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. :
:
- - - - - - - - - - - - - - - - - - - -x Volume 5

HEARING ON THE MERITS

Monday, September 7, 2009

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

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

PROF. GABRIELLE KAUFMANN-KOHLER, Presiding Arbitrator

THE HON. CHARLES N. BROWER, Arbitrator

PROF. JAMES R. CRAWFORD, Arbitrator

Secretary to the Tribunal:

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C O N T E N T S

P R O C E E D I N G S

PRESIDENT KAUFMANN-KOHLER: So, good morning to everyone. I hope you had a good Sunday and we'll have an enjoyable Labor Day now. Make it as enjoyable as possible, right.

Good morning, Dr. Franklin. Thank you for being here.

THE WITNESS: Good morning.

CLAIRE FRANKLIN, RESPONDENT;S WITNESS, CALLED

PRESIDENT KAUFMANN-KOHLER: And I see before we start with your examination we have received the table that you had asked for a few days ago. That's the document. Well, maybe we should give it a number. You will tell us what number it could bear so we can identify it. It doesn't have to be now, but sometime later.

MR. DOUAIRE de BONDY: All right. I can just perhaps add for your convenience that it's--Dr. Costa's Second Report, Tab 22, is the draft agenda of July 30, 2001, which is the document you have on the front page with the handwriting on it on the draft agenda, and that's in the Hearing Bundle at Tab 197. And then the document that's now attached to it, which is a table and it says, "prepared by Victoria in preparation for Claire/Marcia Call July 31, 2001," is the attachment, so it could perhaps be simply included alongside the document, in Dr. Costa's Bundle--Dr. Costa's Second Report Tab 22. It follows.

09:00 PRESIDENT KAUFMANN-KOHLER: So, it is the same document like the one attached to Tab 22 of Dr. Costa--

MR. DOUAIRE de BONDY: Yes, the first--the draft agenda is, and then the table was the missing table that the Claimant had requested that follows.

And as you see, we also provided a second version of this table. This first version was one that we were able to locate in the PMRA's internal paper files, and then we went back to our database, which has electronic copies of all the documents relevant to the matter from PMRA, and found a second version of the table, which is this one without the handwriting on the top of it. And as far as I can see, the only difference is under occupational exposure commercial seed treatment, which is on the first page, the third box from the bottom under main issues or status, the sentence which is incomplete in the first version with the handwriting is completed on that second.

I just had a few other points to make about this. One was if the Tribunal will recall, on February the 2nd, when requests responding to or rather on February 16th, when the Claimant responded to Canada's initial production, it raised a number of what it described as, I believe, deficiencies in our production in the sense of missing bits of letters, whose handwriting this was, could you please provide this table and so on, and this was not among their requests. That's the first point.

09:02 The second point is simply to explain why it wasn't produced. The document, that version that was in our database actually didn't have a date on it and wasn't in the electronic database, which contains thousands of documents electronically linked to the table or agenda for the meeting, which is why otherwise we would have certainly produced it, and it was missed.

And the third and final point is simply that if you look at the version from our electronic database, this is the one "Lindane Summary of PMRA/EPA Issues," without handwriting at the top, you see at the bottom left-hand corner of that document an electronic coding which says "EVHCA Tip," and then there is some numbering, and that tells me that these--this document formed part of a series of documents that were pulled together by PMRA in response to access to information requests and then provided to us to form part of our database of documents, our base de données.

And so, what I was left wondering was, was this document not already produced to the Claimant at some point in the near or more distant past in connection with an access to information request. I wasn't able to determine that over the weekend simply because it's Labor Day weekend, but the Claimant might be able to illuminate us on that point.

PRESIDENT KAUFMANN-KOHLER: Fine. Thank you very much for having done all this work researching this document.

09:04 Any comments on the Claimant's side on this?

MR. SOMERS: Just that the document which is associated with the draft agenda, as counsel has pointed out, Dr. Costa, number two, Tab 22, the table was not accompanying that exhibit. So, if we had been given it, which I'm not aware of, it would have been an orphan document. We wouldn't have known it's the table that's referred to in this document. So, a long trip to come back to thank you. We are grateful for Canada giving us the document.

PRESIDENT KAUFMANN-KOHLER: Fine.

MR. SOMERS: I have one other matter before, and it's not to obtain a resolution necessarily at this time, but to put the Tribunal on notice that we're inquiring about whether--there's some ambiguity in the schedule as to whether there will be actual Closing Argument on Thursday or, in fact, if the Tribunal would prefer to have Post-Hearing Briefs or some combination of those two things. We're beginning to put all the information together to attempt to assemble a Closing Argument that could be delivered in two hours. There is an immense amount of material. Our, and I'm sure Canada's efforts as well, could be better focused if it we knew whether the Tribunal would be asking for formal closing statements or Post-Hearing Briefs.

And I guess just to say it on Claimant's part, a strong preference, just in the interest of coherence and

clarity, would be for Post-Hearing Briefs to amass and organize the immense amount of not necessarily aggregated material and the testimony and in the documents that we have had in the record to date.

PRESIDENT KAUFMANN-KOHLER: We need to have a procedural discussion on this, and I appreciate that it would help you to have it not too late. I can say, and I am speaking under the control of my co-Arbitrators, that the Tribunal certainly would appreciate Post-Hearing Submissions simply because there is a lot of evidence, part of it which is rather technical that will have to be gathered by the end of this hearing, and it will help us a lot if you could systematize this in Post-Hearing Submissions.

But I'm saying this for your consideration, and maybe you can discuss it among yourselves. You can have only Post-Hearing Briefs, or you can have some Closing Argument and Post-Hearing Briefs. Obviously, we can discuss this.

I'm not always sure that post-hearing oral--that oral submissions make sense in addition to written submissions because you improvise more or less your oral submissions, and then you do the real submission in writing, so--but some Parties like to have the opportunity for some closing oral statement.

So can we--I would suggest we leave this aside now, you think about it, and maybe we schedule discussion on this

late afternoon before we close today. It gives us--it gives you time to think about it and gives the Tribunal time to think about it as well over the breaks. Does that make sense?

MR. SOMERS: Sure. Yes.

PRESIDENT KAUFMANN-KOHLER: Good.

Anything else that you wish to raise now?

MR. SOMERS: Not here.

PRESIDENT KAUFMANN-KOHLER: Fine.

So, then, Dr. Franklin, thank you for your patience.

For the record, can you please confirm that you're Claire Franklin.

THE WITNESS: Yes, I am.

PRESIDENT KAUFMANN-KOHLER: You are currently a faculty member at the Cyprus International Institute at Harvard School of Public Health; is that right?

THE WITNESS: That's correct.

PRESIDENT KAUFMANN-KOHLER: You've held positions at the PMRA during the time that we are interested in here, and we have read this in your affidavits.

You gave two affidavits?

THE WITNESS: Yes.

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

Can I ask you to confirm this by reading into the

record the Witness Declaration that you have in front of you, please.

THE WITNESS: Certainly.

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

PRESIDENT KAUFMANN-KOHLER: Thank you.

You know how we will proceed. You will be asked some introductory questions by Canada's counsel, and then we will turn to Chemtura's counsel for cross-examination.

Mr. Douaire de Bondy.

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

DIRECT EXAMINATION

BY MR. DOUAIRE de BONDY:

Q. Good morning, Dr. Franklin.

A. Good morning.

Q. Dr. Franklin, my questions be brief and will relate to three areas. The first is your meeting with Mr. Ingulli of October 4, 2000. The second relates to the two Gaucho products, the insecticide-only products that Claimant submitted to PMRA for registration in connection with the Voluntary Withdrawal Agreement. And, three, brief questions about the Board of Review appointment process.

Now, on my first topic concerning this October 4th, meeting, October 4th, 2000, can you confirm whether you

09:09 attended a meeting with Mr. Ingulli on October 4th, 2000?

A. Yes, I was at that meeting.

Q. And that meeting was arranged at whose request?

A. It was arranged in response to a letter that Mr. Ingulli had sent in July, the previous July, requesting a meeting.

Q. At the meeting, did you discuss issues relating to PMRA's ongoing scientific review of lindane?

A. Yes. There were some issues raised and discussed.

Q. And did you raise the issue of worker exposure in your discussions at the--

A. I did.

Q. What did you say about worker exposure?

A. Well, my intent was to discuss with Mr. Ingulli and other members of his staff that we were aware that steps had been taken in the United Kingdom to remove lindane, and the basis was occupational health.

We were also aware that in the E.U. there was a re-evaluation going on, and that Austria was the Rapporteur country, and occupational health seemed to be arising also as an issue.

And the U.K. took action in '99, so that would have been done prior to the meeting that we had with Mr. Ingulli.

Q. Now, Mr. Ingulli suggested in his testimony before the Board of Review that worker exposure was only raised in passing

09:11 at this October 4th, 2000 meeting, and that you didn't signal that the PMRA had any particular concern about this issue in connection with the ongoing Special Review. Do you agree?

A. Well, my recollection of the meeting is that it was more than a just in passing discussion. The issue, of course, is when I would be at meetings like that, the intent would not be a technical discussion of the science specifically involved, so that I think it's fair to say that most companies would understand if I had raised it that it had worked its way up and that I was familiar with that.

We also had a discussion about some of the ways in which the data were gathered. We use in Canada a database that's called FED, and they use a different database in the U.K., and so there was a discussion. It's interesting in the sense that I actually had been involved with establishing that database, and Ed Johnson was involved during his tenure as the head of the Office of Pesticides Programs at EPA.

Q. Okay. We will come back to that data issue in a moment, but I just wanted to clarify, Dr. Franklin. Were you called to testify before the Board of Review?

A. No, I was not.

Q. Was it PMRA's expectation that the Board of Review would be considering issues relating to the science only?

A. That's my understanding of the context of a Board of Review, the basis for the regulatory decision.

09:12 Q. Since you weren't directly involved in the Special Review, it wasn't expected your testimony would be necessary?

A. I--by the time the Board was actually called, I was no longer working at the Agency, so I'm not familiar with the context for that decision.

Q. But in any event, the Board of Review never heard your evidence about this--

A. They did not, no.

Q. Okay. Going back to this data issue you mentioned in passing, Dr. Franklin, if you could turn to Mr. Ingulli's notes of the meeting, this October 4th, 2000 meeting, they're attached to your first Affidavit at Exhibit CF-12. If you could pick up your first Affidavit. It's the red one, I believe, and it's at Tab CF-12, and it's at the last page of CF-12.

A. Yes.

Q. You're with me. So, at the top it says, "Concerns of PMRA."

A. Yes.

Q. "Worker exposure."

A. Yes.

Q. And Mr. Ingulli goes on to write, "Told PMRA that EPA reviewed and accepted seed treat"--looks like seed treat--"worker exposure study."

To which study is Mr. Ingulli referring here?

09:14 A. He was referring to the study that had been completed in 1992 and done by Mr. Dupree.

He also at the meeting did suggest that Mr. Dupree should send the study to PMRA, and two days later that study arrived at PMRA.

Q. So, at the meeting of October 4th, 2000, Mr. Ingulli himself was encouraging PMRA to rely on the Dupree study?

A. Exactly.

Q. And did he specifically mention it?

A. Yes.

Q. Thank you.

MR. SOMERS: Madam Chair, I hate to interrupt, but this is lifted virtually verbatim from the Witness Statement affidavits of the witness. I'm not sure that this is within the bounds of our understanding regarding direct examination, and I'd like to put that up forward as a question.

MR. DOUAIRE de BONDY: Thank you. I only have two other brief areas of questions, so it should last no more than five minutes, I should think, if that's all right.

PRESIDENT KAUFMANN-KOHLER: That's fine.

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

BY MR. DOUAIRE de BONDY:

Q. Now, I want to turn to my second topic, which is a question about the registration of the two Gauchos. This is

09:15 Gaucho 75ST and Gaucho 480. These are the ones that the Claimant had actually submitted to the PMRA for registration in 1998.

Now, as you know, both of these products were registered by PMRA in October and November 1999.

My question to you, Dr. Franklin, is: Were the PMRA registered products that had no use?

A. No, they would not. That would be contrary to the legislation.

Q. And when you say, "contrary to the legislation," what do you mean?

A. The legislation embodies safety, merit, and value, so that if a product either does not provide efficacy, if it doesn't--if it doesn't impact on whatever. So, if the chemical in this case was to kill flea beetles, we would certainly have to know that it would do that. And the other aspect is the economic impact. There should be benefits that flow from the use of a product.

Q. So, it's fair to say that in order to register a product, the would-be Registrant has to demonstrate the product can be used and has value?

A. That's correct.

Q. All right. So, if you registered Gaucho 75ST and Gaucho 480, it was because they both had value?

A. That's correct.

09:16 Q. Just a specific question, do you know if an insecticide-only Gaucho can be mixed with a fungicide?

A. Well, my recollection, and this goes back a number of years, but my recollection is that Vitavax RS, which was the fungicide component, has a statement on the label that says that Gaucho 480 can be mixed with it.

Q. Thank you.

My third and last area of questions concerns the Board of Review appointment process.

What was the Minister asking the PMRA to do in relation to this Board appointment process?

A. The Minister--

(Pause.)

A. The Minister asked PMRA to identify a range of potential candidates for the Board of Review, and that is standard procedure for the way in which this process is done in Canada and under our legislation.

Q. Okay. You may recall that in about June of 2002, the Claimant brought an application in Federal Court against the Minister, alleging PMRA's involvement in the appointment process was improper. Do you recall that?

A. Yes.

Q. And I understand that PMRA suspended its work on the Board's selecting candidates, pending the outcome of the suit.

Do you recall what happened in May 2003 regarding the

09:17 Claimant's Federal Court application?

A. My understanding is that it took that period of time for there to be a hearing, if that's the correct term, and that in--in around that time the Claimant actually withdrew their requests that this be considered.

Q. So, the Claimant was agreeing and PMRA could be involved in identifying appropriate--

A. That's correct.

Q. So, my question was the Claimant was agreeing that PMRA could be involved in identifying appropriate candidates after all; is that correct?

A. That's correct.

Q. And just to be clear, did any PMRA employees act as members of the Review Board panel?

A. Absolutely not.

Q. Was there ever any question of this?

A. Never.

MR. DOUAIRE de BONDY: Thank you. Those are my questions.

PRESIDENT KAUFMANN-KOHLER: Thank you.

Mr. Somers, now it's your turn.

CROSS-EXAMINATION

BY MR. SOMERS:

Q. Good morning, Dr. Franklin.

A. Good morning.

09:18 Q. My name is Greg Somers, and I'm asking you a few questions this morning on behalf of Claimant Chemtura.

A. Okay.

Q. In relation to the questions that your counsel just asked you about the Lindane Review Board, have you read the Lindane Review Board Report?

A. I have read it, not in intense detail because I was no longer working in the Government when that review came forward.

Q. I take it you don't agree with their conclusions?

A. I don't--in what sense specifically?

Q. In relation to--

A. Which--there were a lot of statements in there. That's a pretty open-ended question, so perhaps you could specify which statements they were making.

Q. All right. It's at paragraph 112 of the Report, and this is in the Joint Hearing Bundle, Volume 9 at Tab 275.

A. And which?

Q. Paragraph 112. I will read it. "Nevertheless"--

A. No, sorry, that's not what I have in front of me here.

Q. Paragraph 112 under Tab 275.

"Nevertheless, the Board is of the view that once PMRA knew its focus in the Special Review was going to be occupational risk, it should have advised Crompton, knowing that the Special Review Announcement made no mention of occupational risk and knowing that all communications it had

09:20 with Crompton were primarily in respect of environmental concerns."

A. Yes, I disagree with that statement.

Q. All right. And I suppose with Paragraph 113 as well. Could you tell me what you think.

ARBITRATOR CRAWFORD: I'm sorry. Why do you disagree with this statement?

THE WITNESS: It indicates in the statement that once we knew the Special Review was going to be on occupational, it should have advised them, and it made no mention of occupational health.

The statement for the announcement of the Special Review was very broad. It indicated a number of things. It indicated that special review was being called because of the issues through the international POPs committees, various groups such as that, and that there were a number of arising issues on health and environment; and it also indicated, to the best of my recollection, that there could be issues that would come up.

This was a very broad announcement. It did not preclude focusing on some aspects.

ARBITRATOR CRAWFORD: Thank you.

THE WITNESS: And I think that it should have advised Crompton. I do think that the meeting that we had both the May 11th meeting that was held with staff from PMRA where, in

fact, occupational health was discussed, and then the meeting that I attended we also raised the issue of occupational health.

So, I would think that it would go without saying that there were several signals that came forward that would fit in under the Statement of the Special Review Announcement.

BY MR. SOMERS:

Q. I'm going now to Paragraph 113.

A. Okay.

Q. Although the process may be different in respect of new evaluations, as compared to re-evaluations, including Special Reviews, the Board feels that PMRA does have an obligation to advise the Registrant of the focus of its inquiry and review. Proceeding in this manner could have led to a more robust scientific inquiry and assessment."

You--

A. I guess I'm not--sorry.

Q. I'm asking you for your reasons for disagreeing with the Lindane Review Board in connection with the obligation that the Board found to advise Chemtura of the focus of your inquiry.

A. Well, I believe that the fact that it was discussed, that the company indicated to us at that meeting that they had a study that that should assuage any of our concerns about occupational health clearly indicates they were well aware of

09:23 this as the process was unfolding, so that--and--and it was also within the context of the announcement that indicated. It's sometimes difficult to be very specific at early stages, but I think it was certainly clear that we had reason to take on a special review.

Q. Could I ask you to turn to your first Affidavit, the red covered one, and turn to--well, Page 6 of that document, please.

A. In the first Affidavit?

Q. Yeah.

A. Okay.

Q. I'm looking at Paragraph 19, and ask you to. I'm just going to read a section from the first part of that.

"Given the information that was publicly available about the approach the Canadian Government was taking to the reevaluation of pesticides, any stakeholder as sophisticated as the Claimant should have been aware that international regulatory action taken on lindane prior to or concurrent with the PMRA Special Review would be given serious consideration by the PMRA."

I then go to Paragraph 22, and I'm reading from the first part of that: "Information concerning the Canadian Government's approach to its re-evaluation program and the ongoing regulatory activities in Europe was publicly available. As such, the significance of the subject of worker safety

should have been evident to all of the participants.

A. Yes.

Q. And so, your testimony is that rather than--well, perhaps not rather than--that Chemtura should have been aware from these sorts of international actions that PMRA's focus was going to be on occupational exposure?

A. The statement is that the significance of worker safety should have been evident to them, and I think that with regulatory action having been taken in another country, it certainly is a flag, a trigger, that worker exposure, worker safety has been a concern.

And they were aware of it. I mean, they were aware of it at the May 11th meeting, as the minutes attest to, and certainly aware of the situation at the October 4th meeting.

Q. I would like to explore with you what they were aware of in terms of worker exposure at the meetings.

A. Yes.

Q. Could you turn to Paragraph 28 of your statement.

There, you state, "I also indicated that worker exposure was generally an area of concern to the PMRA because the use pattern for seed treatments in Canada often differed from that of other countries.

A. Um-hmm.

Q. At least one of those other countries where use patterns differed had been the U.K.?

09:27 A. Yes, that's correct.
Q. And referring back to Paragraph 20 of your Affidavit--
A. Um-hmm.
Q. --the last sentence, you state: "The U.K. review led to an announcement in June 1999 of a ban on seed treatment uses because of concerns about worker safety."
A. Yes.
Q. Are you aware of the differences between use patterns in the U.K. and in Canada at about this time? Do you recall those?
A. That would not be the detail, the level of detailed information that I would be familiar with, what their use pattern was versus the Canadian use pattern.
Q. But in Paragraph 28 you said, "I also indicated that worker exposure was generally an area of concern to the PMRA because the use pattern for seed treatments in Canada often differed."
A. Often differed. That's a very general statement that would not be out of context, that patterns will differ or could differ. That's--
Q. As a general proposition?
A. Just as a general statement.
Q. And so, from that, would Chemtura not have understood that PMRA was concerned about data that would come from other countries in connection with worker exposure that wouldn't

09:28 accurately reflect or precisely enough show the kind of worker exposure issues that you'd have to deal with here?

A. They might have been, but I think you have to recognize that we were not basing or had no intention of basing our decisions specifically on the fact that it was removed in the U.K., we would automatically remove it in Canada. That's the purpose of doing a review.

And that's why in some instances there are different decisions that are arrived at, because something that may be used in one country may not have exactly the same--I mean, the use pattern is what results in exposure, and exposure is really the trigger as to whether you're going to have an unacceptable, potentially have an unacceptable health effect, so it's very important that one understands that.

So that the fact that the worker exposure was an issue when it was being raised would be a trigger to say that that's something that attention should be paid to. It's not that it's to be the basis for the specific decision that's taken, so that we would very clearly be reviewing. And the point of the study that Mr. Ingulli indicated that they had done was for the purpose of saying that we have a study that we believe will satisfy any concerns that you might have about worker exposure.

There was never any discussion of relying and just taking a decision that was done in one country and then applying it to our situation.

09:30 Q. Could I ask you--you're going to need a little help with this. I'm looking at--I'm going to be referring to the Joint Hearing Bundle, and while we're at it, Volumes 2, 3, and 6.

(Pause.)

A. I think the bundles are here. Now it's to find where in these bundles you want me to be.

Q. All right.

In Volume 2, it's Tab 41.

A. Okay.

Q. The document entitled, "Lindane Seed Treatment Update," October 2, 1998.

A. Yes.

Q. You have it.

Do you recognize that document?

A. Yes.

Q. Did you write it?

A. No.

Q. Do you know who did?

A. No.

Q. I wanted to ask you just some questions about it, then.

In the second paragraph, it states: "The EPA is concerned about the continuing use of lindane on canola in Canada, apparently with a view to seeking cancellation of the

use."

Was that--was that usual, typical, or even occasional for the EPA to be concerned about lindane on canola and seeking or any pesticide and seeking Canada to cancel a particular use?

A. I don't think that's what this statement says.

Q. Tell me what you think it says.

A. They're concerned about the use in Canada, apparently with a view in seeking cancellation.

Q. To seeking cancellation; right?

A. Yeah, yeah.

Q. Seeking cancellation of its use in Canada because they're concerned about the issue?

A. In Canada, yes.

Q. Is that typical of the EPA to seek cancellation of use as registered in Canada?

A. I can't answer. I don't know if that's typical or not. I would think the context of lindane one has to consider is that--lindane was a product that, in fact, most of the uses had been discontinued either voluntarily or withdrawn for all aboveground uses, so that by 1990 there were actually very few uses left. There was enormous international activity because of the long-range transboundary movement of lindane, so I think it's fair to say that all countries were very aware of the challenges with lindane and concerns.

And because, of course, you don't have control in one

09:33 country as to what is actually used in another country, these transboundary and these international groups are really seeking ways, legal ways, that one could address the movement from one country to another for these kinds of products. So, that statement may simply be reflective of the international activities in seeking ways to mitigate the movement of this, of Persistent Organic Pollutants in the environment.

Q. As I read the statement, the EPA is seeking cancellation of the use of lindane on canola in Canada. Do you read it differently?

A. Well, they would have no jurisdiction to seek cancellation in Canada.

Q. That's my understanding as well, and so that's why I'm asking you.

A. Nor would I have jurisdiction to effect a cancellation in the U.S.

Q. No, indeed.

And the paragraph goes on, "PMRA is not in a position to recommend such action unless there was agreement for concerted action on all Lindane Products with the USEPA.

In other words, if EPA would agree with you for concerted action on all Lindane Products, you might well be in a position to recommend canceling the lindane on canola use.

A. In a way, I guess I still think that we're not in full agreement on the first sentence because they're concerned about

09:35 the use on canola in Canada. The--seeking cancellation of use can be very broad. I mean, the seeking cancellation of lindane use worldwide was actually to mitigate against the transboundary area, so I think that is perhaps evident with the next statement because, in fact, when we're talking about the NARAP--this is an activity similar to the POPs activity where there are ways of seeking out whether or not the movement across borders is something that needs to be addressed, so that--and I think that what we're seeing very clearly is that, unless those steps are gone through, unless we go through the fulsome process that's available to address whether there are issues that there needs to be regulatory action, our point was that we're not in a position to short-circuit those, that we will address these through the processes and particularly NARAPs and after process.

Q. I'm going to the third paragraph now which begins: "The resulting proposal has emerged after follow-up to this issue both with the Canola Council of Canada and the EPA staff."

And in the third bullet it says, "Commitment between EPA and PMRA to work together to phase out all uses of lindane."

A. Right.

Well, the only thing I can say about that is this is a very short sort of a bulletized form, and there are a lot of

things that are being discussed in that paragraph. And that statement actually comes right after the voluntary removal one, so it's certainly--could be attributed to that, that the uses of lindane in the products that were being targeted through the Voluntary Withdrawal Agreement.

But I think I would refer you back to, if you're looking at that writ large, that, in fact, we have indicated that we would not consider doing anything unless it had been through an appropriate process to see whether it was warranted or not, which was the NARAP process.

Q. I'm sorry, could you refer me to where it says that in this document.

A. It says in the second sentence, in the paragraph above, "is not in a position to recommend action unless there was agreement. The consideration is a candidate for NARAP is one mechanism for this cooperative action."

So, really what we're saying is we need to do this through an appropriate process to see whether or not that's the action that should be taken, and then if the decision through a review such as that is such that cancellation is appropriate that we would work together to ensure that there was a sensible way to have this happening because, if things are phased out--this is all conjectural on the basis of what comes out of that review, but it would certainly not put us in a particularly good position if we were phasing things out at

09:38 different stages, given the whole purpose of the NARAP was to get harmonization.

Q. But the document says, "a commitment between EPA and PMRA to phase out all uses."

A. That's correct. But as I say, this is a very bulletized summary done, I'm presuming, for internal purposes that simply indicates some of these points that are occurring, so I certainly don't read into that that it's a foregone conclusion. We have already stated above that we would only pursue any type of activity subsequent to an appropriate review that would be done through the NARAP process.

Q. In fact, the document says, "The consideration of lindane as a candidate for a NARAP under the CEC was identified as one mechanism for this cooperative action."

A. Right.

Q. Presumably one among alternatives; otherwise, no?

A. I don't know.

Q. All right.

A. I wasn't at the meeting, and I wasn't part of that.

Q. I'm sorry, the meeting? What meeting?

A. Well, whatever--whatever was the purpose of this memo being written.

Q. Oh.

The last bullet in that first cluster of bullets is. "Commitment by both agencies not to register any new Lindane

09:40 Products."

And the fourth bullet in the next set, headed, "Next Steps for PMRA Internal Use," is, "PMRA will hold on any decisions regarding current submissions (lindane-containing products)."

So, reading those two suggests that there was a freeze in effect on any either new or pending lindane registration.

A. That's--that's standard procedure in regulatory agencies when you're entering into a re-evaluation. The issue is such that if you're adding new uses to something--again, I come back to the fact that one of the critical components in doing this is to know what the exposure is. That's a very key parameter that one has to find out when doing a Risk Assessment, so that if you have people--and these are not uncomplicated re-evaluations. There's an enormous amount of information to go through.

