two weeks ago--that in putting together the bundle, we realized that the Claimant had actually associated with this fax cover sheet with the October 2nd, 1998, document that follows whereas, in fact, based on our database, the two documents don't go together, and so there would have been some sort of fax sent attached to October 29, 1998, but not the document that follows. And my understanding was that, based upon our information, the two documents would actually be separated in the hearing bundle, but obviously have not been.

If you look on that October 22nd, 1998, document, there is no fax line. The fax of October 29th refers to a seven-page document.

MR. SOMERS: May I speak? I'm sorry, go ahead.

17:47 PRESIDENT KAUFMANN-KOHLER: It struck me, indeed, that these are not the same dates, that the fax cover sheet has a different date than the next page.

So, what is the explanation, and what we are obviously interested in is the second page, and where does it come from?

MR. SOMERS: Madam Chair, I heard my friend say the Claimant associated these documents, which is not accurate. As you see from the bottom right of each page, Page 006700, and the next one, 006701, it was the production by Canada which associated these pages. We received the fax page. We received this one, and then more documents en de suite (ph.). This association was not made by us.

We did have an exchange with counsel. He suggested that these documents did not belong together and suggested another document which might belong, might not. But a three-page document. We pointed out to him that, in fact, the fax track at the top of the first page showed seven pages transmitted. We received no response from Canada. We left the bundle and the production as it was given to us, and it's part of the joint hearing bundle here.

PRESIDENT KAUFMANN-KOHLER: I think the point is not really to blame anyone. It's just to understand where the second page comes from, who is the author, and when was it sent to whom and so on.

MR. DOUAIRE de BONDY: If I may just follow up on that

17:48 quite briefly, the numbers on the bottom of the page reflect the numbers from our production, and they reflect an electronic production, so, you know, I can understand that someone seeing a fax cover sheet and then a document that follows might think that they go together, but, in fact, based upon the coding within our database, they don't. This was--this 2nd, October 2nd, 1998, document doesn't follow.

As far as the document of October 2nd, 1998, to the best of our knowledge, it is a PMRA document.

ARBITRATOR BROWER: Beyond that--

MR. DOUAIRE de BONDY: But we have no information about this particular October 2nd, 1998, document being communicated to EPA.

ARBITRATOR BROWER: And you can't tell any more from the print in the lower left that includes NAFTA?

MR. DOUAIRE de BONDY: I don't know, actually. I think that might reflect some internal computer coding of the generation of the document, but I don't actually know.

ARBITRATOR BROWER: Well, in any event, Canada does not disown this document as being a Canadian--an authentic Canada document?

MR. DOUAIRE de BONDY: No, we don't disown the document. We simply wanted to clarify, you know, the relationship between the two documents, and I didn't suggest that the two documents didn't go together. I confirmed they

17:50 1 didn't go together which was in a communication to Mr. Somers
2 of the 25th of August 2009.
3 ARBITRATOR CRAWFORD: It may be that you can't answer
4 these questions, in that case don't answer them. And I'll ask
5 them to someone else.
6 Was there, to your knowledge, a commitment between EPA
7 and PMRA to work together to phase out all uses of lindane?
8 THE WITNESS: No, no. No.
9 ARBITRATOR CRAWFORD: I'm sorry, the answer is
10 slightly ambiguous. Was there--do you know that there was not
11 such a commitment, or you're not aware of such a commitment?
12 THE WITNESS: I'm not aware of any such commitment.
13 ARBITRATOR CRAWFORD: If there had been a commitment
14 between the two at the Agency level to phase out all uses of
15 lindane and not to permit any new registrations, what would
16 have been the appropriate way, from an administrative point of
17 view, of giving effect to that agreement?
18 THE WITNESS: I don't know how it could have been
19 accomplished from an administrative point of view because the
20 only grounds for which we could take regulatory action against
21 lindane would be on scientific grounds; that is, that there is
22 unacceptable risk from an environment or health perspective or
23 unacceptable value. Those are the only grounds that we could
24 take regulatory action under.
25 So, I'm not aware of any administrative arrangement

17:51 where that could have been accomplished.

ARBITRATOR CRAWFORD: Was the point, then, of your collaboration with EPA in--as reflected in documents like this, if there is nothing you could have done about it?

THE WITNESS: I'm sorry, I'm not quite sure I understand the question.