So that if you're doing the review and then partway through there is an additional use that's added to it, then all of the calculations that you have done and all of the work that you have done to determine what the exposure is, you have to start over again.

So, that's not--something that's not--that's a pretty standard approach to try to allow the review to go as expeditiously as possible. And as you well know, these are complex--complex--reviews that are undertaken.

09:42 Q. Could I ask you to turn to the next volume in the pile, probably, which is Volume 3 of 11 of the Joint Hearing Bundle.

A. Okay. Which tab?

Q. 117.

You will no doubt recognize that letter. In fact, under 118, the next one was your response to it.

A. Yes, thank you.

Q. The first was the letter of October 27, 1999, and Tab 118, letter of the next day from you to Mr. Ingulli.

Now, you might be aware that Chemtura relied on this exchange of letters after a series of letters between the two of you as evidence of an understanding between the company and the Agency. I actually wanted to get your--your understanding of item four of Mr. Ingulli's letter to you. Again, this is a PMRA EPA sort of issue. I will read for--"In the event that PMRA determines that lindane is safe to be used on canola as a seed treatment or EPA should issue a canola tolerance or determine that lindane is exempt from requiring a tolerance in canola, Uniroyal"--that's Chemtura--"shall request from PMRA the reinstatement of products and uses of lindane on canola that were voluntarily withdrawn."

So, it looks as though, and certainly reads as though, and as I read it, Mr. Ingulli is proposing an either/or scenario that would entitle Uniroyal to reinstatement.

09:44 When you agreed with this in your letter--

A. Yes, we--

Q. Just let me finish the question. It's a transcript issue.

A. I'm sorry.

Q. When you agreed with this, this--these provisions as you said in your letter under Tab 118, you were aware that you were agreeing to either entitlement of Uniroyal for reinstatement if either Agency authorized a tolerance or permitted registration, if the Special Review resulted in a finding of safety or if the EPA issued a canola tolerance, which would imply the same or similar finding there. Is that right?

A. The issue is, I think, what specific aspect of that are you concerned about?

Q. All right. If--did this represent an undertaking by the PMRA in agreeing to this, that if the EPA issued a canola tolerance, you would reinstate the use in Canada?

A. If the EPA issued a tolerance before we had completed our review, then, yes, we were in a position to be able to reinstate. If we had reviewed it and it was not acceptable, and I think that may well be the point on the page before, that if it has adverse effects, that they would not seek reinstatement.

Q. But because your review would not have been completed

09:46 at that time?

A. Right.

Q. You wouldn't have known about adverse effects, so as far as--

A. That's correct.

And, you know, I think the issue with the request that could it be put back quickly was really something that we determined that if the reason that the companies had withdrawn voluntarily was because of the trade issue, and if we had no reason to believe that there were serious unacceptable effects, that we would be prepared to put it back. Now, that could have been a very short-lived period of time because, of course, once the reviews were done, then the potential would be, but we were signaling in good faith that we would--that there was a mechanism for that to be reversed, but it was extremely contingent upon the outcomes of what the re-evaluations were doing.

But it did give that opportunity since they'd voluntarily withdrawn because of trade; that if there were no reason to say that there were unacceptable risks that it could be put back.

So, I think in good faith that was the intent with doing that.

Q. Thank you.

And next, turning to the Joint Hearing Bundle

09:48 Volume 6, now, and I will ask you to do that, this document was the document covering that--the one I'm going to refer to, it's Tab 197 of Volume 6 of the Joint Hearing Bundle. I'm sorry. And it contains an agenda that covered the table, which was the object of some fuss this morning before you started your testimony.

Do you have that?

A. I do, yes.

Q. Oh, okay. I'm sorry. Thank you.

There are several pages under Tab 197--there's two, I'm sorry, of Volume 6, and they're both called "Draft Agenda," but there are some differences between the two. Either they reflect two calls or two different versions.

A. Work in progress.

Q. Right.

This is dated July 30, 2001, called Draft Agenda, and the objective--I'm looking at the very first page--objective to discuss major differences in the outcome of PMRA/EPA Assessments. At the bottom of that is a handwritten notation, "we better go first." Do you know what that might be referring to?

A. No, I haven't any idea, no.

Q. Right. Going to the next page, which is a similar, July 31, 2001, draft agenda, in relation to a PMRA/EPA lindane conference call again to discuss major differences in the

09:50 outcome of PMRA/EPA Assessments.

Is that a customary practice for the two agencies to discuss differences in Assessment outcomes by teleconference in this way?

A. Given that we were working together on this, I think that that would not be anything untoward; that you're really looking to see where you're at, you're looking to see if there are differences, you know. I mean, this is a team. It's like any group of people working together when you're talking about these things that you're looking to see, well, where are you at with this, there is nothing sort of untoward in my view about that kind of discussion with the group of people that are working on something, as has been stated. They're working on this re-evaluation together.

Q. In Roman numeral three of the agenda, it says, "differences, see table A. Are they resolvable?"

A. Right.

Q. So, I'm suggesting to you that it's more than simply comparing notes as to two agencies doing similar things. The two agencies are very, or at least the PMRA is interested in a coordinated outcome.

A. Well, I think that this may be because most of the people involved in this are scientists, and there are always points to be discussed when one is using a large amount of scientific information, and you're looking to see is there

09:51 something that you missed, is there something that somebody else had? There is that kind of to and fro on discussing what's going on.

And, I mean, the point is, maybe they are and maybe they aren't. Maybe somebody found a document that the other group doesn't have, and it would be useful to have that piece of information. I mean, that's the sort of the scientific to and fro that one has in an issue like this, and then it really is a matter of determining, is that the basis if there is a difference. So, in other words, is it resolvable because there is something that was available that wasn't to the other group, or it may not be resolvable.

Q. I'm going back to the--well, on that page of the agenda, there is some handwritten notes on the bottom. And the second bullet has a note appended to it: "Note: Use language on endocrine to support uncertainty factor emphasizing rather than carcinogenicity, et cetera. It may be easier for EPA to support this."

Again, I suggest that that shows an intention on the part of PMRA to coordinate its assessment with the EPA and to accommodate, for example, the differences or the lack--the two Assessments that will emerge in a way they don't contradict each other.

A. Well, I think that when you're working together on something, that is the purpose, that if there is a way that

there is common ground that's scientifically defensible, that one would try to do that, rather than just sort of leave everything hanging out there so that I mean, it's a matter of discussion, and it may or may not be able to be done. That's the purpose of the kind of discussion that's held for these kinds of things.

Science is not so cut and dry, yes or no. There are often all sorts of aspects to take into consideration, and that's really the purpose of scientific discussion. It's not to say that one has to do this or has to do that.

So, I'm not certain I understand your concern about the fact that as a group they were really working together to try to find the scientific truth that would be supportive, so that this kind of dialogue is--that's--there is nothing sort of unusual about that in my experience as a scientist.

Q. I'm suggesting that, in fact, there--rather than this being an objective scientific inquiry, it is a matter of positioning, may be easier for EPA to support this, suggest not an objective comparison of scientific observations, but a managing of the message that would result when the two Assessments are compared.

Go ahead.

A. I'm allowed to speak now? Sorry about that.

No, I mean, that's your view. That's certainly not the view that I would take on the purpose of these kinds of

09:55 discussions, and given that in a toxicological evaluation there are numerous end points that can come into play in the final decision. I think it's really important that one explore. Maybe endocrine is a more important one than something else. That's--that's the kind of dialogue that occurs. That's not a manipulation by any means.

Q. Why would the PMRA be concerned about making things easier for the EPA to support?

A. You know, we were under enormous pressure to try to move forward with this review, so that if there were ways that one could find out the specific end point that would drive the Assessment, I don't think that it's untoward to try to see if that can be brought forward rather than waste or use up an additional excess amount of time to come to that point.

Q. Thank you, but I don't think that was the question. I'll ask it again.

What's the PMRA's interest in making things easy for the EPA to support?

A. You know, I think you're parsing words in the sense that we're--

Q. Oh, all right.

A. And again, these are cryptic notes that somebody is writing down in a meeting. I mean, we were in good faith working with another agency to try to come to scientific truth to support this. We, as an Agency, did not enter into this,

09:57 nor would EPA, that one is going to influence the other in making a decision. One is trying to get all of the scientific facts on the table and see if there is commonality in that. That's the benefit of having larger groups of scientists working together, but it doesn't necessarily make it easier because you're simply going to have more discussion.

But I do believe it drives to the appropriate scientific truth.

Q. Thank you.

Could I ask you to turn to your second Affidavit, the yellow-colored one.

A. That's the yellow one?

Q. Right.

A. You messed with me because my second one that I have at home has a red cover on it.

Okay, sorry. Tab--

Q. Well, no tab. In fact, Paragraph 8, which is sort of the second sheet in.

A. Okay.

Q. And I'm looking at the paragraph under the heading, "Canada Committed to Review Lindane During the Aarhus Protocol Negotiations."

Seven, eight lines down, the sentence begins, "The key is that. The key is that legally Canada could not commit itself at the international level to ban lindane before a

09:59 special domestic review had taken place."

A. Yes.

Q. Can you tell me why that is.

A. We register products under the Pest Control Products Act. And if any action is to be taken against registration, it has to be done under the Pest Control Products Act, which would--we would not ban anything without having a review to see whether that was acceptable or not.

Q. Okay.

A. That's the intent of that statement.

Q. Right.

And so, where Canada could not commit itself at the international level to ban lindane before a special review had taken place, the implication is that after a special review had taken place they could?

A. No. We could take a decision after the Special Review. We couldn't commit to ban before we had done a review.

Q. Right.

A. And we could commit to do a review, and then we would take the appropriate decision based on the outcome of the review.

Q. In terms of either continuing a registration or canceling it?

A. That's correct.

Q. And at that point, would Canada, if the registration

10:00 was withdrawn or terminated, Canada--would Canada be in a position to ban lindane at the international level?

A. If the review--if the conclusion of the review that we had done is that there was no basis to ban lindane, we then would not have been able to sign a Protocol that would, in effect, say that one--that a country was banning it.

Q. Indeed.

And if, on the contrary, if a review would have led to the withdrawal or termination of the registration of lindane, is the converse equally true that Canada could have committed internationally--

A. Canada could--would then have been in a position to sign because it would not have been a registered product in Canada.

Q. Right.

A. So that--

Q. Makes sense.

A. I mean, the whole purpose of this is to be very clear that Canada was not in a position to sign--other countries had already banned lindane, so that they had no problem with signing a Protocol that, in essence, was leading to an overall ban. For them the situation was very clear: It didn't make a difference. It was gone in their country, so they could sign that because, in effect, they had already done that.

We had registered products in Canada, and we had not

done a review, so that there was no way that we were in a position to support a Protocol that, in effect, was going to ban them.

Q. I understand.

A. Okay.

Q. The last sentence in that paragraph states, "This compromised position put us at odds with the European Union, which was pushing for binding phase-out periods."

A. Right.

Q. In other words--well, first, the "us" you referred to there is Canada; is that right?

A. Canada, yes.

Q. And the sense I get from that sentence is that the European Union was pressuring Canada.

A. Everybody was pressuring. I mean, my goodness, countries that had already banned lindane very much wanted other countries that were still using it to stop because, of course, their use could contribute to long-range transboundary, which could then, even though a country had banned it, they could still end up being exposed to it.

So, the whole purpose of these international POPs Conventions was to find a way to deal with it. Our position was that that could well be the case.

But I think it really points out or should point out to everybody that we were not going to take action to ban.

10:03 This wasn't a preconceived idea that Canada had that they were going to ban this, regardless. We clearly stated that we had to do a review to make a decision as to whether a ban was acceptable or not, so that there was not--there was not a--we hadn't taken a decision ahead of time as to what the outcome would be--that was based on the scientific review--despite the pressure from many other countries.

Q. Now, I'm jumping ahead in yellow, second Affidavit of yours, to Paragraph 35 at Page 12. Above Paragraph--do you have it?

A. Okay, Page 12, yes.

Q. All right. Above Paragraph--four lines above the beginning of Paragraph 35, there is--well, I will read from it. "As Ms. Chalifour has also explained, Helix was a good candidate for Joint Review because it was both a lindane replacement and a replacement more broadly for organochlorine and organophosphate pesticides."

And then continuing on Paragraph 35, "For a successful Joint Review, it is critical that there be an early pre-submission consultation among the Applicant and the involved regulatory agencies."

You were involved in the Joint Review process, at least, I assume, at a high level?

A. In establishing it, yes.

Q. All right. When was it established?

10:05 A. The documentation that I have in the--in my statement, I've included the North American Initiative, which outlines in great detail what was occurring. That was '96.

Q. You're not talking--I was asking about the Joint Review of Helix, not the Joint Review in general.

A. Oh, sorry.

Q. Sorry, that wasn't clear, then.

When was the Joint Review for Helix established?

A. I believe it was around the specific date. I think it was November '98, something in that time frame. I could be wrong. I mean, those are not facts that I--

Q. All right. Maybe I'll ask you to turn then to the tab on that yellow Volume CF-25.

A. Okay.

Q. That's a letter from you to Ms. Marcia Mulky of the EPA.

A. Oh, sorry. I'm looking on Paragraph 25.

Q. No, no, no, Tab CF-25.

A. Yes.

Q. And that's a letter from you?

A. Yes.

Q. Do you recall this letter?

A. Yes.

Q. And it may well have been '98, I don't know. But because I turned to the second page of that letter, where it

10:07 states: "You are probably aware that our respective staffs have been meeting with Novartis U.S. and Canadian representatives over several months. The cooperative outcome has been harmonized submissions in both countries covering Helix and thiamethoxim."

So, if the date of the letter is November 18, the respective staffs have been meeting for several months, it was, indeed, at least appears to have been 1998 that it was established.

A. Yes. And your point?

Q. The Joint--this Joint Review of Helix was changed into a workshare program somewhere--at some point in the course of--

A. That's a form of Joint Review, yes.

Q. That's an aspect of the Joint Review?

A. Yes.

Q. I would suggest to you that this sort of intense initiative between the two agencies to single out a single company's product to replace other pesticides would give it an extraordinary market advantage, particularly in the context of what was going on about the product it was to replace in November of 1998. Is that fair?

A. No, I don't think that's fair. I think the issue of Joint Reviews was to address a much broader issue which, in essence, was a trade barrier; that if a product was registered in one country and not registered in another country, then it

could cause enormous challenges.

And that went back to the many, many years before the Agency was even formed. The first Joint Agreement between Canada and the U.S. was a Canada-U.S. trade agreement, and trade barriers were definitely a large part of that initiative.

The Joint Review process that was developed and outlined in the document that I submitted, which really took effect in 1996, was to have a procedure for how this could be done, and there's no question, as was outlined in that document, that this took a lot of discussion not only between regulatory agencies, but also with industry because the challenge to industry was, were they actually going to try to be involved with two regulatory agencies at the same time? One was often challenging enough for industry to deal with, so that it did require a lot of dialogue.

Now, the Joint Review program in initial stages was involved with reduce risk project products, and the issue there being that if there were products coming along that had less risk than other products that were currently on the market, that they would actually be given an opportunity to come in at the same time. And, yes, there were concessions made that this review for these types of products could be done on a shorter time frame.

And from a public health perspective, the intent was that you would then have safer products available so that

people would not continue to have to use products that were not as safe. So, there were a lot of reasons for having a Joint Review process, and the recognition in any new process such as that, that it does take a great deal of discussion.

I had met, along with the head of the Office of Pesticide Programs, with industry as a whole to encourage them to consider putting their submissions into Canada and the U.S. at the same time. Mexico as well, but we were--we were fundamentally capacity building with Mexico to have them participate in this, as well. But the purpose really was to have products that were reduced risk or, as it turned out in the U.S., organophosphorus replacements. And Helix actually met both of those criteria for why there should be a focus on them.

And I'd just like to point out that imidacloprid, which is Gaucho, actually had gone through the Joint Review process, so it had previously availed itself of whatever might be considered to be opportunities and advantages.

Q. The Joint Review of Helix proceeded quickly, considering the category of submissions?

A. Not really. It took twice as long as the performance standard for a Joint Review, so I'd hardly be able to say it proceeded quickly.

Q. Did any Joint Reviews meet the performance standard?

A. Some of them did, yes, yes.

10:13 Q. At the tab that you're at there at CF-25, could I ask you to turn to the next one, CF-26. You'll recognize that document.

And I'm going to Page 19 of that, at Paragraph 1.70.

A. Yes.

Q. At least the Commission--this is a document entitled "2003 Report of the Commissioner of the Environment and Sustainable Development to the House of Commons, Managing the Safety and Accessibility of Pesticides." And in that paragraph, the Commissioner had this to say: "Joint Reviews are not achieving planned gains. The Agency and its U.S. counterpart can share the work of evaluating pesticides because they use similar evaluation processes. Joint Reviews with the U.S. began in 1996 and offered benefits such as reduced trade irritants. They were also expected to make evaluations faster and less costly. In practice, Joint Reviews are not faster for the Canadian evaluators. We noted that the Agency has had problems coordinating priorities and schedules with the U.S. evaluators. It does not know if Joint Reviews have saved it money because it does not track or estimate its costs or level of effort by submission."

A. Um-hmm.

Q. And so, I'll just ask you again to remind myself of what you said. The Helix Joint Review, you said, did not meet the performance standard, and I asked you if--did others meet

10:14 that standard. Do you agree with the Statement of the Commissioner that they have not saved time?

A. The Commissioner is focusing on the fact that the sole purpose of Joint Reviews was to reduce evaluator time. That's not the sole purpose that both of our agencies entered into this. The fundamental purpose of this was to try to reduce trade irritants and find a mechanism to do that so that the auditor has really picked on one piece of it.

And I think that given the complexity of doing any kind of review--given the complexity of doing any kind of--

Q. Please continue. The transcript will reflect everything you say.

A. Oh, I see, I see.

Well, to do any kind of a review--well, now, I have lost my train of thought, so we're even.

(Whereupon, the Court Reporter read back the previous answer.)

A. The point I was going to make there is that the process was available in 1996. We had perhaps one or two submissions so that--and the other complicating aspect is, with an Agency as big as EPA, the group of people that worked on one submission were not necessarily the same group of people that worked on another one.

So that until we had done a critical number of these to, in fact, get all of the reviewers up to speed on this, our

10:17 expectation was not that we were going to meet these performance standards every single time. I think that the timing and the progress and the capacity of this program has continued to grow as time has gone by, and I do believe in the '08 Report the auditor was much more favorably impressed with the strides that had been taken.

I mean, there is no question that the whole process--I started with an Agency in '95 that in fact was multiple departments, and they were all put together under one roof so that we had in a very short period of time an enormous task to do to get everybody up to speed to get new processes in place for the way to do things, and then at the same time to be starting to work with another agency that, in fact, was much more--had been in place for a much longer period of time. This was really quite a challenge for the staff, and they, in my view, rose to the challenge and embraced with enthusiasm doing a lot of these things that I'm sure they must have felt it might have been a lot easier previously before we really started to do this.

And I might add, we were under enormous pressure from all sectors. The environmental groups figured we were too easy. We did things too quickly. Growers figured they never saw the same products as were in the U.S. which, in fact, was not untrue. In many instances they simply weren't sent into Canada, and industry felt that gains should be made and time

10:19 should be faster.

And it's also interesting, at the time we were doing this, the U.S. Government did not have performance standards for the reviews in general. The only ones that they committed to performance standards were for the Joint Reviews.

Q. Could I ask you to turn to Tab in your second Affidavit, Tab CF-19. This point relates to not the last series of questions about Joint Reviews but the issue before that. I'm looking at Page 3 under that tab. Well, the document is "NAFTA TWG on Pesticides Executive Board Meeting."

The TWG on pesticides is a trade Working Group on Pesticides; is that right?

A. That's correct.

Q. Trilateral working group.

On Page 3--

MR. DOUAIRE de BONDY: It's actually Technical Working Group.

MR. SOMERS: Technical? Thank you.

THE WITNESS: Thank you.

BY MR. SOMERS:

Q. Under the heading "Implications" on Page 3, it says "Under our current legislative mandate, Canada cannot at this time agree to the proposed phase-out date of 2005 for the aforementioned minor uses of lindane without voluntary action on behalf of the industry."

10:20 And I'm wondering why you needed voluntary action as opposed to at that point de-registering action, if you will?

A. I'll go back to the previous discussion.

Q. Right.

A. We had not done a re-evaluation, so we were not prepared to have this phase-out, which was part of the props--the POPs Protocol.

Q. But this is the NAFTA.

A. I understand, but this is an update to the NAFTA Technical Working Group on activities that are going on.

Q. Sure, all right. Okay.

So, it is on that same theme as we were talking before?

A. That's correct, yeah.

Q. So, and then that paragraph goes on, "Although Registrants are showing some interest in discontinuing the uses, one Registrant intends to maintain the registration, see Appendix 1."

Appendix 1 wasn't provided, but we could probably guess who that Registrant was.

A. Gee, I wonder.

Q. So, at this point PMRA was in a position where it was interested in or being--I might put it another way. It was under pressure to phase out lindane, and it could not do so absent a voluntary withdrawal by the industry or a scientific

10:21 re-evaluation and, if found unacceptable, a termination of the registrations; is that right?

A. That's correct.

Q. Thank you. That's all my questions.

PRESIDENT KAUFMANN-KOHLER: That completes your cross-examination?

MR. SOMERS: It does, Madam Chair, yeah.

PRESIDENT KAUFMANN-KOHLER: Any redirect questions?

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

REDIRECT EXAMINATION

BY MR. DOUAIRE de BONDY:

Q. I have just one redirect, Dr. Franklin.

If we could go back to the document Mr. Somers just brought you to, the one that's CF-19, that's in your yellow Witness Statement there, he had brought you to a paragraph on Page 3 that says, "Implications, and it said--it says, "Under our current legislative mandate, Canada cannot at this time agree to the proposed phase-out date of 2005 for the aforementioned minor uses of lindane without voluntary action on behalf of industry." It goes on, "Although Registrants are showing some interest in discontinuing the uses, one Registrant intends to maintain their registration (see Appendix 1)." So, there's a reference to minor uses.

If you go back to the previous page, you see at the bottom of the page, and you see the paragraph, "There is a

10:23 strong concern associated with some of the minor uses for lindane (namely tree plantations, lawn use, indoor and outdoor use for nursery stock and ornamentals). For these uses, a phase-out date of December 31, 2004 has been proposed, and has strong support from other parties. Canada is isolated in supporting the occlusion of these uses in the Protocol and is under significant pressure to agree to this deadline during the December negotiations".

So my question is simply, when--the reference under "Implication" to the aforementioned minor uses of lindane and Registrants are showing some interest in discontinuing the uses, those minor uses don't include the canola application.

A. You're correct. I misspoke on that. You're absolutely correct.

Q. Right. Because, in fact, the canola use was the main threat--

A. Not a minor use in Canada, yes.

Q. Thank you. Those are my questions.

A. My apologies for that.

PRESIDENT KAUFMANN-KOHLER: Thank you. Does the Tribunal have questions? Judge Brower?

ARBITRATOR BROWER: No.

PRESIDENT KAUFMANN-KOHLER: Professor Crawford?

ARBITRATOR CRAWFORD: Yes.

PRESIDENT KAUFMANN-KOHLER: Please.

10:25 QUESTIONS FROM THE TRIBUNAL

ARBITRATOR CRAWFORD: Dr. Franklin, during your time at the PMRA, how many Boards of Review were there?

THE WITNESS: Boards of Review--I'm sorry, I have to get my head right.

I don't believe there were any others.

ARBITRATOR CRAWFORD: So, this Board of Review in relation to launder was the first one that you're aware of?

THE WITNESS: For the Agency, yes.

ARBITRATOR CRAWFORD: For the Agency.

THE WITNESS: I might add, they're not very frequent for the whole history of pesticides registration. It's quite an infrequent happening.

ARBITRATOR CRAWFORD: The request from Crompton for the Board of Review, the first request, was on the 18th of February, 2002, and the Board of Review was established in May 2004. Now, obviously the Board of Review was not asked to look at any procedural question about its own constitution, but why did it take more than two years to establish the Board?

THE WITNESS: To name the members? The bulk of the time would be because of the timeout because of the Federal Court request that the company had made, the challenge that they had to the Minister asking PMRA to name or propose names for the Minister to make a determination.

ARBITRATOR CRAWFORD: Following the withdrawal of the

10:26 Federal Court proceedings, which you mentioned in your testimony, did the PMRA actually make recommendations to the Minister's composition of the Board of Review? Maybe this was after your time, so maybe you don't know the answer.

THE WITNESS: I'm sorry, I don't specifically know whether there were names that were put forward before. I think that maybe--I just don't remember the specific time sequence on that.

ARBITRATOR CRAWFORD: You left the PMRA in 2003.

THE WITNESS: '3, yes.

ARBITRATOR CRAWFORD: Thank you. I have no other questions.

PRESIDENT KAUFMANN-KOHLER: When we were discussing earlier the draft agenda for the July 30th, 2001, meeting, which is Tab 197 in Volume 6, if you want to go back to it, you said we were under enormous pressure to move this review. You have spoken about pressure at different times in your testimony, but it is a recurrent theme.

Were you--who was pressuring you?

THE WITNESS: These would be internal. I mean we--with performance standards or target dates or something, we really do try to meet those so that we are actually putting pressure on ourselves to meet the time frames that we've committed to.

Now, there is no question that when there is a target

10:28 to do something, you make every effort to meet it, but you cannot make a decision simply because a certain date has been picked on it.

So, this really would be internal pressure that we had in good faith made a commitment to do things, and we really did want to move things forward in an appropriate time. There would be no external pressure on that, other than the companies in many of these instances saying, well, when are you going to get it done, but...

PRESIDENT KAUFMANN-KOHLER: Though you also spoke of the international activities around lindane and the pressure that was putting--that these activities were putting on PMRA.

THE WITNESS: On Canada.

PRESIDENT KAUFMANN-KOHLER: On Canada.

THE WITNESS: Yes.

PRESIDENT KAUFMANN-KOHLER: Was Canada late in taking action about lindane compared to other countries, or how do you explain this?

THE WITNESS: No. There were a range of--the position on Lindane Products in a range of countries varied, and so that the countries that had taken action were definitely anxious to see that other countries would follow suit, but Canada was not--we were not the only country that had not finalized action on these products.

PRESIDENT KAUFMANN-KOHLER: Thank you.

10:30 Then I would like to go back to the letter of the 27th of October '99, which is a letter from Mr. Ingulli to you, which you answered the next day, basically, by agreeing to the terms of the letter. It is Volume 3, Tab 117, if you want to go back to it.

THE WITNESS: Yes.

PRESIDENT KAUFMANN-KOHLER: You were asked about Paragraph 4. And if I understand you correctly, you said that this meant that if the EPA were to issue canola trial runs, then you committed to reinstate lindane for canola until--assuming your Special Review was not completed.

THE WITNESS: Correct.