ARBITRATOR CRAWFORD: You collaborated with the EPA, as you've acknowledged, in relation to the exchange of data.

THE WITNESS: Yes.

ARBITRATOR CRAWFORD: And you relied upon their database in order not to conduct your own Data Call-In.

THE WITNESS: That's correct.

ARBITRATOR CRAWFORD: So, that's an example of collaboration in relation to the review of lindane. It stayed at the level of exchange of data, or did it extend to discussion on questions of policy, to your knowledge?

THE WITNESS: Certainly some matters of policy might have been germane to both agencies. I must emphasize that the majority of our policies are harmonized with the U.S., so there are many elements when we undertake a data evaluation that we have a similar approach to. We have similar data requirements, we have similar guidelines for how studies are to be conducted. So, there is a high degree of harmonization between those countries. But insofar as we have Canadian-specific policies, we have to implement those and make sure that we treat our

17:53 Registrants fairly. So, if we are using those policies to regulate other products, we equally have to apply them to lindane.

PRESIDENT KAUFMANN-KOHLER: To whom should we direct these questions about the policy, cooperation between EPA and the PMRA and specifically this document? Dr. Franklin?

THE WITNESS: Yes, I think Dr. Franklin would be a good choice.

PRESIDENT KAUFMANN-KOHLER: Okay. Thank you.

Any further questions? No?

MR. DOUAIRE de BONDY: Could I just ask one follow-up on a question that Judge Brower asked?

PRESIDENT KAUFMANN-KOHLER: Yes.

FURTHER REDIRECT EXAMINATION

BY MR. DOUAIRE de BONDY:

Q. Ms. Chaffey, Judge Brower brought you to the--I'm on this document that is at the Tab 41 again, and he brought you to the second paragraph, and that paragraph says EPA is concerned about continuing use of lindane and so on. PMRA is not in a position to recommend such action unless there was an agreement for concerted action on all lindane products with U.S. EPA. The consideration of lindane as a candidate for a NARAP under CC was identified as one mechanism for this cooperative action.

Now, my question was simply, after a product--you said

17:54 that the U.S. proposed lindane for a NARAP, North American Regional Action Plan, in 1998. Can you describe the process for the actual adoption of a NARAP. I think you mentioned that it was actually adopted in 2006.

A. Well, actually, it was--the NARAP was concluded in 2006. It was actually accepted as a candidate. I don't know the exact date off the top of my head. I believe it was maybe in the early 2000s. And at that point in time, there was a--it was referred to the Sound Management of Chemicals Committee to do an evaluation, and following that evaluation of lindane, the document was extensively consulted on. It was taken to stakeholders at all levels that included industry as well as the public at large. And following the consultation process, the NARAP was issued in 2006.

Q. So, does the nomination of a product for a NARAP lead necessarily to the conclusion that there will be a North American Regional Action Plan for that product?

A. No. There has to be reasonable grounds to move forward with that assessment.

Q. And those grounds are determined through this consultation process?

A. That's correct.

Q. Thank you.

MR. DOUAIRE de BONDY: Those are my questions.

ARBITRATOR CRAWFORD: Is there any documentation in

17:56 the record on the process by which that NARAP was concluded?

MR. DOUAIRE de BONDY: I believe the NARAP itself describes the process.

ARBITRATOR CRAWFORD: Which is...

MR. DOUAIRE de BONDY: Which is adopted on, if my memory serves, November 30, 2006.

ARBITRATOR CRAWFORD: Sorry, the draft is--do you have a document number for the draft?

PRESIDENT KAUFMANN-KOHLER: While you are looking, I see that Mr. Somers has his microphone on. Any follow-up questions?

MR. SOMERS: One line, please.

PRESIDENT KAUFMANN-KOHLER: Yes.

THE WITNESS: The NARAP document that's located under my Affidavit Volume 1 of two, the first Affidavit, and it's Tab CC-11.

PRESIDENT KAUFMANN-KOHLER: Thank you.

ARBITRATOR CRAWFORD: What's the date of that document? It's 305.

MR. DOUAIRE de BONDY: Actually, not to bear on the Tribunal's timing, we will just give you the reference first thing tomorrow morning?

ARBITRATOR CRAWFORD: Yes.

MR. DOUAIRE de BONDY: Fine.