PRESIDENT KAUFMANN-KOHLER: Until completion of your Special Review. If that came to a negative decision, then this reinstatement would lapse, expire? Is that--because I'm not completely sure how this works. But if you read Paragraph 4, it does say, "PMRA agrees to grant such reinstatement without any other preconditions, including the possibility that PMRA has not completed its re-evaluation."

And so, I am not clear what that means, is including the possibility.

THE WITNESS: The mechanism for putting--lindane--the product that was registered had lindane in it and two other chemicals. What industry requested was that the--it was a label change, that lindane be taken out of the product and that

10:32 it was still called the same thing, but it now only had two chemicals in it. That's a relatively straightforward type of action.

Our commitment was there was a mechanism that would allow us to put lindane back on the label under the kind of circumstances that it had been taken off, so then it would be a registered product that had lindane in it.

If the outcome of the Special Review indicated there were unacceptable risks, then we would go through the normal procedure for suspending or canceling registrations. It wouldn't utilize that process. That one was take it off and put it back on for the voluntary situation. But if the review indicated that it wasn't acceptable, then we would proceed with the standard way of taking action.

MR. DOUAIRE de BONDY: If I can just help avoid some confusion here, I believe when you mentioned taking lindane off the label, my understanding is that it was taking canola off the lindane Product Label and then potentially reinstating the canola product.

THE WITNESS: No, lindane was not part of the product.

PRESIDENT KAUFMANN-KOHLER: Are you simply referring to Paragraph 1 of this letter?

MR. DOUAIRE de BONDY: Yes.

PRESIDENT KAUFMANN-KOHLER: And Paragraph 4 would be undoing Paragraph 1?

10:33 THE WITNESS: Yes, but in addition to taking canola off--yes, I mean if the product--I see what you're driving at. If that product is registered for a number of different uses, then the other uses would still remain, so--

PRESIDENT KAUFMANN-KOHLER: That's clear, thank you.

If we look at Paragraph 2 of this letter, it speaks about the review by the end of 2000. The review was not completed by the end of 2000. Canada's position is that this is not a time limit, but it's a target date.

THE WITNESS: It was--

PRESIDENT KAUFMANN-KOHLER: Now, why? Is this the way you understand it, and if so, why?

THE WITNESS: It was stated at the very beginning with the Voluntary Withdrawal Agreement that it was a target, that the re-evaluation would be completed in 2000. There are circumstances beyond which one doesn't always have control, so that you can't--you can't guarantee, and that's not--that's not the kind of language that's utilized when we make a commitment such as that.

PRESIDENT KAUFMANN-KOHLER: When you say it was said or agreed at the time of the Voluntary Withdrawal Agreement, then you refer back to the November '98 letter of the Canadian Canola Growers Association? Is that what you had in mind.

THE WITNESS: Do we have--

PRESIDENT KAUFMANN-KOHLER: Just by reading the letter

10:35 of the 27th of October, it is not obvious that it is a target date, or is it?

THE WITNESS: It had been stated many times that it was a target date; and, for any commitment for a re-evaluation, one would give a target date to be completed. There could be circumstances that would prevent that from happening, and so that--I mean, that certainly--we could--it's the same way--we can never guarantee we're going to give a registration to something. We can guarantee or make a commitment that we will do the review, but one cannot determine what the outcome is going to be.

PRESIDENT KAUFMANN-KOHLER: It's a different thing to commit to an outcome or commit to a time line. You could have committed to the time line without committing, of course, to the outcome. That's obvious.

THE WITNESS: That's correct. I mean, we targeted that that would be the time frame that we were doing this review in collaboration with the U.S., and that, unfortunately, we were not able to maintain that target, that time target.

PRESIDENT KAUFMANN-KOHLER: Thank you.

So, these were all my questions, but maybe you have a follow-up question.

ARBITRATOR BROWER: Looking at the same document, this is dated October 27, 1999. You have said basically what you regard as the original Withdrawal Agreement was approximately

10:37 one year before that, and at that time you set a target of also end of 2000 for the scientific assessment of lindane. A year later, when this was written, was that review on track to be completed by the end of 2000?

THE WITNESS: That, I can't say with certainty because it was in progress, that we certainly were still working towards having it done by that point in time. It's not--I don't have at my fingertips when it became readily apparent that that would not be a possible target date to meet.

ARBITRATOR BROWER: You should understand that the Claimant takes the position that in respect of the Claimant, Chemtura, this exchange of letters between Chemtura and you of October 27 and 28 constitute their Voluntary Withdrawal Agreement, and that the Agreement is in the terms set forth, namely at the end of paragraph--that the Paragraph 2--you will provide a scientific assessment of lindane by the end of 2000. It wasn't qualified there.

THE WITNESS: That's certainly correct the way this is written, but I also think that there were--there was such a very large number of letters that were exchanged in and around this time, and we kept coming back, as I did in my response in this letter, that this is remaining supportive of the Voluntary Agreement, so that we didn't necessarily--we, I don't think in any way, at least I certainly myself, did not construe this as a contract. This was the--we were looking to see whether or

10:40 not the company was going to--because there had been many iterations of what they were or were not going to do over the period of time that--from when the--when they actually publicly at the meeting said that they agreed with the Voluntary Withdrawal Agreement.

And subsequent to that, over the next year, there were numerous letters at which there were a range of agreements, not take it off the label, keep it going longer, et cetera.

So, what we were looking for in this was were they meeting the time frames, were they agreeing to the time frames, but again we keep bringing them back to the fact that it's the Voluntary Withdrawal Agreement that had been negotiated by the canola group. That was the driver for this.

ARBITRATOR BROWER: Well, if you look at your letter, which is at Tab 118.

THE WITNESS: Yes.

ARBITRATOR BROWER: It says, "I am confirming that PMRA is in agreement with both your stated commitment to voluntarily remove canola/rapeseed from the product labels Uniroyal Chemical Company seed protectants that contain lindane by December 31, 1999, and the provisions that are outlined in the October 27th letter received from you by fax."

THE WITNESS: Yes.

ARBITRATOR BROWER: So, on the face of it, you accepted--this is the position they take, and on the face of

10:41 it, you accepted to provide a scientific assessment of lindane by end of 2000 as of this writing in late October.

THE WITNESS: We certainly were still in--working under the basis that we would be able to meet it, but I think because we had so frequently stated that this was a target that we did not feel that it was necessary to keep repeating the same thing, that this was a target.

And, in fact, I believe there is internal company letter that does indicate that we cannot be held accountable for things that are beyond our control, such as if the time frame for the re-evaluation that EPA was doing starts to slip, there is no way that we have no control over that, so the company themselves already had acknowledged that internally.

ARBITRATOR BROWER: Thank you.

PRESIDENT KAUFMANN-KOHLER: Fine. If there are no further questions, then I would like to thank you very much.

MR. SOMERS: Excuse me, Madam Chair.

PRESIDENT KAUFMANN-KOHLER: Do you have a follow-up question?

MR. SOMERS: I have follow-up question from Professor Crawford's question.

MR. DOUAIRE de BONDY: And I have a couple of follow-up questions.

THE WITNESS: Thanks for trying.

PRESIDENT KAUFMANN-KOHLER: Yes, please, Mr. Somers.

10:43 MR. SOMERS: Thank you.

RECROSS-EXAMINATION

BY MR. SOMERS:

Q. Could I ask Volume 7 of the Joint Hearing Bundle be put in front of the witness. I'm not sure if you have it.

A. I have two, three, six.

Q. Then I want seven.

I'm going first to Tab 245 In Volume 7. This is a letter dated May 6, 2002, from the Minister of Health to Mr. Michael L. Phalen of Ogilvy Renault. In it the Minister states, "Thank you for your correspondence of February 18 and March 14, 2002, regarding your client's requests for review of certain decisions under Section 23 of the Pest Control Products Regulations. Crompton Company/Compagnie requests have been referred to the Pest Management Regulatory Agency for appropriate action. Therefore, you may wish to direct further communications on this matter to the Agency's Executive Director, Dr. Claire Franklin.

A. Right.

Q. Now, I'd like you to turn, if you would, to Tab 247. This is Michael L. Phalen, counsel for Chemtura's response to the Minister. Second paragraph, "We are unclear as to the meaning or intent of your letter. It would appear that either you intend the PMRA to appoint the Board for the purpose of conducting the reviews contemplated by the Regulations or that

10:44 you intend the PMRA itself to conduct the review. Either interpretation offends principles of fairness and reasonable administrative decision making."

You were at the PMRA at this time?

A. At this time, yes.

Q. And so, at the time that the Board was actually appointed, though, were you still at the PMRA at that time?

A. I don't--what's the date that it was appointed?

PRESIDENT KAUFMANN-KOHLER: May 2004.

THE WITNESS: Pardon me?

PRESIDENT KAUFMANN-KOHLER: May 2004.

THE WITNESS: No, I was not.

BY MR. SOMERS:

Q. So, you weren't there yet.

A. No.

Q. And so, are you aware of the mechanism or the means or the methodology that was used to appoint the members of the Board?

A. The methodology which we were using was to provide a list of names to the Minister's office, have the Minister determine whether or not these were appropriate names, and the letters, I believe, also went from the Minister to the Board members.

Q. Now, you said the mechanism that we were using. At which time? Once the Board was eventually entrained to be

10:46 appointed?

A. The process had started while I was there, that the Board would be--that names would be provided to the Minister and the Minister would then determine which Board members she felt comfortable, and the letter would go from the Minister. The question that was asked earlier was, had I submitted names before I left or after. That, I must say, I just don't remember that, but I do think that I was involved along with some other people to get an idea of people who might have the--remembering that this was to be a scientific review, people who would have scientific expertise in doing Risk Assessment, so that the names that were considered would be people that would have that kind of background.

Q. You'll agree with me in any event that the concerns of the counsel for Chemtura which led to the Court action which led to the Minister freezing all action on the file and a year of delay, the concerns of counsel were not that the PMRA was involved, but that the PMRA would either appoint the Board or that the PMRA would be the Board, and that's what this letter at Tab 247 makes very clear.

A. Right, right.

And I would contest that their concerns were unfounded because that was not the case.

Q. Did you respond at any point to the company as far as--

10:47 A. I did not have any direct, that I recollect, any direct correspondence with the company over appointment of the Board.

Q. Do you know whether the Minister responded to this letter of June 3rd, 2002, at Tab 247?

A. I think they filed action before she had a chance. They filed, I believe, if memory serves me, on the 8th. That would be unbelievable speed for a letter to come from a Minister's office, and so that my recollection is that they actually filed before the Minister had an opportunity to respond and to clarify the situation.

Q. Under Tab 248, the filing date appears to have been June 12, actually.

A. June 12.

Q. Still, unbelievable speed for your Minister?

A. For any Minister, yes.

ARBITRATOR CRAWFORD: If I may make a comment, it's a great pity that the Minister didn't respond because the first letter from the Minister was inappropriately formulated. The Minister should have said, of course not. I make the appointment. I'm simply asking for advice on the members.

THE WITNESS: Yes.

ARBITRATOR CRAWFORD: And it would have saved you a lot of time.

THE WITNESS: But the Minister may have thought that

10:49 the Claimant would be familiar with the legislation, which does indicate, I believe, that this Board is appointed by the Minister.

But you're right. I mean, I think that that's something that could perhaps--and I understand why a Claimant would be concerned, that if the group that's done the review is the one that's going to do the larger review, but that was never the intention.

ARBITRATOR BROWER: Just an aside, if American experience is at all relevant, the Minister never saw that letter except to sign it and it was prepared by his Executive Assistant.

THE WITNESS: If I might add, this particular Minister McClellan was extremely bright, very interested, so I'm not sure I would agree that that would be the situation for this.

And also the fact that Boards of Review were so infrequent that I would be surprised if she did not see that.

MR. SOMERS: Just one more question.

PRESIDENT KAUFMANN-KOHLER: Any further questions? Yes.

BY MR. SOMERS:

Q. In conclusion with the--that oft referred to November 24th, 1998, meeting amongst Registrants, Canola Council, and PMRA individuals, you weren't at that meeting, were you?

10:50 A. No.
Q. Thank you.
PRESIDENT KAUFMANN-KOHLER: Mr. Douaire de Bondy, you said you had questions as well.
MR. DOUAIRE de BONDY: Just a few follow-up questions.
FURTHER REDIRECT EXAMINATION
BY MR. DOUAIRE de BONDY:
Q. Dr. Franklin, when the Tribunal was asking you a few questions, they were asking about this reference in the letter of October 27th, 1999, in the Joint Hearing Bundle at 116, number two, the second comment, in accordance with any data call-in at regulatory requests and provide--
A. Could you tell me where you are at as well.
Q. Sure. I'm in this third hearing bundle. Sorry. I'm going to quickly.
And I'm at Tab 116.?
A. Yeah.
Q. And I'm at point two, and the point here was simply this was about the timing for the outcome of the Special Review, and it says, by the end of 2000.
Now, you mentioned that there had been frequent references to 2000 being a target date, and I just wanted to turn you to Joint Hearing Bundle Volume 2.
A. Yes.
Q. Okay. And it's at Tab 88, which is the Special Review

10:52 Announcement, so this would be the document that was establishing the terms for the Special Review.

And I'm just wondering if you could look to the last page, the paragraph where it ends. Can you confirm--

A. The target date for completion is December 2000, yes.

Q. So, when you mentioned earlier that you had said 2000 was a target date, was this one of the things you were referring to?

A. It's definitely there.

Q. All right.

A. It's right out of the block it says target date.

Q. All right. And if we could turn to the next tab in the same bundle, it's Tab 89, this is a letter you wrote to Mr. Ingulli. It's Joint Hearing Bundle 89, it's Exhibit WS-28. Letter of March 25th, 1999.

And again, if you could turn to the second page of the document, the first paragraph.

A. Right.

Q. Could you tell us what you say there about the timing for the Special Review.

A. PMRA has recently announced a special review of all uses of lindane, with a completion target of December 2000."

Q. Okay. So was this a document you were thinking of again?

A. Yes.

10:53 Without being able to specify dates for them, I know there were numerous...

Q. Just in general, would you expect a--would you think it was a reasonable expectation on the part of a Registrant for a complicated scientific review to finish come heck or high water, if I can put it that way, by the end of December, by a specific date, would that be a reasonable expectation?

A. Well, if one looks at the track record in regulatory agencies for re-evaluations, I think I would have to agree that it is not a reasonable expectation because there is frequently additional information or other issues that arise once the review is started that are beyond the control of the people doing the review.

I believe for one thing that one of the studies that was to be submitted was actually from the company was late. I think these were some of the data the U.S. had requested. And if memory serves me right, they were late on submitting the carcinogenicity study well beyond 2000, so that obviously would be a sufficiently important end point that one could not complete a review without having that information.

Q. Okay. Let's go back to this letter of October 27th, 1999 in the Volume 3 of the Joint Hearing Bundle Exhibit WS-40, and again we are back at Paragraph 2. Are you with me?

A. Number two?

Q. Yeah.

10:55 A. Yes.

Q. So, document 116, and it starts, "PMRA and EPA shall coordinate and collaborate on the timely review and re-evaluation of any new lindane data already submitted," and so on, "and provide a scientific assessment."

So, your understanding is that the Registrant Chemtura was requesting as part of its series of requests here that the PMRA collaborate with EPA on the scientific review?

A. Yes.

Q. Okay. I'm sorry to flip you around in documents so much, but if you could turn now to the Joint Hearing Bundle at Tab 162.

A. Which bundle?

Q. We will get to that.

It looks to me like it would be Volume 4; is that right? 5, sorry.

A. I either have to take something out or get a higher microphone here.

Q. So, we are at--

A. Tab 162?

Q. Yes.

A. Okay.

Q. It's Joint Hearing Bundle 5, Tab 162. This is a document that was originally produced by Canada as Exhibit WS-89 to, I believe it's Wendy Sexsmith's second

10:56 Affidavit, and it's an E-mail from Rick Turner, who is of Gustafson--that is the Claimant's--one of their companies--dated the 14th of December 2000.

And I just wanted you to look down to the third sentence. It says, "As I read and recall, the Withdrawal Agreement PMRA had committed to a review by of lindane by December 2000. EPA was slated to have their review completed by October. While December has not yet expired, I do not know how PMRA can complete their review because they were relying on EPA Assessment as part of their Special Review process."

Now, you said earlier you remembered internal documents that showed the Claimant itself understood the PMRA review had been delayed because of their collaboration with EPA. Is this what you were referring to?

A. Yes, and I do think there was an original letter as well that reiterated that.

Q. So, it's fair to say that the condition of collaboration that the Claimant itself asserts it was imposing was the reason why the date was slipped from late December to October 2001?

A. Yes.

Q. Okay.

Just a general question, now you know that the Special Review came out in October 2001 because data from USEPA on the toxicology side was brought together with occupational exposure

10:58 data and that the PMRA Special Review team reached a negative result.

I'm just wondering if the data had been delivered to PMRA any earlier; that is, if the Special Review results had been issued any earlier, would it have made any difference to the outcome of the Special Review in the sense that, based on the same data, would PMRA have reached a different result if it had the data in hand a few months earlier?

A. I think that's highly unlikely that they would have reached a different decision. The action simply would have been taken earlier.

Q. So, in other words, the delay--well, let's go back to the results of the Special Review.

As a result of the Special Review, the PMRA was required to--requests of Registrants voluntary suspension, and in absence of that suspension--

A. Voluntary withdrawal or suspension.

Q. Or suspension, right.

So, up to the time this Special Review results were released, Chemtura's other Lindane Products remained on the market?

A. That's correct.

Q. So, if the Special Review results had been released any earlier, it simply would have led to an earlier suspension or withdrawal of their remaining Lindane Products; is that

10:59 correct?

A. That would be my conclusion as well, yes.

Q. All right. Those are my questions.

PRESIDENT KAUFMANN-KOHLER: So, that was a redirect after the recross. If you still have question, it is, of course, fair that I give you the floor.

MR. SOMERS: I'm grateful, Madam Chair, but I think this ground has been tread several times already. Thank you.

PRESIDENT KAUFMANN-KOHLER: Thank you.

No further questions. Then this time I can release you.

THE WITNESS: You're sure now?

PRESIDENT KAUFMANN-KOHLER: I'm sure now, yes.

Thank you very much, Dr. Franklin.

THE WITNESS: Thank you.

(Witness steps down.)

PRESIDENT KAUFMANN-KOHLER: We will take a 20-minute break, and then continue with Dr. Costa; right?

(Brief recess.)

LUCIO COSTA, RESPONDENT'S WITNESS, CALLED

PRESIDENT KAUFMANN-KOHLER: Professor Costa, good morning.

THE WITNESS: Good morning.

PRESIDENT KAUFMANN-KOHLER: You're Lucio Costa?

THE WITNESS: Yes, I am.

11:25 PRESIDENT KAUFMANN-KOHLER: You're a professor of toxicology at the University of Washington in Seattle.

THE WITNESS: Yes.

PRESIDENT KAUFMANN-KOHLER: You have given two expert reports in this arbitration?

THE WITNESS: That's correct.

PRESIDENT KAUFMANN-KOHLER: As an expert, you are under a duty to make only such statements that are in accordance with your best belief. I think that's what the declaration says. Can you please read are it into the record to confirm that you understand such duty.

THE WITNESS: I'm aware that I'm heard as an expert witness in this arbitration, and that I'm under a duty to make only such statements which are in accordance with my sincere belief.

PRESIDENT KAUFMANN-KOHLER: Thank you.

You know how we proceed because you have heard the hearing earlier on today. I will now turn to Mr. Douaire de Bondy for some introductory questions.

MR. DOUAIRE de BONDY: Thank you, Madam Chair. I'm actually going to pass the floor to my colleague, Mr. Kurelek.

DIRECT EXAMINATION

BY MR. KURELEK:

Q. Professor, I just have one question for you: Do you adopt and affirm the contents of your two expert reports filed

11:26 in this action?

A. I do.

MR. KURELEK: That's my only question, Madam Chair.

PRESIDENT KAUFMANN-KOHLER: Please.

CROSS-EXAMINATION

BY MR. SOMERS:

Q. Good morning, Dr. Costa. My name is Greg Somers, and I am representing Chemtura in this proceeding.

Before I start on the substance of your Report, I just wanted to ask you a couple of questions about your expertise.

You are a toxicologist, of course.

A. Yes, I am.

Q. Are you an expert in Risk Assessments?

A. I have substantial expertise in Risk Assessment, that's right.

Q. And are you an expert in risk mitigation?

A. No, I'm not.

Q. Are you an expert in pesticides for agricultural uses?

A. I am--consider myself an expert with regard to the health effect of pesticides, not on the agricultural side.

Q. Not in terms of--

A. I'm not an entomologist or an expert on crops or so.

Q. Okay. Are you an expert in the regulation of pesticides or other toxic substances?

A. I'm not a regulator. I'm a scientist, but I know the

process, regulatory process, for pesticide registration, yes.

Q. Internationally?

A. Certainly in the U.S., and it's similar in most countries.

Q. I see.

Earlier today, we were given--on this side of the room anyway, we were given a document, and I don't know if it's been assigned an exhibit number yet, but it's LC-22, and then I will say Page 4 of it because it was completing one of the tabs that were included in your Second Expert Report. It was completing Tab 22, which contained Exhibit LC-22. It's a table. It's a table comparing two regulatory agencies' conclusions on lindane.

A. Yes.

Q. Thank you.

You have that in front of you, then, that table?

A. Yes.

Q. All right. My copy, in the upper right hand because apparently there were two of them, has written in hand prepared by Victoria in preparation for Claire/Marcia call July 31, 2001. Is that the one you're looking at, too?

A. Yes.

Q. Okay. I'm looking at the last row on that table, and I would like to direct your attention to it, where it says on the left column, "Issue: planting treated seed."

11:30 "PMRA," down the column, "neither wheat/canola meet target MOE."

Next column over, "EPA" at the bottom, "Both wheat and canola are okay."

"Main issue or status, different studies used leading to vastly different results."

Now, I take this to be an expression of the principle that would appear to apply here that, depending on the selection of the data, apparently innocuous or reasonable, alternative choices of data can lead to vastly different results. Is that fair?

A. In the Risk Assessment process?

Q. Yes.

A. There is certainly a possibility that, by looking at the same data, two different regulatory agencies may reach different conclusions.

Q. Did you say in looking at the same data?

A. Yes.

Q. And, therefore, all the more, if two regulatory agencies select or look at different data, they can very well lead to substantial differences.

A. It's possible.

Q. Would you consider that two agencies looking at different data and arriving at vastly different results are still within the scope of reasonable disagreement between

11:31 scientists?

A. Yes, they are.

And you should also consider the fact that there may be different legislations in different countries, and this may have an impact on the final outcome of a Risk Assessment.

Q. Thank you for that, but I guess I was trying to focus more on your expertise, which is more of the scientific as opposed to the legal--the legal side, but I have your answer on that regard as well, thanks.

Looking at now your First Expert Report of October 9, 2008, and I'm turning to Page 15 of that and Paragraph 77, and I'm saying that because if you want to refresh your memory as to what Paragraph 77 is about. I don't want to read that lengthy and complicated paragraph into the record. But at the end of that paragraph on the top of the next page you conclude, "Thus, it is my opinion that the use of an additional 3X uncertainty factor for age sensitivity is scientifically justified. The EPA applied the same 3X uncertainty factor in its 2002 RED."

And all I'm trying to find out is what did you look at and take into consideration in arriving at this conclusion that it was scientifically justified? I'm just wondering what the source--the set of materials that you examined to conclude that was.

A. Yes. The additional uncertainty factor that one can

11:34 apply to the standard uncertainty factors related to interspecies differences and intraspecies differences are based on potential additional toxicological concerns.

And this additional uncertainty factor can go anywhere from--usually from 2 to 10 as a value. In this specific case, there was evidence based on the fundamental neurotoxicity study and also multi generational reproductive study, that lindane had neurotoxic effect in the pups as compared to the mother, and therefore this raised the flag for potential development of neurotoxicity of lindane.

If you look at the internal policy document of PMRA itself, such a situation calls for the application of an additional safety factor which will go from 3 to 10, and here I simply say that, based on the data available, I agree with the fact that an additional safety factor should be applied in consideration of the potential development of neurotoxicity of lindane, and this is exactly what I wrote here. It is my opinion that the use of an additional 3-fold uncertainty factor for agency sensitivity is scientifically justified.

Q. Did you review those studies that you just alluded to in arriving at your view?

A. I reviewed a lot of studies. Of course, I did not review all the original studies on which the Risk Assessment was based upon, and that's obvious because it took many scientists at the PMRA and many scientists at the EPA many

11:36 years--

Q. Exactly.

A. --to read all those studies, to evaluate all those studies, so it was beyond my ability to look in detail, all the studies.

But, I've read basically the summary of the studies published not only by the PMRA, by many other bodies that addressed the issue of lindane, and that includes JMPR, the ASTR, the California EPA, the EPA itself, and obviously the PMRA.

Q. Would the same consideration and the same answer--if I had asked you that question in relation to Paragraph 82 for immunotoxicity and endocrine factors and an additional 3X factor, would your answer be the same?

A. For immunotoxicity, yes, although I remember I've looked specifically at a couple of studies, original studies as well.

Q. All right. I'm jumping ahead in your Expert Report to Paragraph 111. At Paragraph 111 and item D, you state, "The Board indicated that, in its view, an additional uncertainty factor of 10X was not fully justified and recommended that PMRA consider a lower uncertainty factor."

I'd like to get the actual lindane Review Board Report in front of us so we can discuss it more carefully, I'll say. And that is at--sorry, it's at Volume 9 of Tab 275.

11:40 Unfortunately, in the copy that's in the Joint Hearing Bundle, the Report is not complete. It's missing Paragraphs 220 through 222, which is the very paragraph that I want to refer to, and if that's the volume in front of you, I have the page that completes the Report so that, in fairness, it's in front of you when we turn to discuss it.

(Document handed to the witness.)

Q. And I presume that your conclusion in Paragraph 111(d) of your Expert Report was derived from the statement in Paragraph 222 of the Lindane Board of Review Report, but I will ask you to confirm that.

A. That's what it says, yes.

Q. Yeah, okay. So, and I'll just read it in. This is the Lindane Board of Review at Paragraph 222: "The Board is of the view that the additional 10X uncertainty factor is not justified.

Where a scientist makes a finding or a determination that is not justified, would you say that that is within generally acceptable scientific parameters?

A. I think so. The application of these additional uncertainty factors, it's left to the scientists who conduct the Risk Assessment, and it's often very possible that different scientists, as I mentioned earlier, by looking at the same data, may reach different conclusions.

It's also--you could find also differences in the

11:42 amount of this uncertainty factor. It could be, as I said, anything from 2 to 10. So, there are differences.

The way I read the Paragraph 222 is that not that the Board recommended that the additional uncertainty factor be totally removed. It says that, "it therefore recommends that PMRA consider an adjustment factor added in additional 10-fold maximum default."

In other words, my interpretation of this recommendation on part of the Board of Review is that, "PMRA, you have decided to apply a 10-fold safety factor," which is the maximum basically. "Why don't you go back and look at the data again and see whether you can go by and consider and use a different safety factor?"