PRESIDENT KAUFMANN-KOHLER: Thank you. Now,

17:59 Mr. Somers, you had a follow-up question.

MR. SOMERS: Yes.

RECROSS-EXAMINATION

BY MR. SOMERS:

Q. This is referable to Professor Crawford's question to you about collaboration with the EPA. If I could ask your helper to put the joint hearing bundle document Volume 6 of 11 in front of you, that would help. At Tab--I'm going to look. I'm turning to Tab 197, which talks about PMRA EPA collaboration at a meeting that you apparently attended. Volume 6 of 11, Tab 197. This is a draft agenda. It's titled "PMRA EPA lindane conference call, July 30, 2001." And I see in the upper right everyone from Claire Franklin to you is there.

A. Oh, yes.

Q. I'm sorry.

A. That's the right page.

Q. And the objective of that meeting, of which this is the agenda, is to discuss major differences in the outcome of EPA PMRA assessments, and in Roman numeral three, differences see table. That table was never produced.

Do you recall this meeting?

A. I recall the meeting. The table? I can't recall back to 2001 as to there is a table provided at that meeting or not. I'm sorry. I can't recall that.

18:00 Q. Right.
A. I'm sure there must have been, but--
Q. Right. So, I'm with you on that one.
A. I can't remember at this time.
Q. The Point A under that is, "are they resolvable," and I'm not sure what is meant by that. Do you recall what the discussion was about?
A. I think we at that point in time had identified some differences. We knew that, for instance, there were differences in the application of the uncertainty and safety factors as one area, and that at least that was the area that I'm most familiar with, and it's standard practice among scientists when we are doing collaborative work of that to discuss our risk assessment and our findings and what we think those factors should be.
Q. First of all, in the objective you called them major differences, not just differences, and second, you say are they resolvable. Meaning it's not enough to discuss them and find out why they're different, but you wanted to resolve the difference.
A. I think we are asking if they were resolvable. I mean, if they are resolvable, maybe they are. You know, when we undertake dialogue on scientific issues, I think we have to acknowledge that sometimes other people can come up with thoughts you may not have come up with yourself, and that may,

you know, lend further insights into your own evaluations, so part of this was just a natural ongoing dialogue between two regulatory authorities as to the nature of their Assessments.

Q. Yeah, that's part of it, but the other part is resolving the difference, which means working it out and doing away with it to the extent possible. That's where I'm going with the question, but I don't understand you to be aware of having resolved the difference, simply having discussed it?

A. I don't think there ever was any need for us to resolve these. I mean, if we felt that at the end of the day we still had to have these differences because they reflected our own scientific opinions, we could continue to have those opinions and still respect each other's processes.

Q. Thank you.

PRESIDENT KAUFMANN-KOHLER: No further questions?

MR. SOMERS: None. Thank you, Madam Chair.

PRESIDENT KAUFMANN-KOHLER: Fine. Then I thank you very much for your explanations Ms. Chaffey.

MR. SOMERS: I'm sorry, before we break, if we were about to--

PRESIDENT KAUFMANN-KOHLER: Yes.

(Witness steps down.)

MR. SOMERS: With respect, I would like to ask for a point of clarification. Now that our case is essentially in except for our experts, I wondered if the Tribunal could make

clear what exactly would constitute a direct examination so that we don't have to face what we did today for every Canada witness, and there's a lot of them.

PRESIDENT KAUFMANN-KOHLER: It is true that the Procedural Order did not give any specifications of what the direct examination should be except to say that it is there to complete the Witness Statement, if necessary. And I usually explain this by saying that it can happen that facts or information have become known after the Witness Statement of the last Witness Statement of that witness. For instance, the case for the Claimant's witnesses, who have later received a Respondent's Witness Statements and have not been able to respond to this.

And that is actually the main purpose, plus some--some actual facts that have occurred two weeks ago, for instance, and that would need to be addressed, and that is the main purpose of completing the Witness Statement, and the other purpose is simply to ask a few so-called warmup questions for the witness to be more at ease in what can be perceived as a stressful situation.

And I think it would be good if we can stay with these guidelines, will make things more equal.

Mr. Douaire de Bondy, is that acceptable this way?

MR. DOUAIRE de BONDY: Thank you, Madam Chair. Yes, it is acceptable. I think there was a difference of

18:05 interpretation about what complete meant and about warm-up, but that's fine. Our intention in having witnesses give brief comments on their direct testimony in the Witness Statements was simply to assist in communicating some of these technical points to the Tribunal viva voce, but if the Tribunal feels that this would not be of assistance, we'll just stick within the limitations you suggested.

There probably--there may well still be brief questions, but taking into account your clarifications today.

PRESIDENT KAUFMANN-KOHLER: It's really a question of a few minutes. It really should not be more than that because the bulk of the examination is cross, of course, and then redirect, if there were issues arising out of the cross-examination.

ARBITRATOR CRAWFORD: To make the point, you must assume that the Tribunal has read the Witness Statements.

MR. DOUAIRE de BONDY: Yes, Professor Crawford. I'm also aware that some information is more easily digested when the actual Expert or person in question is communicating it viva voce like a Professor before a classroom.

PRESIDENT KAUFMANN-KOHLER: It's just an example, of course.

ARBITRATOR CRAWFORD: Not necessarily a good example.

PRESIDENT KAUFMANN-KOHLER: Fine.

So, any other practical organizational issues?

18:07 MR. DOUAIRE de BONDY: Madam Chair, simply that the short hiatus since we were considering the draft NARAP issue has permitted us to identify the reference, and I think the confusion comes from the fact that the draft in question dates from 19th April 2000, and it's in the record at WS-81 that is attached to the second.

PRESIDENT KAUFMANN-KOHLER: WS-81?

MR. DOUAIRE de BONDY: Yes, the second affidavit of Wendy Sexsmith.

ARBITRATOR CRAWFORD: And the date?

MR. DOUAIRE de BONDY: It's dated, this Commission for Environmental Cooperation document dated the 19th of April 2000.

ARBITRATOR BROWER: Is it in the joint bundle? Is this in the joint bundle?

MR. DOUAIRE de BONDY: I can verify that right now. It may not be.

ARBITRATOR CRAWFORD: It's not.

MR. DOUAIRE de BONDY: If it would be of assistance, we would be happy to provide an additional copy.

ARBITRATOR CRAWFORD: That would be helpful.

MR. DOUAIRE de BONDY: All right.

PRESIDENT KAUFMANN-KOHLER: Fine. Thank you for the clarification.

MR. SOMERS: One more with apologies for the hour. We

18:08 were discussing in my last question arising a table that was not attached but referred to in a document at Tab 41 of the bundle, and--no, I'm sorry, I'm stuck on that number. It was Tab 197 of the bundle.

I'm in the Tribunal's hands, but I would like to make a formal request for my friends in Canada to make us at least a search for that table and produce it, if at all possible, whether that should be done by writing, in writing or verbally today. I would like to do so.

PRESIDENT KAUFMANN-KOHLER: So, you are referring to the table that is referenced in Tab 197 of the hearing bundle 6, Volume 6?

MR. SOMERS: Exactly, exactly, Madam Chair. It's originally the provenance of the document was Exhibit 22 to one of Canada's witnesses, Lucio Dr. Costa.

PRESIDENT KAUFMANN-KOHLER: I think if Canada can locate that table, we would certainly be interested in seeing it, and I think the request is hereby made and granted.

MR. SOMERS: Thank you.

MR. DOUAIRE de BONDY: Thank you, Madam Chair. I would simply note that if table wasn't attached to the document in the first place, it was because the table didn't exist. I mean, one of the problems with this matter is that we are dealing with things that go back to 1999, and things go astray.

PRESIDENT KAUFMANN-KOHLER: I can understand that, but

maybe you can confirm it, and who knows. Maybe you find the table. Maybe not.

MR. DOUAIRE de BONDY: We will make that search. Thank you.

PRESIDENT KAUFMANN-KOHLER: Thanks.

Can we give the times, please.

SECRETARY VINUALES: The Claimant has used so far two hours, and the Respondent five hours and 19 minutes.

PRESIDENT KAUFMANN-KOHLER: Thank you.

And so, now we can adjourn for the day, being understood that tomorrow we will start with--I don't have the direct binder in front--Mr. Chan, then Mr. Worgan, then Mr. Zatylny, and then Mrs. Buth. Is that the program? Good.

So, I thank Mrs. Chaffey, thank you for your patience, and wish everybody a good evening.

(Whereupon, at 6:10 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