The Board didn't say, "You should use 2 or 3 or 5 or 7." It simply recommended PMRA to take another look at the data and see whether they could apply a lower uncertainty factor.

Q. I read it in a similar fashion. But what I'm suggesting to you, and asking you to comment on, is why did the Board send them back to consider another uncertainty factor? Isn't that because the uncertainty factor, which PMRA used, was unjustified?

A. Well, as I mentioned earlier, there are differences in opinion.

Q. Indeed.

11:44 A. One may say that a 3-fold uncertainty factor may be sufficient to cover everything. Another person, another group of scientists, might say, "No, we believe that a higher uncertainty factor is more appropriate."

And these differences of opinion are within the boundaries of acceptable sciences. Obviously, if you apply a higher safety factor, you are leaning toward a more conservative position, and this is what PMRA seemed to have done. They have chosen a more conservative safety factor.

And although you could say, you know, "You have been too conservative, you could have chosen a lower one," you also have to think that PMRA is the Canadian Agency which is responsible for the safe use of pesticide in the State of Canada, and so it's the responsibility to assure that the use of any pesticide would be within the realm of safety. That's their duty and their mission. And from this point of view, it's not surprising they may be leaning toward a slightly more conservative position.

Q. I appreciate that. We discussed at the beginning that your experience and expertise in terms of regulation and public policy. I was more interested in the scientific aspect and toxicology aspect of things.

When you choose an uncertainty factor in a toxicological assessment, a risk assessment that you have carried out, I assume, in the past, I suggest to you that you

11:47 choose an uncertainty factor on a principle basis for reasons that you can demonstrate to your peers are the best choice that would be justifying the choice. It's not whimsical: "I'm going to pick 5 today." It's reasoned, and it's supported; that means it's justified. Would you agree with me that's how you'd choose them?

A. Yes. When there are--we are talking, to make it clear, about this time for additional safety factor.

Q. Yes, we are.

A. Which goes beyond to the 100-fold safety factor. In this particular case, PMRA had three different additional toxicological concerns: One was developmental neurotoxicity, as we already discussed; the other was potential immunotoxicity; and the third one was potential endocrine toxicity.

And for the--if you look at the internal policy document by PMRA, the developmental neurotoxicity concern calls for an uncertainty factor ranging between 3 and 10, and the other two concerns call for an additional safety factor of each one of 3. So overall, they applied a safety factor of 10, which takes into account all of these three different concerns.

So, I don't--basically, if they--you know, if you want to go down to the math, to the mathematics and the numbers, they might have applied a safety factor of around 3 for developmental neurotoxicity, and another factor of around 3 to

11:49 cover both immunotoxicity and endocrine toxicity for overall safety factor, which was 10.

Q. And that's because, as they add uncertainty factors, they get multiplied together; is that--

A. They're always multiplied, yes.

Q. So one would be 3 and the other--

A. 3 times 3 would make 9.

Q. So that's why you say--

A. So they can round it up at 10. You can rarely see an uncertainty factor of 9. It's usually 10.

Q. Thank you.

In Paragraph 112 of your First Report, I will just read it quickly: "The Report by the Lindane Board of Review contains a number of criticisms of the activities of PMRA related to the re-evaluation of lindane. Some criticisms are outside the scientific area and deal with the procedural issues in the Special Review."

As far as the procedural issues go, we can agree that you are not opining on those; is that right?

A. That's correct.

Q. On the arithmetic that we just talked about, the uncertainty factors, I wanted you to clear up some confusion in my head about how that was done at the--in the Re-evaluation Note, and you discuss it at Paragraph 130 of your First Report.

Unfortunately, there is no other way to go through

11:51 this other than to actually speak this thing. "With the exception of the acute dietary Reference Dose to all other NOAELs, a total uncertainty factor of 1000-fold was applied. This included two uncertainty factors of 10-fold each for interspecies differences and intraspecies variability, and an additional 10-fold uncertainty factor for additional concerns. Previously, these additional concerns were identified as sensitivity of the young, about 3-fold, uncertainty factor and immunotoxic and endocrine effects also about--approximately 3-fold uncertainty factor."

"In the 2008 REN, there is no clear specific discussion of the additional 10-fold uncertainty factor, though these three end points are briefly considered," and you cite where.

"It would appear that there was a diminished level of concern for immunotoxicity with respect to the previous evaluation and testimony. For the acute dietary Reference Dose, an additional uncertainty factor of 3-fold was chosen as the NOAEL was derived from a developmental study."

Okay. So, the way I read this is--I'm going back to the middle of that paragraph--previously these additional concerns were identified as sensitivity of the young, approximately 3-fold; and immunotoxic and endocrine effects, approximately 3-fold. Multiply those together, we get the 10X. That was from the original Special Review; is that right?

11:52 A. Yes.

Q. Okay. Then it would appear, you say, that there was a diminished level of concern for immunotoxicity. Doesn't sound clear, but let's accept that.

For the acute dietary reference dose, an additional uncertainty factor of 3-fold was chosen.

Now, while there was decreased concern for immunotoxicity, apparently, there still remains sensitivity of the young at about 3-fold and endocrine effects at about 3-fold.

A. Yes.

Q. And if an additional Reference Dose, as you say at the last line in that paragraph, an additional uncertainty factor of 3-fold was chosen, wouldn't we now have an additional uncertainty factor of 30?

A. No.

Q. Good.

A. Perhaps my language was not very clear. What I meant here is that, when consider--if you look at the first sentence of Paragraph 130, it says "With the exception of the ARfD"--

Q. Right.

A. --"to all other NOAELs, a total UF of 1000 was applied."

So, the last sentence in this paragraph reconnects to the first statement here, and discuss the ARfD.

11:54 Now, the ARfD was a number based on a developmental study. Therefore, instead of applying a safety factor of 1000, they only applied a safety factor of 300, which consists of the following: A 10-fold uncertainty factor for interspecies differences, a 10-fold safety factor for intraspecies difference, and a 3-fold safety factor for additional toxicological concerns--in this case, endocrine toxicity, primarily. They didn't apply the developmental neurotoxicity safety factor because the number from which this Reference Dose originates was coming from a developmental study. So the developmental aspects were already included in that number. And so for this particular Reference Dose, the safety factor applied was 300, not 1000, so it was not in addition to the previous.

Q. All right. So, in the REN itself, then they would have ended up with, depending on the particular exposure scenario they were looking at, they would have ended up with two different overall uncertainty factors: One a thousand, and one 300?

A. Yes, because it all depends on where you derive your no observed adverse effect level, and for--you know, this is not related to occupational exposure. This is related to exposure of the general population. And they derived this number, as you can read in Paragraph 129 from the developmental neurotoxicity study, which provided a NOAEL of 0.8 milligram

kilo body weight data. And to this number they applied a 300-fold safety factor. No need to apply a safety factor for developmental neurotoxicity because the number was already derived from a developmental neurotoxicity study.

Q. All right. For purposes of the occupational exposure analysis, it was a thousand, the overall uncertainty factor in--yes?

A. Yes.

Q. And so it was the same as the Special Review.

A. Yes.

Q. Okay. In your Report, and indeed in the REN itself, I was trying to find the justification that the Board at least, the Lindane Board of Review as we saw, was missing from the original Special Review. In your Paragraph 145, about halfway down, at the sentence--it's about six lines down from the top of Paragraph 145, you say, "Nevertheless, I feel that, given the importance of this issue in the overall risk evaluation of lindane, this aspect needed perhaps a better and more comprehensive re-discussion in the 2008 REN as one may argue that a 3-fold additional uncertainty factor might have been sufficient to accommodate all concerned."

Now, the Special Review happened and came out with a conclusion. The Lindane Board of Review at least came out and said the additional 10-fold factor is not justified, and we have the REN in 2008, which comes out with the exact same

11:58 number for occupational exposure anyway, but, if anything, well, no justification in addition to the Special Review that I could find.

So, my suggestion to you at least is, as to the scientists at PMRA and the scientists at the Lindane Review Board, they did not agree. They did not justify--PMRA did not justify in the way that the Lindane Board of Review asked them to, because when I lay the Special Review side by side with the REN 2008, I don't see any difference in the justification, I guess, and I was wondering if you did and if you could help me with that.

A. Well, as I said earlier, regulators have the possibility of applying different numbers.

Q. Yes.

A. It could be 3, it could be 10. PMRA applied the factor of 10. The Board of Review said, "Why don't you consider a lower value?" PMRA, in their 2008 REN, decided to stick to their number and applied again a 10-fold safety factor. As I mentioned earlier, you could say that this is leaning toward a somehow conservative position, but in my opinion, it is a scientifically acceptable position and justified by the role and mission of PMRA.

One other thing that--it's also written in the paragraph you pointed out to--is that even if PMRA had chosen a safety factor of 300 instead of 1000, thereby somehow appearing

12:00 to be a little bit less conservative or assuming that this additional 3-fold safety factor instead of 10 would have covered all the toxicological concerns, several of the values of the margin of exposure, about 50 percent of those under different scenarios would have still been below the target of 300. And on this basis alone, PMRA could have reasonably concluded that it was an acceptable risk for workers the continuous use of lindane.

So, in the end, this is what I want to say: They chose 1000, but even if they had chosen 300, the bottom line would have been the same.

Q. We were talking about justifying the selection as opposed to the end result of the whole analysis of the Risk Assessment. But, in any event, had a lower uncertainty factor had been chosen, that would go to the risk mitigation issue or the potential for risk to be mitigated, I would assume; is that right?

A. Well, risk mitigation, which as I said in my answer to one of your first questions, which is not my specialty, it's not really part of Risk Assessment.

Q. Right.

A. It's part of risk management.

Q. Right.

A. And it refers to things you can do basically to decrease exposure: Can you use a different type of gloves?

12:03 Can you use some overalls? Can you use a clothes transfer system? And so on.

And these mitigation measures, personal protective equipment measures, are taken into account in the evaluation of pesticides, including lindane. In fact, if you just compare the margin-of-exposure values in the 2001 Special Review with those that are indicated in the 2008 Re-evaluation Note, you will find that they are different. They are higher in the 2008 REN. And why are they higher? They are higher because, for exposure assessment, the 2001 REN utilized the 1992 Dupree study where certain mitigation measures and personal protective equipment was used; while in the 2008 Re-evaluation Note, PMRA utilized the 2004 Jones and Korpalski study where additional personal protective equipment was used, and this obviously led to a decreased exposure which explains the higher margin of exposure number that were obtained in the 2008 REN.

Q. And just for my lay understanding, a higher margin of exposure means a more--a smaller amount of risk to be mitigated?

A. Yes. A target here is 1000.

Q. Right.

A. Which is determined by the uncertainty factors. And so you want your margin of exposure, which is basically the ratio between the no-observed effect level and the exposure to be higher than 1000. So, you want to have high margin of

exposure.

Q. And so, for example--were you finished?

A. Yes.

Q. Okay.

If the PMRA had chosen a less conservative--your word--uncertainty factor of 300, the margins--the mitigation measures that might have been possible to reach and exceed that--in other words, to get the 350 or 400 margin of exposure or something over--well, I shouldn't use that--would be smaller. The mitigation measures would not have to have been as drastic as possible had it had an uncertainty factor that was smaller be--had been used; is that right?

A. I cannot answer specifically to your question. I would only say that for some of the exposure scenarios, the margin of exposure, even considering the Jones and Korpalski study, which already included a lot of mitigation measures, were in the single digit, and even with a target of 300, you know, unless you had the workers go around with a space suit or something, I don't know how you could manage, but again, this is not my area of expertise, so I am just guessing.

Q. Oh, all right.

Could I ask you to turn to another part of your--actually, this is your Second Expert Report. Sorry, that's what I'm looking at now. But don't put your First Report away because I guess I want to put together two

12:08 statements of yours and have you help me with them.

Do you have both Paragraph 52 of your First Report as well as 59 of your Second Report open, I should say.

All right. You've got them?

A. Yes.

Q. Good. First, I'm looking at Paragraph 52 of the First Report--I kind of misled you there--and it says: "In general, the chemical Risk Assessment process consists of two parts: An analysis of the potential health effects caused by a chemical, the so-called 'hazard characterization'; and, two, an estimate of the exposure to that particular chemical. The first part of the process is aimed at determining the level above which a chemical is believed to cause adverse effects in humans; the second part is aimed at determining actual exposure to the chemical." And that makes perfect sense, at least to me.

Now I'm going to--and so, to put it in summary form, one looks at the potential health effects of a chemical, and then one looks at how much of that chemical the subject would be exposed to, and mitigation would come in there to control the amount or limit the amount that the subject would be exposed to. In order to perform the Risk Assessment you'd have to do both of those steps; is that right?

A. What I write--what I wrote in Paragraph 52 simply points out in later--almost what is the process of Risk Assessment, you have to consider whether the chemical is toxic

and how toxic, and all this information is usually based on animal studies.

And then you have to determine whether and how much is exposure to this chemical because it's product of this interaction between toxicity and exposure which produces risk of adverse health effects.

Q. I understand.

A. You can have a barrel of the most toxic chemical in the world, but if it stays somewhere, it doesn't leak, nobody gets ever exposed to this, then the risk would be zero basically or close to zero.

So, it's important to consider toxicity and exposure.

Q. I appreciate that summary. It's much better said than I did.

Now I'm looking at Paragraph 59 of your Second Report, and there you're summarizing the debate that's going on, the exchange of letters that's going on between PMRA and Chemtura after the draft REN has come out, and I wanted to ask your view about the last sentence and a quote from the PMRA there. Pick up the text of the sentence at the word "finally": "PMRA indicates that since it finds health and environmental risks of lindane to be unacceptable, there is no point of suggesting optimal production facilities for an active ingredient that is inherently unsafe. Worgan in 2009-C."

For a toxicologist, in accordance with the definition

12:12 that you've just given about Risk Assessment where you look at toxicity and you look at exposure, I suggest to you that there is no such thing as a product which is inherently unsafe. If the exposure is zero, the risk could presumably be zero; isn't that right?

A. Well, one of the things we say in the field is that it's always difficult or impossible to prove a negative, and so overall I agree with your statement.

As you can see, these are not my words. These are words by Mr. Worgan--

Q. I appreciate that, yes.

A. --which I quote.

Q. All right.

MR. SOMERS: Those are all my questions, Madam Chair. Thank you.

Thank you very much, Dr. Costa.

PRESIDENT KAUFMANN-KOHLER: Thank you.

Are there redirect questions, Mr. Kurelek?

MR. KURELEK: I have a few questions for Dr. Costa.

REDIRECT EXAMINATION

BY MR. KURELEK:

Q. I'll work in the order that Mr. Somers did with his questions.

Starting with your qualifications, Professor, would you please tell the Tribunal what your education is.

12:14 A. I have a doctorate in pharmacology from the University of Milano, Italy, and then I did post-doctoral training in toxicology, first at University of Milano and then at University of Texas in Houston Medical Center.

Q. Can you give us a brief history of your academic career.

A. Since 1983, I have been at the faculty at the University of Washington in Seattle.

I raised through the rank. I was promoted Full Professor with tenure in 1992. I have directed a toxicology program at University of Washington for a decade, from 1991 to 2000.

Q. And which professional organizations do you belong to?

A. I'm a member of the Society of Toxicology, the U.S. Society of Toxicology; Society for Neuroscience; International Neurotoxicology Association; Italian Society of Toxicology; and other scientific societies, as well.

Q. And have you won any awards for your academic work?

A. Early in my career, I won a Special Emphasis Research Career Award from the National Institute of Occupational Health in the U.S.

I won an Achievement Award for Young Toxicologists from the Society of Toxicology.

I won a Zeneca Award also from the Society of Toxicology.

12:15 I am an elected Fellow of the American Association for the Advancement of Sciences.

I am a European-certified toxicologist.

I'm also a Fellow of the American Academy of Toxicological Sciences.

And--

MR. SOMERS: Madam Chair, I'm sorry to interrupt--indulgence as I interrupt--this is not arising from my cross-examination. It appears to be a sort of direct examination that postdates the cross-examination. And all of these matters, as impressive as they are, a matter of--clearly a matter of record in Dr. Costa's thorough Report.

PRESIDENT KAUFMANN-KOHLER: Mr. Kurelek?

MR. SOMERS: I nearly observed--

MR. KURELEK: I disagree.

PRESIDENT KAUFMANN-KOHLER: You disagree? Why do you disagree?

MR. KURELEK: I disagree. What Mr. Somers did at the beginning of his cross-examination, in my view, was call into question the qualifications of Dr. Costa. These are questions that I would have raised on the--

PRESIDENT KAUFMANN-KOHLER: Sorry, could you point us to where Mr. Somers puts Professor Costa's qualifications into question? Because that's not how I remember it.

MR. KURELEK: It was at the very beginning, and my

12:17 interpretation of his questions concerning Dr. Costa not--sorry?

PRESIDENT KAUFMANN-KOHLER: I know what you mean. But I understood the questions as defining the scope of the expertise, which certainly is interesting to the Tribunal. Is that what you had in mind?

MR. KURELEK: That's where I'm headed more broadly perhaps than Mr. Somers was with his questions, but that's exactly where I'm headed.

PRESIDENT KAUFMANN-KOHLER: Not an expert in risk mitigation, expert on health effects of pesticides, but not agricultural side. Is that what you have in mind?

MR. KURELEK: That's part of where I'm headed, yes.

PRESIDENT KAUFMANN-KOHLER: That had nothing to do, in my understanding, with the quality of Professor Costa's expertise, but it was just a matter of defining the scope.

MR. KURELEK: Indeed. Indeed.

PRESIDENT KAUFMANN-KOHLER: So, is there anything after you have said that? Is there anything else you would like to ask? And I think we can leave this expertise aspect aside or what Professor Costa has now answered to your questions we could find in his CV actually?

MR. KURELEK: Yes, but his CV is, for instance, his bibliography is over 50 pages long, and I think he has over 245 or 250 abstracts, 14 books and the like, and, for a

12:19 non-scientist such as me and, I presume, the Tribunal Members, it might not be obvious. For instance, what percentage of that bibliography relates to pesticides, for instance, as opposed to some area of toxicology. And that's partly where I was headed.

PRESIDENT KAUFMANN-KOHLER: Fine. So, why don't you ask him this question.

MR. KURELEK: Okay. That's exactly where I was headed next, and I will try to limit myself to perhaps two or three more questions.

ARBITRATOR CRAWFORD: There is no speed limit in the Tribunal.

MR. KURELEK: There is no speed limit in the Tribunal?

ARBITRATOR CRAWFORD: Go on.

MR. KURELEK: Thank you.

BY MR. KURELEK:

Q. So, as I tip my hat here, Professor, turning to the bibliography that's attached to your first expert report--and I know that it's over 50 pages long, and I have already given the numbers I guess of what you published, the 14 books, 65 book chapters, and 245 papers and 220 abstracts--can you tell me what percentage or roughly of that written material deals with pesticides?

A. I would say about half of my scientific production, which may even be higher than the one you mentioned since almost two years have gone by, maybe about half would be

12:20 devoted to pesticides.

Q. And two more questions: Can you point to some of the more significant publications that would relate to the evidence you're giving in this NAFTA hearing.

A. Well, I've carried out a lot of original research in the area of pesticides, and there are many peer-reviewed articles that show this. I have published a couple of books on pesticides. I have published several book chapters related in general to the toxicology of pesticides, in particular--I like to mention one--which is a chapter called Toxicology of Pesticides. It's included in a book called Casarett and Doull's Toxicology. And that's a most authoritative book in toxicology in the U.S. and also in the world, and it's sometimes referred to as the bible of toxicology. And there are additional publications that I have in the area of pesticides, and you can see the details in my bibliography.

Q. And turning to the final subject on this topic, Mr. Somers asked some questions about your qualifications to talk about risk mitigation.

Do you feel qualified to provide an opinion on the effects that risk mitigation would have on the context of a Risk Assessment? You--earlier you made the distinction between Risk Assessment and risk management. Are you qualified to talk to us today about risk mitigation?

A. I mentioned earlier that I'm not an expert on risk

12:22 mitigation. I know what it is, in general. I know its objective which is that of reducing workers' exposure, but beyond this I would not comment.

Q. Turning to the complex issue of uncertainty factors, and we've heard many witnesses at this hearing talk about the 10 times 10 times 10. You referred to it, as well. The first 10 uncertainty factors often referred to as interspecies differences. The second one is intraspecies differences.

Is it true that before the Board of Review, Chemtura argued that there should be a lower than 10 times 10--in other words, a hundred--uncertainty factors for lindane? Just for those first two.

A. That's correct.

Q. And what was the Board of Review's conclusion on Chemtura's submission with respect to those first two uncertainty--groups of uncertainty factors?

A. The Board of Review didn't buy the arguments raised by Chemtura and reiterated the fact that the first two safety factors should be 10 and 10 for a total of 100. Chemtura had recommend--suggested to use 32 instead of 100. And this was based on some technical aspects related to toxicodynamic and toxicokinetic--I don't know if you want me to go into this technical detail, but basically the bottom line is that they proposed that the first two safety factors should be a total of 32 instead of 100, and the Board rejected this proposal and

12:24 agreed with PMRA that the first two should be 100.

Q. Okay. And then in your testimony you also talked about how the Board recommended that the PMRA reconsider the final 10-fold factor that it applied for all three of those other uncertainty factors; is that right?

A. Yes.

Q. And did the Board of Review consider an additional or a different uncertainty factor in the REN process? It, in other words, followed the Board of Review's recommendation to go back and re-look at whether it should apply a 10-fold safety factor for that final third?

A. Well, the third uncertainty factor chosen in the Special Review was 10. As we discussed earlier, the Board of Review suggested to PMRA to consider a lower uncertainty factor. In the 2008 REN, PMRA decided to maintain the 10-fold additional safety factor.

Q. There is a related question here: Mr. Somers pointed you to a paragraph in your First Expert Report, I believe, where you limit yourself, so you're not talking about procedural policy issues here. You're opining about scientific issues; is that right?

A. That's correct.

Q. But would you agree that--and again, Mr. Somers was heading down this path--that there is a certain degree of policy that impacts on the choice of uncertainty factors? Is

12:26 that correct that an Agency would use in terms of deciding which number it should apply?

A. Well, each agency, I guess certainly PMRA, from the document that they've read, have their internal policy document.

And in case of PMRA, I specifically recall that there is a table in one of their policy documents, which indicates in detail the uncertainty factor that the scientists should consider in different situation, and this specifically says, for example, "developmental neurotoxicity it should be a factor between three and 10," and then it goes more in detail on other aspects of developmental neurotoxicity. So, it depicts different scenarios that you could encounter in a database.

So, from this point of view, yes, there is a policy.

Q. And is this what you were referring to when you were talking about the PMRA adopting a perhaps more conservative UF? But that's part of their mandate in terms of when their entitlement is--in terms of their mandate to protect Canadian health and environment.

A. Yes. They--they relied on their internal policy for pesticide registration; and, as I mentioned earlier, there is an option in general to choose between several numbers going between 2 and 10, and PMRA chose 10, and this is scientifically acceptable. It's in accordance with their own policy. But, as I mentioned earlier, could be seen by somebody as slightly

12:28 conservative.

Q. Okay. Then turning to my final set of questions on the same related issue, you had used the phrase, I think, single digits when you referred to MOEs, margin of exposures, when you were comparing an application of 300 uncertainty factors versus 1000, and I just wanted to make sure the Tribunal understands exactly what you meant by that, because I think again Mr. Somers was headed down the path, "Well, if you apply a lower uncertainty factor, 300, versus a higher one, 1000, then presumably you would have to--you wouldn't have to have the same degree of PPEs or personal protective devices to protect yourself." And you also made the comment about a moon suit.

So, if you could maybe just take us back to what you meant by "single digits," so we would understand what would happen in terms of lindane in a 300 UF was applied versus the 1000 that Canada--PMRA applied.

A. Well, first of all, the 2008 REN used as study for determining exposure the Jones and Korpalski study, which already included a lot of mitigation measures and personal protective equipment and so on. And they calculated, they being the PMRA's scientists, they calculated their margin of exposure, so the target was 1000, which means that for a margin of exposure to be acceptable, it had to be higher than 1000, had they chosen 300 as their uncertainty factor, while each

12:30 margin of exposure should have been higher than 300.

What I said with the single digit was that, to my recollection, in the tables in the 2008 REN, which described the margins of exposure, some of this margin of exposure were in the single digit range. There were eight, for example. So, eight is substantially lower than 300 or their 1000. And so, I don't know, given that the Jones and Korpalski study already included a number of mitigation measures, I don't know which other mitigation measures you could apply in order to increase this margin of exposure for a value of eight to 300 or to 1000.

Q. So, just so we are absolutely clear, in order for lindane to be safe if you apply these mitigation measure, they should rise above the UF factor. The numbers should be above 300 or in the case of PMRA 1000, if you want to be safe, the number has to be above 1000?

A. Yes. It has to be a high number, to be safe.

Q. Okay. Thank you.

MR. KURELEK: Those are my questions.

PRESIDENT KAUFMANN-KOHLER: Thank you.

Do my co-Arbitrators, Judge Brower, Professor Crawford, have any questions?

QUESTIONS FROM THE TRIBUNAL

ARBITRATOR CRAWFORD: If you look at--Professor Costa, if you look at Paragraph 315 of the Board of Review Report, which is Volume 9, Tab 275, at Page 51, it says, "The Board is

12:32 not persuaded that the available pharmacokinetic and pharmacodynamic data are adequate to support a departure from the standard default assumption of 100 times."

Does that mean they supported the application of a standard default? Obviously, they were talking about Crompton's argument that it should be reduced below a hundred, and they reject that. But reading their Report, which UF do you think they supported?

THE WITNESS: Well, this paragraph deals with a topic that I mentioned earlier, the fact that Crompton/Chemtura had suggested to the Board that instead of applying a uncertainty factor 100 to take into account for interspecies and intraspecies difference, one could get by by applying uncertainty factor of 32, and this was based on technical aspects, basically a subdivision of each safety factor in two components, toxicokinetic component and a toxicodynamic component. For example, in case of the interspecies difference factor, the toxicokinetic component is--was 4, the toxicodynamic was 2.5. Chemtura made the arguments that toxicokinetic could be reduced from 4 to 2, and so the total would have been 2.5 times 2 instead of 2.5 times 4 for a total of 5 instead of 10.

And they made similar argument for the other uncertainty factors, so that the total, the first multiplied by the second, would be 32.

12:34 The Board did not agree with this. They said there is insufficient evidence that this approach, though an interesting approach, because the Board, indeed, said the idea was an interesting idea. If we had enough data, information to be able to come up with numbers other than 10, because, you know, sometimes in the toxicology arena we laugh, we say, "why do we have this number 10? You know, where does it come from?" I say, "Well, because we have 10 fingers. If we had 11 fingers, maybe the number would be different." But the number is 10, by default. And if we could find scientific ways to make it more precise, this would be very welcome.

But in this particular case, the Board thought that the scientific evidence put forward by Chemtura to reduce these two uncertainty factor was not strong enough, so it recommended, as it says in this paragraph, that the first two uncertainty factors should be kept as they were, 10 and 10 for a total of 100.

ARBITRATOR CRAWFORD: The Board went on to doubt the validity of the additional uncertainty factors taken into account in the Special Review. They referred to endocrine effect, toxicological endpoints and so on. And what it says at Paragraph 226 on Page 54, "The Board feels that reconsideration of these elements could potentially bring the MOEs within an acceptable range."

When I read that, I thought they were going to go on

12:36 and say, "In those circumstance, lindane could or even should have been passed the examination."

First of all, do you agree that's what they're saying? And, secondly, do you agree with the statement that I have just read?

THE WITNESS: Well, the Board had some criticism and some suggestion for PMRA. And, you know, the suggestion was, for example, the one to consider a lower additional uncertainty factor. Another important suggestion was to do not conduct--not conduct aggregated exposure between dermal and inhalation route, and this was a scientifically correct observation, on part of the Board. And they also recommended that the PMRA utilize the more recent Jones and Korpalski study instead of older Dupree 1992 study which was a reasonable suggestion, but obviously the study was not available at the time of the Special Review.

So, all this suggestion and recommendation were taken into account and considered by PMRA in their 2008 REN. And, indeed, they utilized the Jones and Korpalski study. They did separate inhalation and dermal exposure scenarios.

I should also mention that this was a criticism of the Board review of the PMRA, but I consider this a minor criticism because in occupational exposure, dermal route, it's a primary route of exposure, so the inhalation component--it's a minor component. Nevertheless, it's technically a correct

observation on part of the Board.

With regard to uncertainty factors, PMRA chose to retain what they had decided, which is 10, instead of another lower one, and this again, it's within acceptable science and Risk Assessment. But what I think the Board says here is that if you consider all of these aspect, most likely the margins of exposure will go up. And as we said earlier, what we want for a chemical to be safe is this margin of exposure are higher than our target.

And, indeed, they went up. As I mentioned earlier, if you compare the margin of exposures indicated in the Special Review in 2001 with those indicated in 2008 Re-evaluation Note, you will see that the second ones are higher. This is because all these issues were considered by PMRA. And what the Board says here is that the consideration of all these elements could potentially bring the margin of exposure within an acceptable range. And, unfortunately, they were not in an acceptable range. They were higher, but not high enough. So, they were still below the 1000 target. And as I mentioned earlier, even if PMRA had chosen a 300 target, many of those MOEs would have been below that target.

ARBITRATOR CRAWFORD: Is it very unusual to have an additional uncertainty factor of 10 leading to a target of 1000? Is that unusual? Unheard of?

THE WITNESS: No, that's not--that's not unusual at

12:41 all.

The first two are standard, so the first to 100. Then, it depends on the database, whether there are toxicological concern of different nature. One could apply a 10-fold uncertainty factor. In the United States, for example, because of because of the Food Quality Protection Act, there is an immediate default 10-fold safety factor applied for taking into account developmental neurotoxicity, unless you prove that the compound is not a developmental neurotoxicant. And thereby, the companies are now required to do all this developmental neurotoxicity study for U.S. registration.

There are cases I'm aware of where a 1000-fold safety factor was applied both in Canada, I think, and the U.S. For example, compounds like malathion, I think, or rotenone. I think the same--the compound was mentioned earlier this morning, Helix itself at the 1000-fold safety factor. So, there are other cases where because of toxicological concern, a 1000-fold safety factor has been used.

ARBITRATOR CRAWFORD: Thank you very much.

MR. KURELEK: If I could just clarify, when the 1000 UFs were applied in those cases, did the pesticide pass, unlike in the lindane case?

THE WITNESS: The case that the pesticide that I mentioned, they all passed, yes.

PRESIDENT KAUFMANN-KOHLER: Have you considered what

12:43 additional UF you would have attributed? You're saying in your First Report that one may argue that 3 would have--may have been sufficient. Is that what you would have taken? Or have you not looked at it this way, which may be an answer as well?

THE WITNESS: Well, I have not been asked to come up with an opinion of what would I have done if I were assigned the duty of doing this Special Review on lindane. That's not--that was not the scope of my Report, which was, instead, that of bringing to this table my opinion on whether, I think, what PMRA did was within acceptable science, and I think it was.

In order for me to answer your questions specifically and tell you with certainty, I think it should be three or five or 10, I should, indeed, review all the original studies that were reviewed by the PMRA scientists.

PRESIDENT KAUFMANN-KOHLER: Thank you. I understand you have not done this review, and so I will not continue. I'm sure you probably have some kind of an opinion on what you would have done, but I'm not asking this now.

Do I understand you correctly that if you had--if PMRA had chosen three, the outcome of the Special Review in terms of acceptability of risk would not have changed?

THE WITNESS: Yes, because if you look at the margin of exposure values in the 2008 REN, you see that a large percent of them, about half of them, were still below the

12:45 target, below 300. And so, in a situation where you have so many different exposure scenarios where the exposure is considered unacceptable for the safety of workers, then PMRA could reasonably conclude or reach the same conclusion that the compound was not safe.

PRESIDENT KAUFMANN-KOHLER: Thank you. I have no further questions.

No further questions on any side? Then--

MR. SOMERS: I do have one arising from--

PRESIDENT KAUFMANN-KOHLER: Of course, then, please ask it.

RECROSS-EXAMINATION

BY MR. SOMERS:

Q. Dr. Costa, in responding to question from the Chair, you were discussing the fact that even a factor of three had been chosen, some of the margins of exposure were so low that 3, 10, same result.

Now, I realize that you have confirmed a couple of times that you're not an expert on mitigation, so I'm just asking you if this is reasonable.

You had, in jest, earlier said, "Well, if risk is that high or the margins of exposure that low, you need a moon suit or something like that in order to control or mitigate the risk sufficiently." Now, that's obviously an impractical suggestion. But the personal protective equipment and these

12:46 sorts of this measures are things a worker would use to coat themselves to diminish the exposure, but aren't there other means of reducing exposure, such as controlling and reducing the rate at which the material is supplied, the area over which it's applied, the coating with which it is applied to the agricultural commodity and so forth?

A. As I said--

Q. I--I'm sorry, go ahead.

A. As I said, mitigation is not my area of expertise. I would not feel comfortable providing an opinion on this.

Q. Okay. Well, as long as you take the bit about the moon suit back, then we will be agreed.

A. It was just a joke.

Q. It--so is mine. Thank you very much.

PRESIDENT KAUFMANN-KOHLER: Thank you very much, Professor Costa. That completes your examination.

(Witness steps down.)

PRESIDENT KAUFMANN-KOHLER: We will now take a lunch break of an hour.

The Tribunal would like to see council just to--because we have discussed this question of Post-Hearing Briefs and oral submissions, and would like to make some suggestions before you further consider the issues, just off the record, if that is fine with you.

(Whereupon, at 12:47 p.m., the hearing was adjourned

12:47 until 1:45 .m., the same day.)

AFTERNOON SESSION

PRESIDENT KAUFMANN-KOHLER: May I ask someone in the back to close the door, please. Thank you.

JAMES AIDALA, CLAIMANT'S WITNESS, CALLED

PRESIDENT KAUFMANN-KOHLER: Mr. Aidala, thank you for waiting and thank you for being here.

For the record, you're James Aidala?

THE WITNESS: Yes, I am.

PRESIDENT KAUFMANN-KOHLER: You're Vice-President Policy and Government Affairs for The Acta Group.

THE WITNESS: That's correct.

PRESIDENT KAUFMANN-KOHLER: You're heard as an expert. You have given two expert reports.

THE WITNESS: That's correct.

PRESIDENT KAUFMANN-KOHLER: And as an expert you are under a duty to make only such statements that are in accordance with your sincere belief. Can I ask you to confirm this by reading the expert declaration.

THE WITNESS: Of course.

I'm aware that I'm heard as an expert witness in this arbitration and that I'm under a duty to make only such statements which are in accordance with my sincere belief.

PRESIDENT KAUFMANN-KOHLER: Thank you.

You know how we proceed. You have been here earlier already, and so I will turn to Mr. Somers for direct questions,

14:01 please.

MR. SOMERS: Thank you, Madam Chair.

DIRECT EXAMINATION

BY MR. SOMERS:

Q. Good morning, Mr.--no, it's afternoon, Mr. Aidala. It's been a while.

Before I ask you to adopt your statements, I understand that there is some corrections you would like to make?

A. I do. Unfortunately, the pagination of the document I was referring to in my second statement had a different pagination than your bundle, so I have a handful of just those kind of corrections as well as a few editorial ones.

My first statement at Paragraph 18, at the end of the first sentence, it should read "environmental effects."

And the last sentence of Paragraph 18, let me just read the sentence and then correct it for the record: "Notwithstanding these concerns, the EPA later did issue tolerances for a number of foodstuffs," strike "treated with chlorfenapyr," insert "residues which," insert "could allow," et cetera.

And then in my second statement, again most of these are because of the pagination differences, so the Tribunal is not confused about the pagination. The pagination I have in document I was reviewing from EPA, I think their Web site is

14:03 different than what's in the bundle.

Paragraph 17 of my second statement, the reference to Page 46 at Paragraph 17 should be "Page 44."

At Paragraph 19, at the end of that paragraph I make a reference to Page 44. That should be "42."

In the middle of the next paragraph, Paragraph 20, referring to Page 45, should read "Page 43."

In Paragraph 23, on the next page, I do one inserted word that was dropped, "issues which EPA had not explicitly addressed. Insert "explicitly."

PRESIDENT KAUFMANN-KOHLER: You're in Paragraph 23; is that right?

THE WITNESS: Right.

PRESIDENT KAUFMANN-KOHLER: Which line are you in?

THE WITNESS: The very first line, which EPA had not insert explicitly addressed.

The next page, Paragraph 26, term of art, second line, active ingredient, insert "ingredient pesticides." It's active ingredient pesticides.

And then the last change is in Paragraph 27, another page reference towards the very end of the Paragraph 27, refers to Page 44, and that should be Page 42.

And again, apologies to the Tribunal for the pagination differences.

BY MR. SOMERS:

14:04 Q. Thank you. Now I would just ask you if you will affirm and adopt your statements made in this proceeding.

A. I do.

Q. Thank you.

MR. SOMERS: No questions, thank you.

PRESIDENT KAUFMANN-KOHLER: Thank you.

Please.

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

CROSS-EXAMINATION

BY MR. LUZ:

Q. Good afternoon, Mr. Aidala.

A. Good afternoon.

Q. My name is Mark Luz. I am counsel for Canada, and I have a few questions for you, as I'm sure you expected.

Just before we get into the substance of the questioning for today, do you have copies of your Expert Opinions with you?

A. I do.

Q. And do you have--well, actually, if there is anything else available to you that we need, someone will hand them to you, but I just wanted to point out before we proceed the three documents I will be primarily referring to are the 2002 RED, the 2006 HCH Study, and the 2006 Addendum, all of the EPA, and they are in various places, but there is a binder on your desk

as the first Statement of Dr. Goldman, and there I think it's been distributed just for the convenience of the Tribunal and everybody, but, of course, if the Tribunal wants to refer to the same documents that they were referring to last week, that's fine. I understand, if you're taking notes and so on, you may want to use the same copy. But I will give multiple references to make sure that we avoid the problem some of the copies in the Joint Hearing Bundle were missing pages. So, that's why.

A. All right.

Q. And just to confirm, Mr. Aidala, you were present in the room during the testimony of Mr. Thomson and Mr. Johnson?

A. Yes, I was.

Q. And first I would like to your professional background for the record.

You wrote in your First Report that between 1993 and 2000 you worked as an associate Assistant Administrator at the EPA office of prevention, pesticides, and toxic substances; is that right?

A. That is correct.

Q. I can refer to that as OPP? Is that the acronym?

A. No, you should refer to that as OPPTS, not to be confused with OPP, which is EPA's Office of Pesticides Programs, and I hope we try to avoid too many acronyms.

Q. Okay. I will try to avoid it, but if I accidentally

14:07 say OPP, you will know that I am referring to OPPTS?
A. Well, that could be confusing, but I will do my best.
Q. Okay, thank you.
And in 2000, you are appointed as Assistant Administrator for OPPTS; is that right?
A. Yes.
Q. Okay. So you overlapped with Dr. Goldman while she was Assistant Administrator of OPPTS; is that right?
A. Yes.
Q. Okay. So, you were her successor when you were appointed Assistant Administrator in 2000?
A. Right.
Dr. Goldman left in January '99, at the end of '98, and as of January '99 and for the next two years I was the senior political appointee, and then had the official title at the end of administration.
Q. Okay.
A. Both those positions are political appointments at EPA.
Q. Okay. And in 2001 you left the EPA to join Jellinek, Schwartz & Connolly; is that right?
A. That's correct.
Q. And you were there from 2001 to 2003?
A. That's correct.
Q. And since 2003, you have been with The Acta Group?

14:08 A. Yes.
Q. Okay, since then. Okay. So, since the time you've left the EPA and during the time that you were with JSC and Acta, was Chemtura ever a client of yours prior to being retained in this arbitration, of course?
A. Not a client of mine. I don't know they were ever a clients of the firm, those firms. They're not a client of mine. I did no work for Chemtura before this.
Q. Okay. So, during that period you were not aware of Chemtura's efforts before the EPA to obtain a tolerance in registration for lindane use on canola? You were not aware of what was--what Chemtura was doing?
A. Not--not that I can recall, no.
Q. Okay. And during that same period, did you ever work with TSG, Mr. Johnson's Technology Sciences Group?
A. Occasionally, in the last eight years, I have worked with TSG staff. I don't think I have worked with Mr. Johnson. He technically would have been my boss when he was head of OPP and I was a summer intern in that program, but that was irrelevant, really.
Q. Sure.
So, during that time--during this period prior to your engagement as an expert in the arbitration, you were not aware of what the TSG was doing on behalf of Chemtura with respect to obtaining a tolerance for lindane use in the United States?

14:09 A. That's correct.

Q. Okay, great.

I would like to turn now and discuss your opinion, your first opinion, and the likelihood of a canola tolerance in the United States in light of the 2002 RED. If you could turn to Paragraph 11 of your First Report, your first opinion.

A. Okay.

Q. You write that your goal is to offer your opinion on the likely outcome if Chemtura had pursued its application to the EPA for a tolerance for lindane and canola food products, oil, meal, and seed for crushing; is that right?

A. Yes.

Q. If we turn to Page 7 of your opinion, which is at Paragraph 26 and 27, the top of the page is a very clear statement of what this section is about, "the likely outcome if Crompton had pursued its application for a tolerance in light of the EPA 2002 RED Assessment." Do you see that?

A. Yes, I do.

Q. And then paragraph 26 you said that you reviewed the evidence of Mr. Johnson.

And in Paragraph 27, you came to the following opinion: "Based on my review of Mr. Johnson's statement and the 2002 RED, in my opinion, the EPA's 2002 RED indicates a strong likelihood that the EPA would have approved registration and a tolerance for lindane in canola, or at a minimum an

14:11 import tolerance after fulfillment of the requested data. Assuming prompt submission of this data and allowing for some time for evaluation by the EPA, a decision about the registration and tolerance, or at least an import tolerance, should have been made in early 2003."

Now, this paragraph in your opinion here talks about registration and a tolerance as well as an import tolerance, so since they're slightly different issues, let's keep the import tolerance aside, issue aside for a moment, and just focus on lindane, a tolerance for lindane use on canola in the United States. Is that okay?

A. Well, it would make a distinction if it was a tolerance, whether it be an import tolerance or tolerance. The two categories as indicated here are tolerance and registration allowing approval in the United States or secondly just in a tolerance.

Q. Okay. Great.

Now, in addition to the documentary evidence in the record, both Mr. Thomson and Mr. Johnson confirmed in their oral and written testimony that the 2002 RED required a Plant Metabolism Study and that the EPA would not grant a tolerance for lindane use on canola in the United States until that study is submitted. You don't dispute that, do you?

A. I would say it was not something that had to be done before any tolerance could issue. I have no reason to dispute

14:12 that's what they were told at the time. That's why a tolerance did not issue at that time.

Q. Okay. So, I will repeat the question. They both confirmed in their written and oral testimony that the RED required a Plant Metabolism Study to be produced and--

A. As a result--I'm sorry.

Q. And they both confirmed that the EPA would not grant a tolerance for lindane use on canola before that study was submitted and approved. You don't dispute what they're saying and what the documentary evidence says on that, do you?

A. I'm not disputing what they're saying, but I'm attempting to draw a distinction between that the RED said that we had outstanding data requirements, and that's what they were referring to there. And that, secondly, that that would be--at the time that's what they were told was the bar to getting a tolerance approval at the time. I do agree with that.

Q. Okay. So, they were told the EPA--that was the bar before getting an approval at that time; is that right?

A. Yes.

Q. And you don't dispute Mr. Johnson and Mr. Thomson's oral and written testimony in addition to the documentary evidence that they did not submit the study until 2005. You don't dispute that, do you?

A. I believe that's the date on the study in question.

Q. Okay. And then in addition to the documentary

14:14 evidence in the record, Mr. Johnson and Mr. Thomson both confirmed that it was their understanding that the EPA was still reviewing the Plant Metabolism Study in February 2006. You don't dispute that, do you?

A. Not that they were--they were reviewing that study as of that time, that's correct, or that would be my understanding also.

Q. So, if I go back to Paragraph 27 of your first opinion and see what you write here, you say that a tolerance would have been available for lindane use on canola after fulfillment of the requested additional data by the RED.

Is that right?

A. Yeah, if--yes.

Q. And your conclusion in the last sentence of your testimony here says, "Your conclusion that a tolerance should have been available by early 2003 is based on the assumption of a prompt submission of the requested additional data, and it also assumes some time for the EPA to evaluate that data; is that right?

A. That's one--that's an assumption, and that's an area, that's correct.

Q. Okay.

A. Excuse me, there's also other scenarios that could have obtained, but I think we will get there, but go ahead.

Q. I'm clarifying what your assumptions were with respect

to that statement?

A. That statement, that's correct.

Q. Now, given that Chemtura did not submit the required Plant Metabolism Study until 2005, and given that the EPA was still reviewing the Plant Metabolism Study as of early 2006, February 2006, the key assumptions underlying your opinion that a tolerance decision would have been issued in early 2003 are not present, are they?

A. They were not present in realtime, and that's why it's a hypothetical situation about. Had they had a reason to get that information in earlier, and I think those witnesses also testified that they were really focused on Canada. There is, if you will, that's where the action was, that's where the primary regulatory discussion they were having, and what the Tribunal's deliberations have been about, that they were not moving, shall we say, rapidly towards getting their--getting their tolerance back in the States.

Q. But since you had no involvement with Chemtura or TSG during the time in question here, you obviously can't speak to what their motivations were, what their incentives were, what they wanted to do. You're only making that observation not as part of your Expert Opinion; is that right?

A. I'm making that observation in terms of two things: One is what we referred to here at the Tribunal, but obviously what I wrote this statement before that time.

14:16 But mostly that the record would indicate that again, under the hypothetical, that they get that data in. And that kind of study normally takes some amount of time but not as long as it did. And if they had either submitted that study and, I think Mr. Johnson may well have talked about this, if they submitted that study early in 2003, say in the first quarter, and again if there was a priority, a need for a priority to be reviewed, you could see a tolerance in 2003.

Q. But again--

A. The real events as they occurred are as they occurred.

Q. So, as you used the word hypothetical, this is not reality that the Plant Metabolism Study was not submitted until 2005. The EPA was still reviewing it in 2006; hence, the basis for your assumption, the basis for your opinion in Paragraph 27 you already agreed are not present, therefore you would have to agree that a tolerance for canola--for lindane use on canola in the United States was not possible by early 2003; is that right?

A. I would disagree with that. There is also ways that in light of missing data, after the '02 RED, 2002 RED, presented a rather thorough case and analysis of the requirements the EPA would ordinarily have to go through. There were, as I say in my statement, some remaining outstanding data requirements. If there is a need for EPA, and I think Mr. Johnson may have referred to action forcing or

something pressing, EPA would have some options to still find a path for it, notwithstanding those data deficiencies, and that's--well, that's I think what he was referring to at some point.

Q. But again, since you weren't there at the time, you can't comment on what priorities Chemtura was setting for itself, why it took so long, why it took three years to do a study that you classify as routine and so on. So, you're only talking about the fact that your opinion is based on the assumption of prompt submission of the required data. You've already said the Plant Metabolism Study was required data; hence, you have to agree that tolerance was not possible by early 2003. Is that right?

A. I would disagree again. The tolerance is possible in early '03 because if EPA had made some bridging assumptions, for example, in the EPA review process, they can include an additional what they call database deficiency uncertainty factor. Those are the kinds of things EPA can use to act without--with a deficit in the database.

So, for example, there is a compound in my reviewing it in getting ready to appear, where there was a chemical called cyhexatin, which is an organo tin compound. Many, many years ago it had been forbidden for all uses in the United States. It still had many tolerances, I think 40 or so, 41 tolerances I believe. EPA as part of its FQPA review getting

14:20 rid of all those tolerances. Somebody raised their hand and said I'd like to keep the imported orange juice tolerance. EPA did an analysis, determined the risk cup--I think that's familiar terminology by this point--that the risk cup was not full. In that case it was 35 percent full for children and needed more data, though, to make the final determination. EPA then granted a time limit tolerance to then in addition to adding a "database uncertainty" to make up in their analysis of the risk cup in order to allow time for that product to still be potentially present as a residue in imported orange juice.

I'm sorry, that's an example of where EPA would use a database uncertainty factor to add to the need and allow time to develop the data.

Q. But they did not do that; is that right?

A. Not here they did not.

Q. And they did not issue a tolerance between 2002 and 2006--

A. No, they did not.

Q. And as the documents say and as Mr. Johnson and Mr. Thomson said, they knew that the EPA would not do that because the Plant Metabolism Study was still outstanding; is that right?

A. It appears that that was their understanding that EPA--they weren't going to get a positive--you know, they weren't going to get a decision from EPA at that time, that's

14:21 correct.

Q. Thank you.

Now, since we are on the topic of a Plant Metabolism Study, can I--I just want--Mr. Johnson gave a good summary of what that--how one undertakes that, but I want to get an idea of the basic purpose.

Now, plant Metabolism Study is also known as nature of residue study; is that right?

A. I think it's been referred to that among other things.

Q. It's a residue chemistry study?

A. It's a chemistry residue requirement. That's correct.

Q. And the point of collecting residue chemistry data is to assess potential dietary risk in order for the EPA to make the requisite safety finding. Is that right?

A. It's to characterize the metabolites in the various forms of the compound that may be expressed in the plant which would then be fed into the dietary risk assessment of the EPA.

Q. Now, let's go back to Paragraph 27 of your Witness Statement with respect to an import tolerance because if we go back to that same paragraph, you say that the EPA would have approved a registration and tolerance for lindane in canola or at minimum an import tolerance after fulfillment of the requested data.

And again, you set out the conditions, the assumptions on which your opinion is based, prompt submission of the data

14:22 in allowing some time for the EPA.

And then it could have possibly gotten an import tolerance.

Now, you're aware that the EPA never granted Chemtura an import tolerance; is that correct?

A. No, they did not.

Q. Okay. And you don't make any distinction here with respect to an import tolerance, and I think you said earlier that the data that would have been required for a regular tolerance would have applied for an import tolerance as well; is that right?

A. Yes.

Q. Okay. So, they could not have had an import tolerance between 2002 and 2006?

A. Well, again, remember that the data requirements--

Q. Sorry, just if you could answer the question yes or no or maybe, and then explain it so that it's clear for the record.

A. Sure. You want to repeat your question then to be more precise?

Q. Yes. And you don't make the distinction here with respect to an import tolerance, and I think you said earlier the data that would have been required for a regular tolerance would have applied for an import tolerance as well; is that right?

14:23 A. The data requirements are the same, or the findings--to be more precise or most precise, the findings are the same, and so again, for example, in this organo tin compound I just mentioned, the requirements are there for a tolerance all the time. They're always consistent. EPA has to make findings under the law. They can have, for example, I'm just going to pick a number, if there is 50 studies or 20 studies or 10 studies that are required, the requirements say you need all of those, but that's really based to try and find--to make the findings under the law. In some cases you might be able to make that finding speaking in EPA's voice, and EPA may be able to make that finding with less than all 10 studies or 20 studies or what have you.

Q. But the EPA did not make that finding between 2002 and 2006, did they not?

A. It did not, not in this case.

Q. I'd like to talk to you about--well, now that we have talked about that period 2002 to 2006, if we could talk about 2006 after the release of the HCH Report, and in your first Expert Opinion at Paragraph 29, you say that you've reviewed the EPA's 2006 Addendum to the RED, and you say my understanding of the context of this document and from other supporting materials indicates that the Registrants had agreed to the cancellation of the registrations before the 2006 Addendum was issued. Given this, there was no need for the EPA

14:25 to continue or revise its dietary risk evaluation of lindane residues."

So, that's your understanding of the context of the 2006 Addendum?

A. Well, one element of the context, yes.

Q. Okay. Context is obviously important. You would agree with that general statement?

A. Sure.

Q. I don't see anywhere in your first Witness Statement mention of the EPA's 2006 HCH Study that was released in February 2006?

A. I don't recall if it's in or not. I believe--

Q. I didn't see mention of it.

A. I'll take your word for it.

Q. I mean--

A. I don't recall precisely, but the whole point was that in the point of that paragraph that you're citing in my statement is that at that point once the Registrant leaves the field, they don't continue to have that dialogue with the Agency about whatever the concerns may be, whatever the other additional data, the disputes about the interpretation of data.

Q. Okay.

A. Basically all that, and I think that's what some of other witnesses described, too. All that, well, you could continue, I guess, but there is absolutely no need to on the

14:26 part of either the regulator or the regulated.

Q. Okay. You were aware that the HCH Study existed when you wrote your first Witness Statement; is that right?

A. Yes, because that's decided even in the Addendum.

Q. In the Addendum.

And were you aware at the time you wrote your first statement that Chemtura had not yet withdrawn its registrations for existing uses on canola?

A. I'm sorry, just say the question again.

Q. Were you aware at the time you wrote your first Witness Statement--Expert Opinion that Chemtura had not yet withdrawn its registrations for existing uses on canola at the time the HCH Study came out?

A. Well, all their registrations were still valid at the time of the HCH registrations as well as their pending applications.

Q. Hence, you must have been aware that they had not yet withdrawn it; is that right?

A. I don't recall precisely. I'm trying to be precise here on the record, but the focus of the '06 RED Addendum was the '06 Registrations that were still valid as of that time. Canola was still pending, so that's the only reason I'm hesitating. I'm trying to--

Q. Sure.

A. --be difficult.

14:27 Q. If we could--if I could point you to the HCH Study, which is at Tab 16 of that binder on your desk, it is also at Tab 16 of Dr. Goldman's First Report. The HCH Study. If we could just turn right to Page 50.

A. Okay.

Q. Actually, I'm sorry, if we could turn right back to Page 3.

A. Something tells me I will mark Page 50 for later use.

Q. Yes. Just go back to Page 2.

The first full paragraph, "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 document represents the EPA's continuing review of lindane which obviously had continued on since the 2002 RED was published; is that right?

A. It's representing, as the title says, it's an HCH and lindane together. As part of the continuing jacket, EPA refers to the data file as a jacket. It would be part of the lindane Assessment.

Q. Okay. And this is the revised Assessment of risks as related to continued registration of lindane. That's what it says; right?

14:29 A. That's what it says. I would not really call it a revised Risk Assessment in terms of the parlance of the program. Because, for example, in the earlier document, in the '02 RED, you have got precise quantification of risk. You have got calculations supporting it about the risk cup and so on and so on. You don't see any of that kind of discussion here.

Q. So, when the EPA says here this document presents EPA's revised Assessment of risks related to the continued registration of the insecticide lindane, you don't think they actually mean that's what this document is?

A. I would say as part of the continuing Assessment of the risks of lindane and HCH-related isomers.

Q. Okay. So, it means what it says?

A. I'm not sure that's quite the same, but we just may be parsing words.

Q. Okay. Well, let's turn to Page 50. In the top Section 5, it says "additional concerns and information request."

"Additional concerns related to lindane and the HCH isomers have been raised in public comments on the Lindane RED and Risk Assessments"--I will skip the docket numbers parts--"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."

14:31 So, this indicates that there has been no final determination with respect to lindane use in the United States; is that right?

A. At that time, yes.

Q. Okay. And it lists out five different areas of information and concern that the EPA has, including infants' exposure to lindane in breast milk, cancer classification, 10 times FQPA safety factor, cultural practices, and potential impacts to subsistence populations, and liver effects; is that right?

A. Those are the headings they are inviting comments on, that's correct.

Q. All right. Can we flip forward to the Addendum to the RED, which is going to be at Tab 18 in that binder of yours. And just for the record, it's also at Dr. Goldman's Second Report at Exhibit 32.

A. I'm there.

Q. Great.

Could you turn to Page 13.

A. Okay.

Q. And I'm going to read--I'm looking at the last paragraph in Section C, which is entitled "Infant Exposure to Lindane From Breast Milk and Resulting Risk," and the first sentence of that paragraph says, "There is a dearth of long-term studies of the effects of infant exposure to lindane

14:32 in breast milk," et cetera, et cetera, and then the last sentence in this paragraph is, "However, EPA believes that, because of lindane's prior detections in breast milk, its physio-chemical 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 a lack of data."

Do you see that?

A. I do.

Q. If you could flip back to Page 3 of the Addendum.

A. Of the Addendum.

Q. Second paragraph on that page.

A. Okay.

Q. And the third sentence starts off, "EPA believes that dietary exposure to lindane from the seed treatment use may pose a risk to nursing infants who consume breast milk contaminated with lindane. EPA, however, is not able to quantify that risk at this time or determine whether current exposures result in any harm."

Do you see that?

A. Yes, I do.

Q. So, in July 2006, at the time this document was written, the EPA was not able to quantify the risk with respect to lindane in breast milk; is that right?

A. Yes, and that would not be necessarily unusual.

14:34 Q. Okay. And it was at this time unable to determine whether current exposures would result in any harm; is that right?

A. They concluded in the earlier documents--

Q. I'm sorry, I'm asking you right here, not the earlier document. Right here, July 2006.

A. I'm talking about the response to comments that they had in light of the comments they invited on these issues, I'm sorry.

Q. Go ahead.

A. Say what it says, yes.

Q. I don't want to take--

A. Go ahead. You may need to repeat the question because I butted in, I apologize.

Q. I'll repeat it. And it was at this time unable to determine whether current exposures would result in any harm; is that right?

A. Correct.

Q. Okay. So, this is in July 2006.

A. That's the date of document, yes.

Q. Now, I take it that if the EPA in July 2006 was not able to quantify the risk with respect to infants' exposure to lindane, and the EPA was not able to determine whether current exposures would result in any harm, I take it you would not be able to make that determination either, would you?

14:35 A. You mean me personally?
Q. Yes, you personally.
A. No, I could not, but the record--this information and the same fact that it can't be quantified is the same comment they have--I'm sorry, the same conclusion they have in response to comments in the earlier iterations of the Risk Assessment that are in the docket behind the lindane molecule. This was about the--well, as we have seen the chronology and the history goes very far back, but you've got in the RED process, you have got a preliminary Risk Assessment, a refined Risk Assessment, and then this document. In fact, that is one reason they don't really call it--they call it revised again, and there's comments on each of those phases in the record. In fact, in Dr. Goldman's second statement there is some attachments that talk about the comments--I'm sorry, what the Agency calls response to comments.
And so, earlier in those other response to comments, they take into account these kind of considerations and say that we can't quantify the risk, and so, for example, in one earlier round of comments they say, but we thought about all that when we looked at the data, when we did our '02 RED Assessment, and, in fact, found that risk to children, infants and children are acceptable.
At another time in the later round of response to comments before the '02 RED, they expressly say that when the

14:36 breast milk issue was asked for in comments, and in my statement I make a--because it's only a passing reference in the '02 RED, in my second statement I make I cite that passing reference about breast milk, and the response to comments there before the '02 RED conclusions, they say specifically in light of a comment from the public that you didn't appropriately look at breast milk residues and potential exposure. They say this phrasing about we can't quantify the risk, but we conclude that, in light of the studies that we looked at and the additional safety factors under the law that there is no--that the--let me be precise.

The analysis is protective of nursing infants, and they use that specific phrasing, they say protective of nursing infants.

So, they thought about all these things, and they may have changed their mind by now. That's absolutely true. And that's one of the issues, as I say in my statements they would have to be engaged with with the Registrant, but again, that's just--dialogue back and forth just never occurred.

Q. So, you said a lot of useful information there, but I want to go back to make sure that your answer to the question was clear. I said, I take it that if the EPA in July 2006 was not able to quantify the risks with respect to infants' exposure to lindane, and the EPA wasn't able to determine whether current exposures would result in any harm, I take it

14:38 that you also would not be able to make that determination either, would you?

A. Me personally, no.

Q. You personally. And you said no.

Now, if you would not be able to say with certainty whether there is a risk of harm, you also can't say with certainty whether the EPA would or would have found an acceptable amount of risk that would enable it to issue a tolerance for lindane use in canola, can you?

A. They could still issue a tolerance by saying--after explaining to the public why you're issuing this tolerance in light of whatever considerations, whether they raised them or outsiders raised them in public comments, and they would then say, for example, things that they could add, additional uncertainty factor, and they have done that in other cases, it's partly their evaluation of the data, partly their policy choices, but when I described in my statements a path forward, those are the kind of things that decision-makers would be faced with when they would be brought the full set of facts and analyses for determination.

Q. And do you know how long it would take for that full set of facts and analyses for the determination, how long the path forward would be?

A. It can vary greatly, even very complicated cases can sometimes if they have to be resolved, for example, in the

14:39 scenario that someone discussed here about trade irritants, there is just a need--again, Mr. Johnson, I think he described that as the potentially action forcing event, that, in fact, to solve a trade irritant, to address a trade irritant, you have to act quickly.

In some cases, and especially even in realtime, you find a case of contamination, you find a material where you didn't think it was before, and the first thing you have to do is at least do a quick analysis to make sure there is no imminent harm to the public. That's not this case--I don't want to try and represent that--it could be done quickly, but the record will indicate nothing here was done quickly.

Q. Okay. So, that sounds like there is a lot of uncertainty as to how long it would take, how complicated it would be, what the results would be and so on.

A. There are many issues that would have to be dealt with. Again, as I think Mr. Thomson may have indicated, and then that's when the company decided there would be some other paths they could take in light of all the facts they saw at the time.

But again I was not--as you indicated, I was not working for Chemtura at the time or any other time.

Q. So, given all of that uncertainty, you can't say with any certainty if and when the EPA would have ever issued a tolerance for lindane use in canola--

14:40 A. Absolutely.
Q. Is that right?
A. I'm sorry.
Q. I'll ask the question again. Given that level of uncertainty, you cannot say with certainty, and the first uncertainty is referring to the studies, the analysis, the possible results of a study for lindane in breast milk, for example, and seems they were going broader than that, taking all that into consideration, you cannot say with certainty if and when the EPA would have ever issued a tolerance for lindane use on canola in the United States, can you?
A. Not with absolute certainty, no.
Q. Thank you. I don't have any more questions.
PRESIDENT KAUFMANN-KOHLER: Any redirect questions, Mr. Somers?
MR. SOMERS: Thank you, Madam Chair.

REDIRECT EXAMINATION

BY MR. SOMERS:
Q. In your response to questions from Canada, Mr. Aidala, you mentioned that there were, in addition to the hypothetical that was contained in your first statement, there were means or ways that could present a way forward to the company, even in the absence of the immediate availability of the data that the Agency had required.
A. Yes, that's correct.

14:42 Q. And I'm wondering if you could present the other of those options, please.

A. As I said in the questioning, there is a number of ways EPA can deal with data deficiencies. There is, in some sense, and almost in sort of casual parlance, EPA is never satisfied. There is always a need for more information. You'd always be improved, you'd always want more information. Why not? These issues are usually data rich, and you can see, as I mention in my statement, there is, I think it's a 40-page-plus bibliography, and there is a long two-page list of the EPA Assessments alone on this material going into the '02 RED.

So, was there a fundamental bar in the '02 RED at that time frame, and the answer is, okay, they had data deficiencies, certainly for an import tolerance alone, plant metabolism, and for a registration they had a few other registration-related issues or data gaps. This is not unusual for many, many compounds. Again the example I mentioned before, this material called cyhexatin, it was neurotoxicity, and a metabolite that they hadn't characterized and some other things, and they allowed time, give it tolerance and allowed time to develop the data, number one.

Number two, you would increase--and in that case, for example, they said there is a database uncertainty factor, an additional safety factor because regulatory agencies are very typically, if you will, need to make decisions in various time

14:43 frame, and so what EPA could have done here, for example, and especially because the risk cup was empty--I shouldn't say empty, fairly roomy, it was 17 percent of the risk cup after all their calculations because calculations included conservatism, including things like in light of the missing Plant Metabolism data, what they called a total--TRR. If you look in the heading of the tables, total radioactive radio residues, there's conservatisms built in that could lead to them to make a case if they were to approve a tolerance that would be the justification, that would be their rationale, that would be their explanation of how it met the standards of the law.

So, they could add these extra safety factors if they needed to act more quickly, among other methods, or just allow a time-limited one because they were secure enough, given the risk cup calculations at that time.

Q. So, in other words, the missing study, the missing Plant Metabolism Study or the one that only arrived years later after the '02 RED, was not an obstacle to the issuance of the tolerance that an alternative would have been what you've just described?

A. Correct. There are alternative ways to get to a positive determination, that's correct, in my opinion.

Q. Thank you.

MR. LUZ: I'm sorry, may I follow up just on that?

14:45 PRESIDENT KAUFMANN-KOHLER: Yes, you may.

RECROSS-EXAMINATION

BY MR. LUZ:

Q. I believe I heard you say, Mr. Aidala, one of those options was a time-limited import tolerance; is that right?

A. That's a tool that the Agency has.

Q. Okay. And you were here last week when I asked Mr. Johnson if Chemtura had asked for that time-limited tolerance, and I believe his words were, we were constantly calling the EPA trying to get them to move with respect to the time-limited import tolerance.

And when I asked him, did the EPA ever give a time-limited import tolerance, do you recall what he said?

A. Well, no, they never got a time-limited tolerance. I believe that's what he said because that's what happened.

MR. LUZ: Thank you.

PRESIDENT KAUFMANN-KOHLER: I have no questions, so that allows us to close your examination, Mr. Aidala. Thank you very much for your explanations.

THE WITNESS: My pleasure.

(Witness steps down.)

PRESIDENT KAUFMANN-KOHLER: I suggest we take 10 minutes--not more--and then we can start with the examination of Dr. Goldman.

(Brief recess.)

14:51 PRESIDENT KAUFMANN-KOHLER: Good afternoon.
THE WITNESS: Good afternoon.
LYNN GOLDMAN, RESPONDENT'S WITNESS, CALLED
PRESIDENT KAUFMANN-KOHLER: You're Lynn Goldman?
THE WITNESS: Yes, I am.
PRESIDENT KAUFMANN-KOHLER: You're a pediatrician and epidemiologist, and you're a Professor and you're focusing on environmental health policies; is that right?
THE WITNESS: Correct.
PRESIDENT KAUFMANN-KOHLER: And you have been a senior official with the EPA during certain time periods that we are interested in?
THE WITNESS: That's correct.
PRESIDENT KAUFMANN-KOHLER: You have given two expert reports.
THE WITNESS: That's right.
PRESIDENT KAUFMANN-KOHLER: And as you have heard before as an expert, you are under a duty to make only such statements that are in accordance with your sincere belief.
THE WITNESS: Yes.
PRESIDENT KAUFMANN-KOHLER: Could I ask you to confirm this into the record, please.
THE WITNESS: I'll read the declaration. I'm aware that I'm heard as an expert witness in this arbitration, and that I am under a duty to make only such statements which are

15:02 in accordance with my sincere belief.

PRESIDENT KAUFMANN-KOHLER: Thank you.

So, I will turn first to Respondent's counsel. To whom do I give the floor?

MS. BEHARRY: Thank you, Madam Chair.

DIRECT EXAMINATION

BY MS. BEHARRY:

Q. I only have one question for the time being, and that is, Dr. Goldman, do you adopt and affirm the statements that you provided in this matter?

A. I do.

PRESIDENT KAUFMANN-KOHLER: Fine.

Mr. Somers.

MR. SOMERS: Thank you, Madam Chair.

CROSS-EXAMINATION

BY MR. SOMERS:

Q. Good afternoon, Dr. Goldman. My name is Greg Somers, and I'm asking some questions this afternoon just on behalf of Chemtura.

A. Hello.

Q. Bear with me. Interactions of several U.S. statutes all at the same time can be fairly complicated.

A. Tell me about it, yeah.

(Laughter.)

Q. And so I'm going to have to ask you to help me

15:03 understand something. In the REDs, I'm looking at your--and I think I'll mainly be referring exclusively to your two expert reports, the one in October and the one from July. Right now I'm looking at the October, the red one. At page 12--

PRESIDENT KAUFMANN-KOHLER: Can you speak into the microphone.

Q. Sorry.

A. I'm there on page 12.

Q. Thanks. I'm looking at the section that says--it's Paragraph 25, and 10 lines down, "EPA went to considerable lengths to discuss its uncertainty about whether under the fairly new standard in FQPA, it needed to incorporate exposures from lindane pharmaceutical use into the aggregate risk analysis and invited comment on this point.

Now, as I understand it, in the 2002 RED, it did not aggregate those risks; is that right?

A. I think that the way I interpret it is that EPA was grappling with that as an issue, and that, in fact, my belief is that it continued to grapple with that issue until 2006, probably early 2006, from what I can tell from my read of the record and the materials that have been submitted to this body, and so that at this point in time it asks for comment, and that's what I said.

Q. Okay. Well, it may be, but I guess I didn't get it. It had to issue a re-registration eligibility decision in '02,

15:05 so it had to make a pro tem for now finding on whether aggregate those risks as well as soliciting views as you just said.

A. Did not have to issue the RED in 2002.

Q. No, that wasn't--

A. It did not have to do that, no.

Q. But it did?

A. It did.

Q. And it--in the 2002 RED it said the existing registrations are eligible for re-registration. In order to do so, it would have had to make an interim call on whether to aggregate those risks or not, wouldn't it?

A. No.

Q. Oh.

A. Because the registration decision is a decision under FIFRA, the Federal Insecticide, Fungicide and Rodenticide Act, and the decision about a tolerance, the food standard, is under a different statute, the FFDCA, the Federal Food, Drug and Cosmetic Act. And the specific provision related to the aggregation of risk from multiple uses was only for the food standard, not for the registration/tolerance.

So, the thing in the 2002 RED is that it said under FIFRA the seed uses would be eligible, would be eligible, but then it went on to say that they were not yet able to determine whether tolerances could be granted, and so--and that's I think

15:06 what I was trying to convey.

Q. Okay. That's fair.

And all I was trying to ascertain was, in deciding whether re-registration of the existing registrations was available, did they aggregate pharmaceutical risk in with agricultural?

A. They wouldn't--there is no aggregate risk standard under FIFRA, so they would not need to do that for re-registration, and they did not address it. They simply said they would need to address that in the future and ask for comment.

Q. Thank you.

Moving on in your statement to Paragraph 26, and I'm looking at the second last sentence in that paragraph, and I will read that into the record: "If the Agency identifies other substances that share a common mechanism of toxicity with lindane, then the cumulative risks of these chemicals will be considered. Indeed, public comments directed to this issue led the EPA to complete a more comprehensive Assessment not only of lindane, gamma HCH, but also the related inextricably alpha and beta isomers.

Now, with that sort of in mind, I'll ask you to turn to Tab 17 of your Second Expert Report, and I guess I just wanted to clarify that I understand what--

A. What I have there is the memo from Mark Howard.

15:08 Q. Yeah, yeah. It's subject, Agency response to Phase III comments on lindane.

A. Okay.

Q. And as I understand it, this document is exactly what the subject line says it is, of course. It was what went into the conclusions reached. It would have been a cornerstone to the conclusions reached in the 2002 RED.

Under Tab 17, it's a few pages long, but I'm looking for Page B 7.

A. Okay. I'm there.

Q. Six, I'm sorry. B 6.

A. Okay.

Q. It's Appendix B.

A. Okay.

Q. And I guess I'm trying to get at the at least the position as of 2002 was that the linkage between the alpha and beta isomers and the gamma or lindane, which is really what we are concerned with here.

In the second public comment at Appendix B, which is Page B 6 of Tab 17 of your Second Report--

A. You're looking at the one, two, three, fourth full paragraph on that page?

Q. Well, actually, I was looking at the public comment just before that, but--

A. And so the third and fourth full paragraphs?

15:10 Q. Yes, public comment and had response because that seems to me to address the isomer issue here, and the public comment is one commenter stated that the beta isomer of hexachlorocyclohexane, HCH, should be assessed in the dietary exposure analysis also due to the transformation of lindane, which is the gamma isomer of HCH to beta hexachlorocyclohexane. And the response of HED of the EPA to this is, "HED believes the available data do not support significant isomerization of lindane gamma HCH to beta HCH in the environment. Therefore, HED will not include beta hexachlorocyclohexane in the dietary exposure assessment."

So, at least as far as the 2002 RED, when I take from that that they're not inextricably linked for purposes of the dietary Risk Assessment.

A. Okay, I need to explain what I meant in what I wrote in my Expert Report, and first I was referring not to the public comments that were received to the draft RED to which this memo alludes in Tab 17. Those were the comments that were received prior to publication of the RED. I was referring to the public comments that were filed to the final RED and that preceded then the creation of the lindane and other hexachlorocyclohexane isomers Report.

But second, when I say related inextricably, what I mean is that when you manufacture lindane or the gamma HCH, you always produce the alpha and beta isomers. And, in fact, you

15:12 produce a larger quantity of the alpha and beta isomers than you produce of the gamma.

So, when I meant chemically that they're inextricably linked, that you can't make the desired product if you made the pesticidal product without making the waste, if you may, the alpha and beta isomers. That's what I meant. And I'm sorry if that was not clear.

Q. It is now. I appreciate it. Thank you.

In the next paragraph on your first statement, first Report, sorry, the last sentence of it is, "These two issues that were"--sorry, I will back up and give the two issues too.

"Second, the Agency stated in the 2002 RED that there is some evidence that lindane may act as an endocrine disruptor. However, further investigation is necessary to ascertain the relevance and impact of such findings on public health. These two issues that were highlighted in the 2002 RED document concerning possible cumulative risk and endocrine disruption, by law, would have had to have been addressed for the EPA to establish the tolerance."

We heard earlier, though, that for in particular urgent or pressing situations, additional risk factors could have been built in or uncertainty factors could have been built in to take into account pending data, data that had not been completely received or analyzed yet by the Agency, and tolerance or time-limited tolerance could issue, pending

15:14 receipt of that data, if--with those additional uncertainty factors for the data gap, I will say, the Agency didn't have a risk of concern.

A. And sometimes that has occurred, and I think we heard a lot today about uncertainty factors. And it depends on what uncertainty factor might be imposed, whether that would quote-unquote work in terms of being able to issue the tolerance, and so how uncertain you are.

And so, for example, in the testimony heard earlier today about the difference between the uncertainty factors that Canada used versus the U.S., that additional uncertainty factors for what I would call database deficiencies, databases incomplete, you put additional uncertainty factor can put you--can make the risk cup overflow, if you may, so if you have a risk of 17 percent of the risk cup, you put a tenfold uncertainty factor on it, you're at 170 percent. You're overflowing. And so, that's possible. That, as far as I know, was never requested. I couldn't find anything in the record suggesting that that was a course that people were on with this particular pesticide.

Q. In Paragraph 29 of the Report, just a couple down, I'm turning the page to Page 14?

A. The back part of--the end of 29?

Q. Yeah. I'm looking at the last, I guess, two sentences of it, reading from there. "In the case of lindane, for any

15:15 food uses not approved under FIFRA in the re-registration process, EPA also would have revoked existing tolerances. It is highly unlikely that EPA would have granted tolerances for canola seed treatment without also approving the registration of lindane for canola."

And I believe you're aware because you were at the EPA at the time there was a trade issue in relation to imports into the United States of canola--lindane-treated canola seed.

A. Right.

Q. It had been coming in contrary to U.S. law, and various correspondence went back and forth between the stakeholders and the EPA on that issue.

One of the sets of correspondence--I'm not sure if it's in your materials or not--was a request from the North Dakota Commissioner of Agriculture for an import tolerance as one option in dealing with this problem. For that to have been granted, it wouldn't have been necessary to have a registration of lindane for use on canola in the United States immediately, would it? Could an import tolerance not have issued absent or pending a registration application?

A. By definition, import tolerances are granted in situations for which there is not a registration or a tolerance. If you have a registration, you could have a regular tolerance.

Now, in terms of the letter, I believe that was from

15:17 Mr. Roger Johnson, who at that point was the Agriculture Commissioner. I don't think that he actually was making a formal request for an import tolerance. I don't remember the exact wording of the letter, but I don't actually think that that was an application for an import tolerance, just to be clear.

Q. And if I suggested that it was, I take it, and I certainly apologize for that, because it was not. It was--I believe the word he used was just tolerance, but I wondered if--

A. But, I mean, that--certainly that time period certainly would have been the, you know, the crisis or the precipitating event that might have caused people to consider that kind of thing as an option.

Q. Right.

A. That was not a road taken at the time, but that, you know. The only time--so, I was at EPA for a little over five years, almost five-and-a-half, and the one time that we did do an import tolerance was a residue of a pesticide on wine from France. The entire pesticide did not have a registration at EPA, had never applied--the company had never applied for a registration, and it, you know, was not a risk issue, but it certainly was a trade issue, and we were able to work it through that way.

But in my experience, they are very unusual events

15:18 1 that precipitate such a thing, I should say.
2 Q. Thank you.
3 I guess on that issue, I'm looking at Paragraph 46 of
4 your first Report, please. And I guess what you mention there,
5 there were mounting concerns particularly about worker risk
6 justifying the Data Call-In, I see that there, but in respect
7 of an import tolerance, as I understand it, concerns about
8 worker risks wouldn't have been pertinent because--
9 A. Right. The worker risk issue would not have been--it
10 would have been an issue with treating the seed, but not with
11 the tolerance per se.
12 Q. At the bottom of that page, it would be Paragraph 48,
13 you state, "Because lindane was manufactured"--I'm sorry, one,
14 two, three, four, five--six lines down up from the bottom of
15 the Paragraph 48, Page--the sentence beginning, "Because
16 lindane was manufactured outside the U.S., EPA had been able to
17 disregard the risks associated with the manufacture and
18 disposal of the large quantities of waste that were produced.
19 Given that, as noted above, for every tonne of lindane
20 produced, approximately 6 to 10 tonnes of the alpha and beta
21 isomers are also produced." And you've alluded to that
22 already, and the lack of authority for EPA to regulate
23 pesticide manufacture and waste disposal in other countries.
24 Is that not the case today?
25 A. Yes. EPA does not regulate how people dispose of

15:21 their wastes in other countries.

Q. I guess the reason--and you go on to say, "But international obligations were engaged in the context of U.S. approval of a pesticide contributing to global pollution," et cetera.

A. Well, as well as our own--okay, we have Alaskan populations that are exposed to that global pollution in particular.

So, there is also a subpopulation, if you may, that's fairly sizable within the U.S. that's going to be on the receiving end of that that has to be considered as well, and I think that EPA was over this time period between 2002 and 2006 increasingly considering.

Q. I guess what had confused me was you said international obligations were engaged when, in fact, that's a domestic obligation, isn't it?

A. It's a domestic obligation.

Q. Okay. I was confused by that.

A. However, the problem, sir, is that we don't--you know, when you see the exposures occurring in the Arctic, you cannot attribute those exposures to any particular contribution from any specific country, and so it becomes an international issue because of the fact that you really have no way of saying what fraction of that is from the U.S. use, the Mexican use, the African use. Where it's coming from, we don't know.

15:22 Q. Jumping ahead now to--

ARBITRATOR CRAWFORD: Could I just follow up on that because as a matter of intellectual interest if nothing else, in that situation where this stuff is produced in Romania or India or China and six tonnes of the beta isomer are produced for every one tonne of lindane, how can the EPA take that into account in any decision it's properly called on to make? You say they don't regulate waste disposal in India or China, which is obviously true. So, how could it be relevant in terms of anything that the EPA has to do?

THE WITNESS: Very difficult, and so what EPA apparently tried to do because they talk about it a lot, and lindane and other HCH Report, the discussion document that they released, they attempted to get information about the circumstances of that manufacturing process, the processing of the waste, the disposal of the waste, and actually the Registrants attempted to provide information to the EPA to assure them, provide some kind of assurance that this was being done safely, and EPA concluded that they could not be persuaded of that.

But I agree with you, and it's the reason, I think, for the POPs treaty and these other international agreements emerging on the POPs because otherwise you kind of have a paradox, which is that you have--right.

ARBITRATOR CRAWFORD: But could EPA lawfully say,

15:24 because we are not satisfied that this is safely disposed of in Romania, therefore we will not grant an import tolerance?

THE WITNESS: They could say that.

And so, one thing that EPA did do prior to this time is that EPA had policies related to dioxin formation with the manufacture of certain pesticides, such as 2,4,5-T, that the most toxic dioxin, 2,3,7,8-TCDD is produced, and on that basis EPA not only did not allow the manufacture in the U.S., but stopped the import of all, you know, all use and registrations, so it can do that, but you know, there aren't--you know, it's not an area with a lot of precedent other than the dioxin one, as far as I can tell.

ARBITRATOR CRAWFORD: It's a professional deformation of mine.

THE WITNESS: No, it's kind of interesting.

PRESIDENT KAUFMANN-KOHLER: You can continue.

BY MR. SOMERS:

Q. On the last bit about the 2,4,5-T, what year was that? Could you tell me?

A. Oh, gosh. Well, I have got to think. It must have been around '86 or '87. I mean, I have to--I'd have to go back and look at the record specifically. I know when I was at EPA, I knew it was--I know it was before '88, and the reason I know that is that EPA was destroying the existing stocks of that while I was still there, and the 1988 law took away the

15:26 obligation of EPA to do that. There used to be this--I'm going to tell you more about the law than you want to hear, but there used to be this requirement, this indemnification requirement that if EPA canceled a pesticide, it was responsible for disposing of it. And we were still burning T when I was at EPA for the first couple of years, so it had to be before '88, but I don't think it was much before '88. I'm not sure about the exact date, and I apologize for that.

Q. The EPA was responsible for disposing of/destroying in a safe manner the leftover pesticides?

A. In the old days, yeah, before the '88 amendments.

Q. Was that pesticide manufactured in whole or part in the United States?

A. That pesticide was manufactured in many places, but certainly in the U.S., and I think our obligation was only to the U.S. Registrants and not the others.

Q. And the fact that it was being manufactured in the United States, did that not give you the jurisdictional hook to regulate the dioxin that I think ended up on fruit or something like that?

A. Yeah, but we didn't allow it for import, either.

Q. No, but I'm talking about the action.

A. Yeah.

Q. Thanks.

In the 2,4,5-T example, when you say dioxin, dioxin

15:27 was an impurity in the product, or was it a byproduct of making it?

A. It was--well, both. It was both. It was a byproduct of making it that remained in the product, in the technical product as an impurity. In making it, it was a byproduct and--just as actually the alpha and beta HCH isomers, there is teensy amounts of them in the lindane product that's marketed as a pesticide. A hundred percent isn't removed, so the typical process is the chemical is manufactured and then they go through purification steps before you have the pesticidal product that's then formulated.

And so at manufacture, it's a byproduct. At the end of the day, it's an impurity. Does that make sense?

Q. I think so. I'm going to stretch it a little bit more, if I can.

The dioxin that was being regulated is--let me back up. There isn't six to 10 tonnes of dioxin produced for every tonne of 2,4,5-T?

A. No. In dioxin land, you're talking about minute quantities that are toxicologically important, you know, so parts per--within the product, probably parts per billion.

Q. And the concern of the EPA was the dioxin as I almost said adulterant, as an impurity in the 2,4,5-T, wasn't it?

A. Yeah, I'm contributing--you know, contributing because it's very persistent. Another one of these POPs.

15:29 Q. Right. And so, 2,4,5-T is whether it's manufactured in the States or imported, it's got some dioxin in it?

A. It has dioxin in it.

And there doesn't seem to be possible to make it without making dioxin, so that's just the way. I don't know why. I don't know the chemistry. I apologize for that.

Q. You and me both.

And so, what happened, in either manufacture, domestic manufacture or importation of 2,4,5-T, dioxin is coming in with it, EPA has the authority to regulate the impurity in a pesticide, or that's a herbicide, I guess, but in that pesticide--

A. In that case, if they had been able to develop a means to manufacture the pesticide without producing the dioxin? Is that what you're asking me?

Q. No, actually--go ahead.

A. Would that have been--the EPA might have looked differently upon the risks of the pesticide. Is that what you're asking? They may have. I mean, yeah, it's possible.

Q. Oh, okay. Well, just to be clear, I guess what I'm saying is EPA does not have the authority to regulate waste produced abroad in the manufacture of a pesticide. That's really what I'm getting at. And in the dioxin example is not exactly one of those because the dioxin that they were regulating was the impurity of the imported pesticide coming in

15:30 on the boat right along with the 2,4,5-T.

A. Oh, so you're making the distinction about whether it's imported on the boat or imported through, you know, global circulation, and so back in the eighties, I think, being imported on the boat would be have the only thing EPA would have looked at.

I mean, you know, these POPs agreements didn't start being developed until the '90s, and so, you know, the Great Lakes Agreement wasn't until what? '96, '97. The UNECE LRTAP agreement not until, say, '97. So, you know, by the mid-'90s there is definitely a focus on not just being imported on a boat, but the global movement of these contaminants.

Q. As I understand it, though, EPA, while working towards jurisdiction or authority over regulating these global trends, doesn't have it, and so at the material time, the time we are talking about, sort of '98, 2002, 2004, in the time period that is material to this, these hearings, the EPA would not have had jurisdiction to regulate out a pesticide based on these global issues that you've just discussed. Not yet anyway.

A. Well, so then going back to my Report and what was in the RED, I believe that what EPA was asking for comment on was partly the extent to which they did have such authority or even an obligation, and I believe when you look at the comments that were filed to the RED, that some of the commenters felt that not only did the EPA have the authority, but was, indeed,

15:32 obligated to deal with this under their existing statutes and others did not.

And so, I mean, you may have your conclusion about it, but I think what EPA was grappling with were those specific issues, and then how those would be relevant to the establishment of tolerances for lindane on these existing seed uses.

So, I don't read into what EPA wrote at that time even this response to comment that EPA had made a conclusion. The way I read it is they're continuing to invite public comment on these issues.

Q. Fair. Thank you.

This is more my ignorance about your statutes of operation. I'm looking at Paragraph 74, fifth line down--well, actually fourth line down, to start at the beginning of the sentence. "She further stated that regardless of the registration status"--I'm in--I'm jumping a bit around, I'm sorry. I'm in the first Report of yours, Paragraph 74. You're describing a letter which is actually tabbed on to your Second Report, the January 12th letter of Ms. Anne Lindsey to Mr. E.L. Moore of North Dakota. In that letter, she stated that in the EPA, Office of General Counsel, the importation of such seeds as described in the Gustafson letter would be a violation of the FIFRA.

She further stated that regardless of the registration

15:34 status, lindane-treated canola seeds would require either a tolerance or an exemption from tolerance, else the food grown from such seeds would be considered adulterated. I thought tolerances were FFDCA things while treated seeds were FIFRA things.

Am I wrong on that?

A. Well, hopefully nobody is eating the treated seeds. That's the question.

Q. That was my thought, too.

A. It has happened, and it's not been good when that does happen.

So, I would love to be able to actually look at the letter. Do you know which tab it's on?

Q. As soon as I find it. It's I believe it's under tab--bear with me, I'm sorry.

Tab 2 of that immense binder on your upper left?

A. In this one or in this one?

Q. Right.

A. So, it's in my first Report.

Q. That's right.

I'm just advised it's contained at Tab 23 of the joint book, which would be Volume 1 of the joint hearing book, Tab 23. It's also--Exhibit WS-2.

A. Yeah.

I mean, I may have misspoke because what she said

15:36 precisely, which I think is correct, is that the pesticide tolerance or exemption from the tolerance could be necessary to avoid adulteration food produced from such treated seed, and then what I went on to say, I think, in my Report is that, given that EPA had in hand no data about how the treatment of seeds might or might not result in residues in food, you know, Ms. Lindsey wouldn't have had a way of being able to say, you know, you definitely need a tolerance or not.

I think--you know, I think she was trying to convey that there was some risk of food being in the market being adulterated as a result of use of these treated seeds.

Q. Right. One of the issues in this hearing is there is treated seeds on the one hand. There is product grown from those treated seeds that may or may not contain residues on the other. If they have appreciable residues, the tolerance would be required; is that right?

A. Minus--yes. I mean, if it's legal, one of the fundamental principles that, you know, we followed at EPA in regulating pesticides is that legal uses of a pesticide should result in legal food. It would be perverse to have the food be illegal with a legal use, you know. And so, of course, one would have to see that.

Q. And so I think I will ask you: Is the language on Page 34 immediately above Paragraph 79 also susceptible to the same--I don't remember what you said--correction.

15:38 A. Yeah, it would be, of course, the potential for residues on the food that would be derived from the treated seeds, correct.

Q. So, if I could--I will try a redraft to the sentence by you to see if I get it even to this extent.

In conclusion, I'm reading from the last sentence of Paragraph 78, "In conclusion, the U.S. closed the border to lindane-treated canola seeds because the pesticide on the seeds were in violation of the FIFRA."

A. And the residues on food grown from the seeds could potentially be a violation of FFDCA, so--

Q. But--I'm sorry to interrupt you, but the sentence begins, "In conclusion, the U.S. closed the border to lindane-treated canola seeds."

A. Right.

Q. So, there is no issue about food yet, or at least not as far as--

A. The seeds were coming in for planting for food.

Q. Right.

A. They were coming in for planting for food.

So, if you are planting those seeds which are treated with a persistent substance, so would you then have that substance persisting in the field being uptaken into the crop and thereby entering the food supply either directly or indirectly? Which is the point, of course, of all the studies

15:39 that EPA wanted in terms of plant metabolism and so forth.

Q. I guess I'm being a little more technical in that I'm saying they closed the border because the seeds were a FIFRA violation?

A. Correct.

Q. They weren't also projecting into the future saying and if these are planted and if they grow and if they're used for food and if the food is produced from them, and if we use the oil in the meal from these and we find residues and there is no tolerance, then there will be a problem. That's not what they did, I'm suggesting. All they did was say, these are pesticide-treated sides, they breached FIFRA because there's no registration for this, border closed. And that's all they really did or had to do?

A. That's what we did. We did that, yes. We closed the border to the importation of the treated seeds. We did that.

Q. On the basis of FIFRA?

A. On the basis of FIFRA.

Q. Can I ask you to--could I ask you to turn to tab--okay. I'm looking at--I'm under water. Paragraph 81 of your first Report?

A. Right.

Q. I will just read from there and then take to you my point. My point is about whether the growers participated or not, and I guess I think they did, but it may be I'm

15:41 misunderstanding again. "Second, once CIEL and Inquinosa filed a petition"--I'm reading from Paragraph 81 of the first Goldman Report. "Second, once CIEL and Inquinosa filed a petition for a tolerance for lindane on canola, it was published in the Federal Register for comment. Likewise, the growers could have filed comments at numerous other points most notably in response to the 2002 RED or in response to the 2005 petition to revoke all existing lindane tolerances. In my experience, often grower groups do file such comments either when they are in need of a new pesticidal use or when they wish to defend an existing use that they believe is important to their industry. The canola growers did not write such a letter."

Part of the issues in this hearing as well as what did the growers really want, and so that's why I'm boring you by reading from your own words, and also so the record reflects it.

Under Tab 17 of your second Report, I'm looking at page--Tab 17, it's that old memorandum, agency response to Phase III comments on lindane again, January 30, 2002. The third page in, A 3, there is an Appendix A that point 3 says "Canadian canola growers and seed treaters comments. Many comments came from canola growers and canola seed treatment businesses in Canada. They urged that lindane be registered for use on canola in the U.S. Currently lindane use as a pre-plant seed treatment on canola is voluntarily suspended in

15:43 Canada."

A. I see that, yeah.

And again, what I was referring to is the comments to the final RED and not the comments during the draft, but your point is taken that the Canadian canola growers certainly wanted the U.S. to register the lindane.

Q. Okay. I'm going to get your second Report.

Now I'm looking at the Paragraph 8 of your Second Expert Report, and again maybe we are getting--I'm looking for a correction or give an explanation or something. I'm looking at the second complete sentence on Page 5, where it starts, "The March 12 letter was communicating that in the absence of a tolerance for lindane on canola, any lindane-treated seeds entering the food supply would be subject to enforcement under the FFDCA."

A. Right. If they happened to enter the food supply, and so--which is not to say that we expected them to legitimately go into the food supply, but it was a warning that if they were inadvertently to end up in the food supply, that it could create a problem.

And so, I mean, if we could go to the letter.

Q. Sure.

That letter is in this one at Tab 1, I believe. It's your and Mr. Herman's letter to Roger Johnson.

A. Part of what we are trying to do is provide a little

15:46 bit of warning, although the EPA is attempting to provide some flexibility about the enforcement of this importation ban by waiting until June 1st, before having the customs department start to halt the seeds, that there really was no such agreement by the Federal Food and Drug Administration, which is a separate Agency.

And the FDA has the enforcement responsibilities for pesticide residues on foods under FFDCA, and so, you know, the enforcement office at EPA over which was Steve Herman, who cosigned this letter, could certainly say we are going to provide some discretion about enforcing FIFRA, but could not make such a commitment with regard to FFDCA. Only the FDA could do that.

And if you note, there is a copy to Bob Lake, who is with CFSAN at FDA. He's in the policy office, Bob Lake, who's with the Center for Food Safety and Applied Nutrition at FDA, because we had been in conversations with Mr. Lake about the fact that this was ongoing, that it was a problem, and they were very clear that, well, we understand that, that's your problem, but it's not the FDA's problem, and that if they were to identify any residues of lindane on canola or canola products from canola, that those--that food would be adulterated. So we felt we needed to provide some mention of that in the letter, that we could make a commitment on behalf of our Agency, but not on behalf of the FDA.

15:48 Q. I'm looking at the letter, Page 2, third paragraph.
A. Yep.
Q. And, in fact, you're rather reassuring about residues where you say, three lines, four lines from the bottom, "EPA has consulted with the Food and Drug Administration and believes that the likelihood of harmful residues resulting from this season's use would be exceedingly small. Nevertheless, EPA urges growers if at all possible to plant only seeds treated with U.S. registered pesticide." That's rather gentle.
A. I'm glad you feel reassured by it because the purpose of what we were writing was to attempt to reassure people. We were trying to calm the waters, and we didn't want people to--what we were trying to do was ease the transition, was ease the transition between the--what appeared to become a routine practice, whereby these treated seeds illegally were crossing the border into the U.S., were being used to grow product in the U.S., then was transported back to Canada to be pressed into oil and other food products. And we did not want to create a disruption in the food supply, and at the same time we wanted a fairly rapid transition to a situation where what they were doing was legal.
So, we were writing this in a way to attempt to be reassuring. And even though FDA wouldn't promise anything to us about what they would and wouldn't do, we were hopeful that they weren't going to, you know, go on some big, you know,

15:49 enforcement thing.

As a matter of fact, I do think that they did do some checking for lindane in canola products, but I'm not sure whatever happened with that.

Q. I can offer a bit of information, not on the FDA checking, but on residues, and I will have to ask for this to be put in front of you so that you have the letter in front of you. It's a letter from the Canola Council to the Canadian pesticide agency. It's Exhibit WS-99. It's not in the joint hearing book, I understand. It's the second to last attachment to this confidential second Affidavit of Wendy Sexsmith.

A. What I see here is a letter from JoAnne, I think, Buth, to Mrs. Wendy Sexsmith.

Q. Yes, that's it.

A. Okay.

Q. And at the bottom of the first page, it states, "Residue testing by the lindane manufacturers have shown .0058 ppm lindane in canola seed, which as far as I know is not a food, but no detectable residues"--I'm sorry, I will interrupt myself to say it's at Tab 212 of the Joint Hearing Bundle of Volume 6.

A. So--does everybody have it? I think what the letter--I have never seen this letter before, but I think what it's saying is that the lindane manufacturers are reporting no detectable residues. That is below the LOQ, the level of

15:52 quantification.

Q. Right.

A. In either the canola oil or the meal.

Q. Right.

In that circumstance, would canola oil or meal be in jeopardy of being afoul of U.S. FFDCA Law?

A. It depends, I mean, and so it depends on two things, one being whether, of course, on review of the study the EPA agrees that it was done properly and agrees with the conclusions. That always goes without saying.

And, second, that the metabolites of the lindane aren't in themselves hazardous and aren't in themselves a reason for concern.

Now, the only other thing that I had seen relevant to this was later in 1998, an E-mail from a C.P. Yip, who works with Gustafson, saying they did find the lindane in the oil, but, of course, I don't think that EPA was aware of that as well, and there were no data associated with that. It could have been found at below--well, it couldn't have been found below the level of quantitation, but that is in the record as well.

Q. Do you recall in addition, here that's right. It depends on the LOQ; right, as to whether--

A. They may have had a lower LOQ.

Q. Do you recall whether that correspondence indicated

15:53 1 whether it was processed or unprocessed oil?
2 A. No.
3 Q. Unprocessed oil--
4 A. No, I don't think it said that. I just think--I don't
5 think it said processed/unprocessed. I don't remember that
6 adjective being there.
7 MR. DOUAIRE de BONDY: If we could be of assistance,
8 the document she's referring to is at Lynn Goldman Report
9 number two, Tab 2.
10 THE WITNESS: Oh, they're saying extremely low, six to
11 seven parts per billion, so I had not remembered that.
12 BY MR. SOMERS:
13 Q. All right.
14 A. Again, I mean, I'm not sure I would really consider
15 that to be actual data. It's just something in an E-mail. You
16 would have to...
17 Q. I'm going back now to--that was a bit of a tangent
18 into Canola Council's Report, back to your second Report at
19 Page 5, and to that sentence I had read that took us to the
20 March 12 letter, the March 12 letter was communicating, it
21 reads, three lines down from the top of Page 5, that, "In the
22 absence of a tolerance for lindane on canola, any
23 lindane-treated seeds entering the food supply would be subject
24 to enforcement." In fact, in--would any thiamethoxim seeds,
25 treated seeds entering the food supply be always subject to

15:55 FFDCA enforcement?

A. That's a good question. Thiamethoxim is not as persistent, so I'm not sure that EPA would have been quite as concerned about warning them about FDA finding them potentially.

So, one problem with a persistent compound is that, you know, until you have the studies, you might be more concerned about carryover from the seed to the plant to the food supply.

Q. I'm sorry, I may have--I have not been clear. Let me come at it another way.

Here you say any lindane-treated seeds entering the food supply would be subject to enforcement under the FFDCA.

Would that be true whether the lindane was registered in the United States or not? Lindane-treated seeds entering the food supply, the green guys, the stuff that--

A. It shouldn't enter the food supply in any case.

Q. Exactly.

A. Right. That's not food, that's correct.

Q. Oh, okay. So, in other words, my question was, any thiamethoxim treated seeds entering the food supply wouldn't be--

A. You wouldn't want. That's right.

Q. So, I go down to the bottom of the Paragraph 8, five lines from the bottom where it says, "Therefore, EPA had every

15:56 reason to be concerned about the possibility that, one, lindane-treated seeds could have inadvertently been entering the food supply."

A. Or that crops containing lindane-treated seeds could have contained lindane residues, which could also wind up in the food supply.

Q. Right. And it goes to the residue issues we were talking about before. That I follow, but it's the lindane treated seeds of--number one, lindane-treated seeds inadvertently entering the food supply. That would be true whether they're registered or not, that would be a problem.

A. Correct. Although if it had been registered, certainly we would still be concerned, but there would be some possibility of small quantities of them going into the food supply and not making the food adulterated. So, you know, by definition, any detectable residue of lindane would have caused the food to be adulterated and therefore unfit for sale.

Q. Here we are talking about lindane-treated seeds, though.

A. Right.

Q. Oh, okay. So, that's not acceptable at any level, I assume?

A. Not acceptable at any level.

But the point about adulteration is that even if it were a small quantity, you could have wound up with food that

15:58 then was not legal food.

Q. I appreciate that.

I'm going now to Paragraph 10 of your statement, and I will be referring to a memorandum, I believe it is, in the Joint Hearing Bundle Volume 2, Tab 41.

A. Which paragraph are you in.

Q. I'm on Paragraph 10 of your statement.

A. Paragraph 10.

Q. Second Report, bottom of Page 5.

A. Okay. Oh, yes, this one. I puzzled a lot about this one, actually.

Q. I'm certainly not trying--I'm putting my cards on the table. On the one hand, no Agency would ever try to influence another and that sort of thing, and on the other there is this document, and I'm trying--

A. Well, in the first place, you know, what I can't understand, I mean, looking at it myself, and I've asked about this, is this a mistake, that these two pieces of paper are together because the fax header doesn't appear to me to go with the next page, and the next page has no fax lines on it. And so, I--this is one of the ones that I was really puzzled about.

MR. DOUAIRE de BONDY: We have confirmed this is a mistake. They shouldn't be associated.

MR. SOMERS: Thank you.

BY MR. SOMERS:

15:59 Q. Never mind let's say the fax cover page.
A. Let's go to the substance?
Q. Let's go to the substance.
I'm happy to assume that this wasn't faxed to Anne Lindsey. It's not material to the discussion.
A. For all I know, it was. I don't know. I don't know if it was--whether it was faxed or not, anyway.
Q. Right. And we can set that aside.
First of all, have you read the--
A. I have read this.
Q. --lindane seed treatment update.
Can you either confirm or help me out with the first sentence.
A. Well, first and foremost, it must have been--it must have been written by somebody on the Canadian side, somebody in probably the PMRA, I assume from reading this. And then it starts with a sentence that attributes to me a certain commitment to clarify our policy with midwestern states and canola growers. They misspelled my name, but I believe this is probably true.
And then they said that we had intended to send out a PR notice, which I know that we did consider such a step. We did consider a PR notice. In fact, it could have been even my idea. I don't know whose idea it was, but you know, when you look back at the record, there had been way back in 1992 a

letter from at that time the Director of the Registration Division, Larry Clean, to the State of Minnesota that clarified for Minnesota whether or not the seed treatments constituted a pesticidal use under FIFRA and whether they were or if they were exempted, and he said, no, it was a pesticidal use, and the importation of an unregistered pesticide is illegal. Therefore, the importation of these seeds would be illegal.

And he even harkened back to a 1990 document that said the same thing apparently.

And so, you know, we did feel an obligation to be more clear to the growers and to all the State agriculture departments, not just one at a time, what the rules were, you know, so that they could be consistently enforced by our own state partners because most of the enforcement is actually done at that level, by the state ag departments.

Q. So the first bullet at the bottom--following the third paragraph or inside the third paragraph is no publication of the current PR notice on the status of treated seeds by EPA. I should have read the header, the resulting proposal has emerged--this is the third paragraph--after follow-up to this issue with both the Canola Council of Canada and EPA staff. No publication.

A. I know that the PR notice was not published. I did not personally participate in any of these meetings, and I don't remember, really, being personally engaged in this.

16:02 When I have gone back and read through the draft of the PR notice, I think I understand why it wasn't published, but that certainly was a policy decision at that time that was made that it was not necessary.

And, frankly, to be clear to everybody, I think by that point in time, everybody did know the policy, so I'm not sure that the PR notice would have been a necessary means of communicating it.

Q. Can you help me or surmise or even inform me, if you know, why that would have been part of the proposal?

A. Why it would have been part--

Q. Not to publish that PR notice.

A. Part of what proposal?

Q. Well, the proposal that the third paragraph identifies, the resulting proposal has emerged after follow-up to?

A. Yeah. I don't know why it's bundled up with these other things. I mean, if we go to the draft PR notice, I can tell you why I think it wasn't published because I think that it opened up.

It basically opened up another can of worms that I don't think was an avenue that EPA wanted to take, and I can explain that. It's a little bit tedious because it gets into some things related to FIFRA that, you know, even I have trouble remembering, but after all, it has been more than 10

16:04 years, but I would be happy to tell you why I think EPA did not take that path.

I mean, I could put it in a nutshell, and that is, that, you know, what it opened up was that the basis for EPA to be able to--EPA had something called a treated article exemption. Treated Article is under EPA Regulations an article that has been treated with the pesticide where the treatment, the pesticide treatment itself is registered as a pesticide, is a pesticide under FIFRA, but a way of EPA deciding whether or not the Article is a pesticide, so you can imagine their Articles and the easiest one to use as an example is a pesticide-treated bed net that they use for controlling malaria. Well, it's an Article treated with the pesticide, but the bed net itself is a pesticide. It is for a purpose of controlling a pest, okay?

Take a treated seed. Okay. The pesticide on the treated seed is just a protectant from the seed. It is not--so the pesticide treated seed isn't the pesticide because it's only to protect the seed. You're not using the pesticide-treated seed as a pesticide. If you were, then it would fall under all these other requirements of FIFRA.

Now, why it got caught up in this is that the basis of the exemption, though, is that the products not the active ingredient, lindane, but the actual product that's formulated from the lindane has been registered by EPA, and once EPA

16:06 started writing all this out for the PR notice, then what became glaringly obvious is there was another problem, which is not only that different active ingredients were being approved in Canada as in the United States, but even if it was the same active ingredients, the Registrants were formulating them into different products. And then would EPA have to go down a road of being able to say not only is it the same active, but it's exactly the same product, and which could then even lead to further conflicts really for no good public policy purpose. There would be no public well-being that would be served. And so, that is why EPA backed away from this.

Why it is now--and it could be at a staff level this was tabled as something that could be bundled with all this, but I can tell you that, you know, EPA was not going to issue that PR notice because it was just going to lead down a path that was not going to be a productive one.

I'm sorry it's so complicated. It's ridiculous.

Q. I think I understood.

The second paragraph of that notice--of that update, states, EPA is concerned about the continuing use of lindane on canola in Canada. October 2, '98, the date of the update, that would have been--you were at the EPA at the time? You would have been aware--

A. Yeah, I was still there, I had two more months at that point.

16:07 Q. All right. So, I will take it up. Again, EPA is concerned about the continuing use of lindane on canola in Canada apparently with a view to seeking cancellation of the use.

Could you recall that?

A. No, but I could guess that that would be the perception that--I think that it has a little bit more of an edge on it than perhaps the way that I would have put it, and probably at the time we all felt that when we were faced with this issue that it's certainly the easiest solution from the U.S. point of view would have been that the Canadian canola growers would stop using lindane. That would have been the smoothest paths forward from our standpoint.

Whether we were seeking cancellation, I think that that's a little bit more of an interventionist interpretation than what we would have done.

Q. I understand.

A. To be honest.

Q. I'm just continuing, "PMRA is not in a position to recommend such action unless there was agreement for concerted action on all Lindane Products with the USEPA."

Now, that--I suppose that's a--well, were you aware of that?

A. Well, yeah. I mean, we started getting signals from, you know, our interactions with Canada during this time that

16:09 both on their end and I think on our end as well, that working together on lindane would be beneficial, and I think that we began thinking about that as a way of being able to address some of the commitments that we were getting into under the LRTAP agreement, that did require that we do a re-assessment. We were both under requirements by the Convention to reassess the lindane uses; and, of course, that eventually lead to a NARAP under the NAFTA.

And so, I think that on both ends that we were becoming increasingly interested.

By this time we already had lindane as an Annex Two substance in the Great Lakes Agreement under the International Joint Commission, and so we had already recognized kind of a bilateral commitment to somehow dealing with the lindane problem in the Great Lakes. And so...

Q. The author, refers, in fact, to that last point I think of yours, well, not the last point in the NARAP, just continuing in the second paragraph, "The consideration of lindane as a candidate for a North American regional action plan under the CEC was identified."

A. Yes, I think we actually jointly did identify that as a potential path to take in terms of the CEC work.

Q. Right.

And as I go down the document into the bullets, no publication of the current PR notice--we have already discussed

16:11 that. Voluntary removal is the second bullet of lindane from products registered for canola seed treatment, apparently part of EPA's wish list as well, or the easiest way forward, as you said earlier.

A. I think that was actually initiated by the canola growers themselves. I think it was the growers that preferred that as a way to move forward, and I have seen this before with other pesticides where if there is a controversy about the pesticides and especially with the food that has a reputation for being a healthful beneficial food that the growers will want to move away from that pesticide.

Q. Oh, I was just recalling that document that we looked at about submissions that the Canadian canola growers put into the--

A. I know.

Q. In 2002, so I guess maybe there is some dissonance in these two theories. Certainly, the Tribunal has heard what you've just said about growers.

A. Well, I don't think it's a theory. I think that it's actually the Canola Council that convened all of the efforts to try to develop this voluntary cancellation plan, so I don't think that that's a theory. I think that that's actually well supported in all of the record.

Q. On the third bullet, it states, "commitment between"--now, I just to want recall at the chapeau as we call

16:12 it at the top of this list of bullets, the resulting proposal has emerged, so this is a proposal the author is describing, and the third point of it is commitment between the EPA and PRMA to work together to phase out all uses of lindane.

Do you recall that?

A. No. I wouldn't have even said it that way, but I could see that it's written here on the page. I think that we were committed to an evaluation, and I think that we were also committed to, in a sense, putting it first. But because of the international commitment that we would take a look at lindane before we were looking at the hundreds of other pesticides that we could have been looking at. And if we saw things that needed to be dealt with, that we would deal with it first. But we were not committing, and we certainly didn't--in the context of any of the international agreements, we were not committing to take any regulatory actions before we did an evaluation.

You know, under U.S. law, we cannot--we are not allowed to shoot first and ask questions later. We go through a very, very comprehensive, very thorough review, and that's--and that's what we were committed to doing.

I mean, I kind of take this as staff notes or notes to the file, and you never know--I have no idea who wrote this, but it certainly isn't something that I approved or saw at the time.

Q. That's helpful, thanks.

16:14 Certainly the author--no one wanted to take ownership of this as far as the people asked, but the author, when we see the next set of bullets under the heading "Next Steps for PMRA, Internal Use," the first bullet is "Proposal is acceptable to EPA, OPP, and EPA regions." So, presumably the person is representing they have done their homework on the EPA side of things?

A. I'm sure, though, that the way people were taking it the way that I understood what we were doing, which was a commitment to do a joint assessment and a commitment to moving that forward, pushing that forward with much more speed than we would have. I'm sure that's how they took it.

The people working for OPP and for our regions both were very well aware of the statutory requirements under which we were obligated to work, and they knew that we didn't make commitments to taking regulatory actions before doing required reviews and so forth.

Q. I'm sure.

I'm going back to your second Expert Report, Volume 1. I'm looking at Paragraph 15.

A. The second Expert Report?

Q. Yeah, with--the yellow covered one.

A. Paragraph 15?

Q. Right.

And near the bottom of the page, four lines from the

16:16 bottom, it states--you state, I guess--"It seems that by 31 July 2002, EPA was persuaded that provision of personal protective equipment could mitigate worker risks to some extent." And you reference Tab 12, which is the 2002 RED. "However, there were still worker risk issues outstanding." So, I turn to Tab 12, and I go to Page 57 of that 2002 RED, and there I find the section in the RED called "Occupational Risk." And rather than read all this stuff because it's fairly dense, I will just try to go to the operative or the conclusory parts of the paragraphs because they evaluate--EPA evaluates occupational risk in several different scenarios. This one here we see "on-farm seed treatment dust formulation." The next one will be "on-farm see treatment liquid formulation" and "commercial treatment" and so on.

And EPA goes through each of those occupational risk categories and determines whether there shows a risk of concern.

A. Yes. So, for the existing registered uses of lindane, EPA concluded that with the application of personal protective equipment that the MOEs were acceptable, and--but there were residual concerns. That's what I said in my Report.

And so, for example, if you look at Page 31, which is Table 12 in the RED, then you can see that there is a column--the third column of Table 12. It gives these MOEs. And remember, if an MOE is less than a hundred, then that's

bad.

And so, under "crop"--so, they have dealt with wheat and corn, and then you have canola on this table as well. And so, for example, the mixing/loading application of liquid formulation treater closed system for canola, that there are inhalation MOEs that are less than 100 in that table. And also for seed handler, bagger, sower, stacker, again commercial seed treatment, there is one less than 100.

And so they have mitigated the concerns other than canola but not canola. They don't talk about it because they did not include canola in the RED. Never having been as registered, it is not re-registered.

The second point I would make, and I found this to be unusual, and I don't quite understand why, but two years after the issuance of the RED, they issue a Data Call-In for more worker information, for more occupational studies. And that I cannot quite explain to you, but they do not issue a DCI unless there is a concern.

So, those two things are the basis for my concern.

Q. On that table, I'm looking at the MOEs that are less than a hundred, and there is--there is a few of them.

A. Right. The dermal ones can be--that's where they would try to litigate those with PPE. The inhalation ones perhaps could be, but that gets more difficult.

Q. Again, I note that the inhalation MOEs, for example,

16:20 if we look at first row, "mixing/loading/planting dry formulation," that the dermal MOEs are under a hundred and, therefore, the personal protective barrier or equipment to rectify those. And the PPE that these include is--include for that first row pesticide respirator and inhalation MOEs are predictably extremely high, and therefore the respirators are effective. The ones where we have an MOE below a hundred, we all see in every single box of the PPE no respirator, so presumably that was the mitigation which the Agency used to conclude in the section that I was in before at Page 57 that there was no risk of concern, and therefore they were eligible for re-registration.

A. The interesting thing being, though, that you have already got in the commercial seed treatment scenario a closed system, so they are already working in a closed system, and that is supposed to be, you know, better than using a respirator.

So, I don't know what the situation would have been because they did not, you know--I merely said there were residual concerns on the basis of this not being mitigated and the subsequent Data Call-In.

Q. In the next paragraph, you also mentioned some issues that you feel are expressed in--

ARBITRATOR CRAWFORD: Paragraph?

BY MR. SOMERS:

16:22 Q. Paragraph 16 of your second Report.

And I wanted to--I'm looking at the first--no, second sentence of Paragraph 16, where you state, "As a result"--no, I will take it from the first position.

"The EPA was also concerned about dietary risk. EPA concerns about risks to subsistence hunters in Alaska appear to have first been detailed in a document from EPA's Health Effects Division," some cites, Tab 16. "As a result, the revised RED concluded that dietary risk for Alaska subsistence hunters was unacceptable, especially for children," and the cite you give there was Tab 14.

So, I go to Tab 14, and I go to Page 3. Now, Tab 14 is a memorandum of May 23rd, 2001, "subject: lindane dietary risk and exposure estimate for lindane through subsistence diets for indigenous people of Alaska."

And on Page 3 of Tab 14, the last of the text above Table 1, two sentences up, "Comparing this exposure to the lindane cPad of .00016 milligram per kilogram body weight per day reveals that the exposure of the indigenous people to lindane is 6 percent cPad and thus would be below HED's level of concern, even using the adult intake amounts and dividing the milligram per day by 10 kilograms weight of child would amount to certain amount of milligram/kilogram day, which is 44 percent of chronic population adjusted dose and still below HED's level of concern."

16:24 So, I wondered am I reading you wrong in Paragraph 16? Because it seems to me that they found that Alaska's subsistence hunters' dietary risk was below the level of concern there.

A. I need a second here to look at these documents.

Q. Sure.

(Witness reviews document.)

A. What I was referring to that I'm not finding right at this moment is not--what you're pointing to is the assessment from the daily dietary intake, and--alone, but they also looked at that in the context of the body burdens that people have, but I'm not finding that quickly. It's going to take me another minute.

I don't know, you can't find the numbers. You pulled them from one of the HED documents, I know I found these numbers, so I may need to--it may be a different tab. It may be a document that's in a different tab. I apologize for that.

Q. That's fine.

A. But I can't quickly see them.

Q. I wanted to make sure I was reading them right.

A. But certainly I was quite certain the combination of the dietary intake and the levels in people, but I'm not able to find that.

Q. Could I ask you to go to Paragraph 52 of your second Report now.

16:28 A. 52?
Q. Right, Page 17.
I'm reading it in so the transcript reflects what it is we are talking about rather than us reading it silently.
"In sum, I do not agree with the Claimant's contention that Chemtura voluntarily canceled its tolerance and registration applications because of a business decision rather than the EPA's risk concerns. Registrants with profitable pesticides will tend to persuade EPA's Pesticide Office to allow them to conduct one study after another in search for scientific justifications to continue registration."
What about, though, as an alternative scenario that we suggest to you, a Registrant with an unprofitable pesticide, wouldn't they routinely ask for--to have a tolerance or registration withdrawn rather than incur the trouble and expense and maintenance fees that would otherwise entail, if it's no longer in the--
A. Sure. When the 1988 law was enacted, about a third of pesticides were not supported with re-registration fees and went off the market. And one of the things--you know, I don't actually know the motive of the company, but I do know that it appears to me that they were aggressively attempting to maintain their registrations and to secure a registration for canola all the way through the beginning of 2006 when I would look at the record--I mean, 2006. And when I look at the

record--and I see that they were continuing to perform studies, continuing to submit studies, continue to pay consultants to do work for them on this, continuing to meet with the EPA.

So--but no, I don't know anything about the finances of the company or, for that matter, the product. I do know that lindane itself probably was not a very expensive active ingredient, and so potentially it could have been quite profitable, but I don't know.

Q. It will be a matter for argument, I suppose.

I had a question as well on Paragraph 58 of your statement.

A. Sure.

Q. Well, again, I will take it from the very beginning. You're addressing the point of the likelihood of obtaining a tolerance in 2006, and you state three lines--four lines down, "Occupational risks to seed treaters and farmers for exposures occurring in other countries would not be considered."

A. Correct.

Q. We talked about that already.

"However, occupational risks for workers were involved with handling and processing treated seeds, and foods and the food industry might have been considered."

A. Correct.

Q. Are you saying that the occupational risk of--

A. So, a person who is planting the seeds, if planting

16:31 the seeds involved handling them such as they might have an exposure to the Pesticide Seed Treatment, that certainly would be an issue. That would be a FIFRA issue.

Q. Okay. The--and so presumably there would be--if there was a concern, then it would have to be addressed with PPE and the usual FIFRA type of--

A. If it's possible.

PPE is not always a solution. You know, there is a tradeoff between potential benefits of PPE versus the practicality of using it. It's difficult to use it in very hot situations such as you might have in mid summer in the Dakotas. People tend to take it off and--when they are hot and sweaty and working all day, and so--and it can be very uncomfortable, and so--but EPA often can mitigate the risks with PPE, but not always.

Q. This is rash of me. They tell you not to do this in cross-examination school, but does the EPA actually try to assess the compliance of the label readers as to whether they will keep their gloves on?

A. It--well, EPA has a policy about PPE vis-à-vis heat stress, so EPA does try to think through the issues of the heat stress involved with the work versus the amount of, if you may, heat that would be generated by the wearing of PPEs. So, you can imagine if you're wearing a moon suit and it's 95 degrees outside, you might get hot; and, if you're working, that you

might get even hotter, okay?

So, I don't know if you have ever traveled in developing countries, you often see people working in agriculture in--shirtless and shorts with a backpack sprayer on, and not because they want to be exposed, but because it is pretty hot out there. So--but does EPA then go out and assess the compliance? This would probably be an area where there would be--if there were a complaint, a tip, that EPA might go out and look. EPA isn't routinely out there on farms. But if there were complaint about PPE or any of the label requirements or there is some general farm worker protection requirements, EPA certainly would respond. And there have been FIFRA violations, obviously, from that kind of thing. It is a FIFRA violation to break any requirement of the label. If the label says "gloves" and you break it, if you don't give the gloves to your workers, that's a FIFRA violation.

Q. Okay. I understand. I didn't put my question clearly. My question was: In the--the EPA determines a risk, it determines a mitigation measure which will offset that risk adequately. That measure is, for example, shirt and gloves. Does it then take an additional step in its risk mitigation assessment and say, "But half the time these people don't wear their shirt and gloves, so we are going to have to either not allow the registration or inject additional mitigation measures" or that sort of thing?

16:35 A. So, if EPA believes that it's not feasible, so certain gloves, I mean, I think the EPA would say that's feasible.

Q. Okay.

A. But what it has to be full scuba? You probably would say no, that's not feasible.

Q. Would there be additional mitigation measures instead of full scuba, they could like lower the application rate or re-entry time?

A. Might have to cancel the pesticide. I mean, there are--so, there was one that was canceled when I was at EPA called "mevinfos," that EPA had imposed requirement of full PPE--respirators, gloves, shirts, all of that--and there were nonetheless workers being sickened enough to have to be admitted to the hospital, and there were enough of those cases that actually--that pesticide proceeded to a cancellation. And so, it doesn't always--if something is very, very toxic, which certainly I wouldn't say that lindane is in this category--I mean, we are talking about this other agent was a Category I acute toxic substance. Sometimes even full PPE can't protect people. In that case you could have--I mean, you could imagine ways to have people in manufacturing facilities, people weren't getting sick from being exposed to this thing.

Now matter what you do with PPE out in the field, you don't get a hundred percent protection, and EPA has a lot of studies about that as well. So, when you say does EPA consider

16:36 the practicalities, the EPA has a lot of field studies that do inform. These handlers use--pesticide handlers, and so you have heard about these pesticide handler databases, that's what that's about, to say how much protection do you get? You certainly never get a hundred percent.

Was that what you were trying--sorry, I may not be addressing your question.

Q. It's all helpful.

My question was actually, in addition to PPE and the complications that might arise from that and people's behavior, there are other mitigation measures that are available for the EPA, in fact, that they used in connection with the Lindane RED here in 2002.

A. Sure.

Q. That would mitigate risks below the level of concern, such as reducing the application rate, was I think the one that was used in the RED in relation to corn.

A. Right. That was one of the issues for the canola. The application rate was higher than for the other seeds.

Q. Right. And so lowering it--

A. Lowering, if it had worked, which I don't know.

Q. It was eligible for re-registration--

A. For those other seeds, yes, it was.

Q. Thank you for waiting.

I'm just--I'm trying to recall an issue in relation to

16:39 the import tolerances. Where there is a pesticide that's registered for use in the United States for certain uses, like lindane was at the time of the RED that we are looking at, but not for a canola use, it would be possible--it would be possible and, in fact, let me suggest, not uncommon to obtain an import tolerance in connection with that pesticide but used on an unregistered use in the United States. Is that fair?

A. You know, in--at the time that I prepared my first statement, and so I got very interested in this issue of the import tolerances because of the fact that I was involved in creating one, you know, and so I did look through the Code of Federal Regulations which, of course, tolerances are regulations, and they are published. They are published in CFR 40, Part 180. And I did find that there were six--no, five pesticides on the books with import tolerances. And, actually, I believe that one of those did have some other tolerances established other than the import tolerances, and the rest of them did not.

So, I would conclude from that, in answer to your question, yes, it's possible, you know.

Q. Fair. Thank you.

Thank you very much. I appreciate your candor. Thank you.

MR. SOMERS: Those are my questions, Madam Chair.

PRESIDENT KAUFMANN-KOHLER: Thank you.

16:41 REDIRECT EXAMINATION

BY MS. BEHARRY:

Q. Dr. Goldman, I have three areas that I would like to ask you very brief questions on. The first is with regard to import tolerances.

You're aware that Gaucho was a registered pesticide for use on canola?

A. Yes. Gaucho was registered, I think, in 1996. It was a tolerance granted on the canola as well as a registration by EPA.

PRESIDENT KAUFMANN-KOHLER: It helps us a lot if you say which Gaucho.

MS. BEHARRY: I think it was just called Gaucho, wasn't it?

PRESIDENT KAUFMANN-KOHLER: There was 75 and 480.

THE WITNESS: I think there were more than one Gaucho formulas, but yeah. Imidacloprid--

MR. DOUAIRE de BONDY: It would be insecticide-only Gaucho at that point at the very least.

ARBITRATOR CRAWFORD: CS FL?

PRESIDENT KAUFMANN-KOHLER: No, it's the 480 and the 75 ST.

MR. DOUAIRE de BONDY: We're talking about registration in the United States, just to be clear, as opposed to--

16:42 THE WITNESS: And in 1996, so it's really prior to all of this issue with the importation of the canola seed, but for some reason has gone through EPA's process.

BY MS. BEHARRY:

Q. Okay. My second question with regard to import tolerances, does the EPA normally grant an import tolerance when there is a registered alternative to the pesticide for which the import tolerance is requested?

A. Not really. I mean, you know, if you look at the circumstances under which the import tolerances had been granted, generally there are things--many of them are things that are not even grown in the U.S.: bananas or the French wine, for example. A lot of us like that and don't want to see that interdicted at the border. But it's usually a situation where also there is some kind of a unique pest control problem on the other end, and that the pesticide that's on the food is needed and would not be needed in the United States.

And so--there was no reason why a Registrant would come for a registration for a product that has no project in the U.S. It's hugely expensive to develop the dossiers and go through the whole process, and so they had not done that. But on the sending in of the exporting end, there is a reliance on the pesticide to deal with some special pest problem.

I will tell you, policy-wise, when I was at EPA, we didn't like granting them, and the reason for that being that

16:44 it required a Special Review very quickly of a bunch of data, rural health data, for a chemical that we had never seen, we were not familiar with. So, it was really kind of an extraordinary situation that would prompt us to grant one.

Q. Okay. Thank you.

The second area of questions relates to Paragraph 16 that Mr. Somers took you to of your statement, the second one.

A. Yes.

Q. And I just want to give you the opportunity to find the reference. And I was flipping through your exhibits, and I was wondering perhaps whether you were referring to Tab 15, which was a revised dietary risk and exposure estimate for lindane through subsistence diets for indigenous people of Alaska.

A. Yeah, I see the number, so I was citing right there. So, I kept looking at 14 and 16, but I guess I made a mistake in the reference.

Q. And for the sake of clarity, where in this document do you see this?

A. So, I see--if you look at Tab 15, this Page 2, the first full paragraph in the Executive Summary, I certainly see it there. And I see it on the last page, the first paragraph, the only paragraph on the last page, so...

Q. What's the page number?

A. Page 5.

16:46 Q. Thank you very much.

My last area of questions relate to the voluntary cancellation of the Claimant's lindane product registrations prior to the release of the 2006 Addendum.

Now, based on your experience at the EPA, why do Registrants normally cancel their product registrations?

A. Well, we mentioned one reason earlier, and that is they no longer wanted to support the product. That's one potential reason. But in the case of an impending cancellation by the Agency, voluntary cancellation is very common. And so I mentioned mevinfos, which was a pesticide that was voluntarily canceled when I was at the EPA. That was in the context of the preparation of not only kind of a final review of the pesticide, but also all of the work that would need to be done to do a cancellation of mevinfos and all of its related products.

And the Registrant was very keen to come in and work out a Voluntary Cancellation Agreement simply because that was, from their standpoint, going to be an easier road to take than going through cancellation proceedings.

And when I look at the e-mails that were flying around within Chemtura, the record that I was asked to read, I see the same kind of phenomenon as that 2006 RED Addendum was approaching, that there was a lot of concern on the part of Chemtura to be able to develop this Voluntary Agreement prior

16:48 to the issuance of the 2006 RED Addendum. They were very much in a hurry to do that, so much so that they were willing to go for an agreement that wasn't exactly the agreement that they wanted from the EPA.

Q. So, in your view, what do you think would have happened to the Claimant's registrations in 2006 if they had not withdrawn them prior to the Addendum?

A. Well, I believe that EPA very clearly stated in the 2006 Addendum and other statements they made after that time that they felt that lindane no longer met the standard for registration, and I think that they said that point clearly.

Q. Thank you, Dr. Goldman. Those are my questions.

PRESIDENT KAUFMANN-KOHLER: Thank you.

Any follow-up questions?

MR. SOMERS: Well, because of that, that's right, that miscitation I got kind of taken off guard there. I wonder if I could follow up with that. I would appreciate counsel pointing out what you meant. It was unlikely for you to pull a number like 138 percent out of the air.

RECROSS-EXAMINATION

BY MR. SOMERS:

Q. Turning to Tab 12 of the 2002 RED, which is the 2002 RED, and Page 14 of the RED. This is the revised, yeah.

At the top of the page--I will just read it in. This is the RED's use of, I assume, that data at Tab 15 and how it

16:50 was incorporated into the Re-registration Eligibility Decision. Now, the paragraph relating to that "The child in concern" reads: "The chronic dietary risks based on consumption of traditional foods are generally not a concern. For the most highly exposed subpopulation, children one to six years, the subsistence diet of Alaskans results in lindane exposures that range from 13 to 65 percent of the cPad with the exception of one scenario, which was 138 percent of the cPad," and that's that number about the children. "This exception was for one community where EPA included a number of conservative assumptions discussed below, including the children ate blubber for 365 days per year for six years." That's conservative. And I suggest to you that the 2002 RED thought that was too conservative, and that's why it wasn't flagged as a realistic concern.

A. Yeah, but you could also point to things that are not conservative. For example, they don't include the consumption of breast milk and whether those children were breast-fed at all in these Assessments.

And so I agree with you: In 2002, you know, they basically had some concerns, but I think the concerns build over time about issues like the presence of lindane in breast milk.

Q. No, fair enough. I'm not asking you to agree that the FDA did what you would have done or anything like that, just

16:52 1 that's the basis that it was made.
2 A. Yeah.
3 Q. That's my only observation. Thank you.
4 A. Fair enough.
5 PRESIDENT KAUFMANN-KOHLER: Thank you.
6 Any questions? No?
7 Then thank you very much for your input, and that
8 closes your examination.
9 THE WITNESS: Thank you very much.
10 PRESIDENT KAUFMANN-KOHLER: Thank you.
11 (Witness steps down.)
12 PRESIDENT KAUFMANN-KOHLER: Question to counsel: Are
13 you ready to have a procedural discussion now, or do you still
14 need some time? Fine.
15 MR. DOUAIRE de BONDY: We are ready. Sorry if I was
16 unclear.
17 PRESIDENT KAUFMANN-KOHLER: That's what I understood,
18 yes. And you're ready, too?
19 MR. SOMERS: Yes.
20 PRESIDENT KAUFMANN-KOHLER: Is it off the record? No?
21 Should it be? I don't think so. No.
22 The first question that we have is what is your
23 preference in terms of oral argument, and then from there we
24 could see what we do with Post-Hearing Briefs. You understood
25 the Tribunal would like Post-Hearing Briefs, so then we can

16:53 discuss when and how, depending on your preference on oral arguments.

Mr. Somers.

MR. SOMERS: Post-Hearing Briefs and, did you say you will invite our views on--

PRESIDENT KAUFMANN-KOHLER: On the question of the oral arguments, yes, when you would like to have the oral arguments this week or after the Post-Hearing Briefs.

MR. SOMERS: After the Post-Hearing Briefs, subsequent thereto.

PRESIDENT KAUFMANN-KOHLER: Fine. What is the view of Canada on this question?

MR. DOUAIRE de BONDY: Madam Chair, Canada would be willing to follow the same procedure of waiving oral argument this week and having it scheduled after simultaneously exchanged Post-Hearing Briefs.

PRESIDENT KAUFMANN-KOHLER: Fine.

So, then the next question is: When do we have the session on oral argument? And as the Secretary told you all during the break, the Tribunal had looked at its diaries, and it's no fun. No, it was not that easy of an exercise, but we identified the 17th of December, subject to confirmation tomorrow because there is some rescheduling that has to be done overnight.

Are these days--is this an acceptable date on the

16:55 Claimant's side?

MR. SOMERS: It is.

PRESIDENT KAUFMANN-KOHLER: It is as well on the Respondent's side, as I understood before.

MR. DOUAIRE de BONDY: Yes.

PRESIDENT KAUFMANN-KOHLER: Fine. So we will hopefully be able to confirm this tomorrow.

Then that leads us to the question of the Post-Hearing Briefs. Since we will have an opportunity to--you will have an opportunity to speak after the Post-Hearing Briefs, we would have only one round of simultaneous briefs, and then we need to--we will give you tomorrow, I assume, late afternoon a number of indications on the content of the Post-Hearing Briefs.

What time limit, and there we are very much in your hands, as long as we have it soon enough to get ready for the oral session? Mr. Somers?

MR. SOMERS: By saying you will leave the time limit or time that it's due in our hands, is it a matter for agreement between counsel?

PRESIDENT KAUFMANN-KOHLER: I don't know whether you have considered it or whether you have already suggestions. If you do, then you can state them.

MR. SOMERS: I'm doing a little bit of mental calendar math.

16:57 In light of the fact that oral argument will occur on December 17th, would it--I would propose sometime before--sometime around the beginning of November would allow us adequate time to refine and sharpen everything down very pointedly. That would give--that would amount to something less than--something less than two months. In fact, seven weeks or so.

MR. DOUAIRE de BONDY: We were going to suggest October 16th, just as a compromise of about five weeks.

PRESIDENT KAUFMANN-KOHLER: You prefer deadlines on the Friday rather than a Monday?

Mr. Somers?

MR. SOMERS: Our more modest team with a nightmarish calendar would move that out further, if possible. In fact--

PRESIDENT KAUFMANN-KOHLER: Can I make a suggestion? Why don't you speak about it between counsel tonight, and then you revert tomorrow with what hopefully is an agreed date.

MR. SOMERS: Thank you.

PRESIDENT KAUFMANN-KOHLER: Then the last thing we need to discuss now is the continuation and end of this hearing. Tomorrow we will hear the two damage Experts. We have scheduled a little bit more than a day for them. Do you think we will--you had scheduled to start late afternoon--no, no, sorry. Mid morning and go until mid morning, end of morning next day. Is this still your estimate, or not,

16:59 Mr. Somers?

MR. SOMERS: Our current estimate--this overstates our current estimate. In other words, we believe that a good half day would probably be sufficient.

PRESIDENT KAUFMANN-KOHLER: For both you're saying?

MR. SOMERS: No, for one.

PRESIDENT KAUFMANN-KOHLER: Your cross, are you saying?

MR. SOMERS: Yes. Half a day.

In fact--yeah, that would be plenty.

PRESIDENT KAUFMANN-KOHLER: How does it look on Respondent's side?

MR. DOUAIRE de BONDY: Similarly for Canada. We are expecting that the afternoon would be largely sufficient for the cross-examination of LECG, or in our case morning since they are going first. So, it seems likely that we could get through both Experts tomorrow.

PRESIDENT KAUFMANN-KOHLER: It seems likely to me as well, to us. I would not release the next morning yet. Let's keep the next morning in reserve just in case so you can plan accordingly.

Is this fine with my colleagues? Yes.

(Tribunal conferring.)

PRESIDENT KAUFMANN-KOHLER: Fine. So, that's confirmed. We may finish tomorrow night. And in case we

17:01 cannot, then we can still complete whatever needs to be completed on Wednesday morning, and that includes the Tribunal's directions with respect to the Post-Hearing Briefs.

Are there any questions/comments before we close for today on the Claimant's side?

MR. SOMERS: None here, Madam Chairperson.

PRESIDENT KAUFMANN-KOHLER: Everything is clear on the Respondent's side?

MR. DOUAIRE de BONDY: That's fine. Thank you.

PRESIDENT KAUFMANN-KOHLER: Fine. So, thank you very much, and have a good evening.

(Whereupon, at 5:01 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.

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DAVID A. KASDAN